Samaritan Health Plans

Prior Authorization Criteria

Small Group Commercial Plans

PLEASE READ: This document contains information about the criteria for coverage for this plan.

Updated on 7/1/2023. For more recent information or other questions, please contact Pharmacy Services at **541-768-4550** or toll free **800-832-4580** (TTY 800-735-2900) or visit **samhealthplans.org**. Pharmacy Services is available Monday through Friday, from 8 a.m. to 5 p.m.

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Prior Authorization Guideline

Guideline Name	5HT-1 Receptor Agonists (Triptans)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	2/13/1998
P&T Revision Date:	11/14/2019 ; 04/15/2020 ; 09/16/2020 ; 03/17/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Zomig (zolmitriptan) nasal spray
Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older. Limitations of Use: Only use Zomig if a clear diagnosis of migraine has been established. If a patient has no response to Zomig treatment for the first migraine attack, reconsider the diagnosis of migraine before Zomig is administered to treat any subsequent attacks. Zomig is not indicated for the prevention of migraine attacks. Safety and effectiveness of Zomig have not been established for cluster headache. Not recommended in patients with moderate or severe hepatic impairment.

2 . Criteria

Product Name: Zomig nasal spray or Brand Zolmitriptan nasal spray	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient is 12 to 17 years of age

AND

2.1.2 Trial and failure (of a minimum 30-day supply) or intolerance to rizatriptan tablet/rizatriptan orally dissolving tablet (ODT)

OR

2.2 Both of the following:

2.2.1 Patient is 18 years of age or older

AND

2.2.2 Trial and failure (of a minimum 30-day supply) or intolerance to two of the following generics [A, B]:

- Almotriptan tablet
- Eletriptan tablet
- Frovatriptan tablet
- Naratriptan tablet
- Rizatriptan tablet/rizatriptan orally dissolving tablet (ODT)
- Sumatriptan tablet/nasal spray
- Zolmitriptan tablet/zolmitriptan ODT

3 . Endnotes

A. All triptans are FDA-approved for the acute treatment of migraines with or without aura in adults [1]. Those agents FDA-approved in pediatric patients include almotriptan, sumatriptan/naproxen, zolmitriptan nasal spray (for ≥12 years of age), and rizatriptan (for ≥6 years of age).
B. Triptans are a well established, effective treatment option for There is limited head-to-head data available, acute migraine [2]. which makes it difficult to recommend the use of one agent over another [2].

4 . References

1. Drugs@FDA [internet database]. Rockville (MD): Food and Drug Administration (US), Center for Drug Evaluation and Research; Updated periodically. Available from: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm. Accessed Accessed January 27, 2023.
2. Schwedt TJ, Garza I. Acute treatment of migraine in adults. UpToDate. Available by subscription at: http://www.uptodate.com/. Accessed January 27, 2023.
3. Zomig Nasal Spray Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. May 2019.

5 . Revision History

Date	Notes
3/2/2023	Annual review: Updated criteria and background.

Prior Authorization Guideline

Guideline Name	Actemra (tocilizumab)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	4/6/2010
P&T Revision Date:	09/18/2019 ; 10/16/2019 ; 04/15/2020 ; 09/16/2020 ; 12/16/2020 ; 05/20/2021 ; 04/20/2022 ; 05/19/2022 ; 10/19/2022 ; 12/14/2022 ; 02/16/2023 ; 5/18/2023

1 . Indications

Drug Name: Actemra (tocilizumab IV), Actemra (tocilizumab SC)
Rheumatoid arthritis (RA) Indicated for the treatment of adult patients with moderately- to severely-active rheumatoid arthritis who have had an inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs). **Systemic Juvenile Idiopathic Arthritis (SJIA)** Indicated for the treatment of active systemic juvenile idiopathic arthritis in patients 2 years of age and older. **Polyarticular Juvenile Idiopathic Arthritis (PJIA)** Indicated for the treatment of active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older. **Giant Cell Arteritis (GCA)** Indicated for the treatment of giant cell arteritis (GCA) in adult patients.
Drug Name: Actemra (tocilizumab IV)
Cytokine Release Syndrome Indicated for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome in adults and pediatric patients 2 years of age and older.

Coronavirus Disease 2019 (COVID-19) Indicated for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adult patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Drug Name: Actemra (tocilizumab SC)

Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) Indicated for slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).

2 . Criteria

Product Name: Actemra IV or SC	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide

- sulfasalazine

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab) or Amjevita (adalimumab-atto)
- Rinvoq (upadacitinib)
- Simponi (golimumab)
- Xeljanz/XR (tofacitinib/ER)

OR

4.2 For continuation of prior Actemra therapy, defined as no more than a 45-day gap in therapy

Notes	*Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Actemra IV or SC	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Actemra IV or SC	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active systemic juvenile idiopathic arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4]:

- Minimum duration of a 3-month trial and failure of methotrexate
- Minimum duration of a 1-month trial of nonsteroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, naproxen)
- Minimum duration of a 2-week trial of systemic glucocorticoid (e.g., prednisone)

Product Name: Actemra IV or SC	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in clinical features or symptoms (e.g., pain, fever, inflammation, rash, lymphadenopathy, serositis) from baseline

Product Name: Actemra IV or SC	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active polyarticular juvenile idiopathic arthritis

AND

2 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [5]:

- leflunomide
- methotrexate

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Enbrel (etanercept)
- Humira (adalimumab) or Amjevita (adalimumab-atto)

- Xeljanz (tofacitinib)

OR

4.2 For continuation of Actemra therapy, defined as no more than a 45-day gap in therapy

Notes	* Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Actemra IV or SC	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 5]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Actemra IV or SC	
Diagnosis	Giant Cell Arteritis (GCA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of giant cell arteritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Trial and failure, contraindication, or intolerance to a glucocorticoid

Product Name: Actemra IV or SC	
Diagnosis	Giant Cell Arteritis (GCA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Actemra SC	
Diagnosis	Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) as documented by the following [6-8]:

1.1 Exclusion of other known causes of interstitial lung disease (ILD)

AND

1.2 One of the following:

1.2.1 In patients not subjected to surgical lung biopsy, the presence of idiopathic interstitial pneumonia (e.g., fibrotic nonspecific interstitial pneumonia [NSIP], usual interstitial pneumonia [UIP] and centrilobular fibrosis) pattern on high-resolution computed tomography (HRCT) revealing SSc-ILD or probable SSc-ILD

OR

1.2.2 In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD

AND

2 - Prescribed by or in consultation with a pulmonologist or rheumatologist

Product Name: Actemra SC	
Diagnosis	Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Actemra IV	
Diagnosis	Cytokine Release Syndrome (CRS) Risk due to CAR T-Cell Therapy
Approval Length	2 Months [A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient will receive or is receiving chimeric antigen receptor (CAR) T-cell immunotherapy (e.g., Kymriah [tisagenlecleucel], Yescarta [axicabtagene ciloleucel])

AND

2 - Prescribed by or in consultation with an oncologist or hematologist

Product Name: Actemra IV	
Diagnosis	Coronavirus disease 2019 (COVID-19)
Approval Length	14 Days [B]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of COVID-19

AND

2 - Patient is hospitalized

AND

3 - Currently receiving systemic corticosteroids

AND

4 - Patient requires one of the following:

- Supplemental oxygen
- Non-invasive mechanical ventilation
- Invasive mechanical ventilation

- Extracorporeal membrane oxygenation (ECMO)

3 . Endnotes

A. Patients should have Actemra on board for initial CAR T-cell therapy and be evaluated for signs and symptoms of CRS for at least 4 weeks after, up to a total of 4 doses of Actemra with at least 8 hours between doses. [1]
B. The recommended dosage of Actemra for treatment of adult patients with COVID-19 is 8 mg/kg administered as a single 60-minute intravenous infusion. If clinical signs or symptoms worsen or do not improve after the first dose, one additional infusion of Actemra may be administered at least 8 hours after the initial infusion. [1]

4 . References

1. Actemra Prescribing Information. Genentech, Inc. South San Francisco, CA. December 2022.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.
3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.
4. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. Arthritis Rheumatol. 2022;74(4):553-569.
5. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Rheumatol. 2019;71(6):846-863.
6. Khanna D, Lin CJF, Furst DE, et al. Tocilizumab in systemic sclerosis: a randomized, double-blind, placebo-controlled, phase 3 trial. Lancet Respir Med. 2020;8:963–74.
7. Fischer A, Swigris JJ, Groshong SD, et al. Clinically significant interstitial lung disease in limited scleroderma: histopathology, clinical features, and survival. Chest 2008; 134:601.
8. UptoDate [internet database]. Waltham, MA. UpToDate, Inc. Clinical manifestations, evaluation, and diagnosis of interstitial lung disease in systemic sclerosis (scleroderma). Available by subscription at: https://www.uptodate.com. Accessed April 11, 2021.

5 . Revision History

Date	Notes

5/3/2023	Annual review - no criteria changes; background updates

Prior Authorization Guideline

Guideline Name	Actimmune (interferon gamma-1b)

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	3/21/2016
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Actimmune (interferon gamma-1b)
Chronic Granulomatous Disease (CGD) Indicated for reducing the frequency and severity of serious infections associated with Chronic Granulomatous Disease (CGD). **Severe Malignant Osteopetrosis (SMO)** Indicated for delaying time to disease progression in patients with severe, malignant osteopetrosis (SMO).

2 . Criteria

Product Name: Actimmune	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Chronic granulomatous disease (CGD)
- Severe, malignant osteopetrosis (SMO)

Product Name: Actimmune	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Background

Benefit/Coverage/Program Information
Effective date Prior to 3/8/2023 Updates the effective date was 1/1/2021

4 . References

1. Actimmune Prescribing Information. Horizon Therapeutics USA, Inc. Deerfield, IL. March 2021.

5 . Revision History

Date	Notes
4/11/2023	Annual review

Prior Authorization Guideline

Guideline Name	Adakveo (crizanlizumab-tmca)

Guideline Note:

Effective Date:	3/1/2023
P&T Approval Date:	1/15/2020
P&T Revision Date:	02/13/2020 ; 01/20/2021 ; 01/19/2022 ; 1/18/2023

1 . Indications

Drug Name: Adakveo (crizanlizumab-tmca)
Sickle Cell Disease Indicated to reduce the frequency of vasoocclusive crises in adults and pediatric patients aged 16 years and older with sickle cell disease.

2 . Criteria

Product Name: Adakveo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of Sickle Cell Disease

AND

2 - Patient is 16 years of age and older

AND

3 - Documentation of 2 vaso-occlusive events that required medical facility visits and treatments in the past 12 months (e.g., sickle cell crisis, acute pain episodes, acute chest syndrome, hepatic sequestration, splenic sequestration, priapism) [1, 2]

AND

4 - Trial and failure or inadequate response, contraindication, or intolerance to one of the following: [3, 4, 5, 6]

- Hydroxyurea
- L-glutamine (i.e., Endari)

AND

5 - Prescribed by or in consultation with one of the following:

- Hematologist/Oncologist
- Specialist with expertise in the diagnosis and management of sickle cell disease

Product Name: Adakveo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduction in annual rate of vaso-occlusive events, increased time between each vaso-occlusive event)

3 . References

1. Adakveo (crizanlizumab) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2022.
2. Ataga K, Kutlar A, Kanter J et al. Crizanlizumab for the Prevention of Pain Crises in Sickle Cell Disease. New England Journal of Medicine. 2017;376(5):429-439. doi:10.1056/nejmoa1611770.
3. Evidence-Based Management of Sickle Cell Disease: Expert Panel Report, 2014. Nhlbi.nih.gov. https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-report%20020816_0.pdf. Published 2014. Accessed December 6, 2021.
4. Brawley O, Cornelius L, Edwards L et al. National Institutes of Health Consensus Development Conference Statement: Hydroxyurea Treatment for Sickle Cell Disease. Ann Intern Med. 2008;148(12):932. doi:10.7326/0003-4819-148-12-200806170-00220.
5. Niihara Y, Miller S, Kanter J et al. A Phase 3 Trial of l-Glutamine in Sickle Cell Disease. New England Journal of Medicine. 2018;379(3):226-235. doi:10.1056/nejmoa1715971.
6. Brandow A, Carroll C, Creary S et al. American Society of Hematology 2020 guidelines for sickle cell disease: management of acute and chronic pain. Blood Adv. 2020;4(12):2656-2701. doi:10.1182/bloodadvances.2020001851.

4 . Revision History

Date	Notes
1/4/2023	2023 UM Annual Review. Updated references

Prior Authorization Guideline

Guideline Name	Adalimumab

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	3/17/2003
P&T Revision Date:	11/14/2019 ; 11/12/2020 ; 04/21/2021 ; 11/18/2021 ; 10/19/2022 ; 12/14/2022 ; 5/18/2023

Note:

This guideline applies to Humira and Tier 2 Amjevita. For nonpreferred biosimilars, refer to the "Managed Administrative Biosimilars Policy" guideline for review.

1 . Indications

Drug Name: Humira (adalimumab)
Rheumatoid arthritis (RA) Indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severe active rheumatoid arthritis (RA). Humira can be used alone or in combination with methotrexate (MTX) or other non-biologic disease-modifying antirheumatic drugs (DMARDs). **Polyarticular Juvenile idiopathic arthritis (PJIA)** Indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients ages 2 years of age and older. Humira can be used alone or in combination with MTX. **Psoriatic arthritis (PsA)** Indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis. Humira can be used alone or in combination with non-biologic DMARDs.

Plaque psoriasis (PsO) Indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. Humira should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.

Ankylosing spondylitis (AS) Indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis.

Crohn's disease (CD) Indicated for the treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older.

Ulcerative Colitis (UC) Indicated for the treatment of moderately to severely active ulcerative colitis in adults and pediatric patients 5 years of age and older. Limitations of use: The effectiveness of Humira has not been established in patients who have lost response to or were intolerant to TNF blockers.

Hidradenitis Suppurativa (HS) Indicated for the treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older.

Uveitis (UV) Indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adults and pediatric patients 2 years of age and older.

Drug Name: Amjevita (adalimumab-atto)

Rheumatoid arthritis (RA) Indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Amjevita can be used alone or in combination with methotrexate or other non-biologic disease-modifying anti-rheumatic drugs (DMARDs).

Polyarticular Juvenile idiopathic arthritis (PJIA) Indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older. Amjevita can be used alone or in combination with methotrexate.

Psoriatic arthritis (PsA) Indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis. Amjevita can be used alone or in combination with non-biologic DMARDs.

Plaque psoriasis (PsO) Indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. Amjevita should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.

Ankylosing spondylitis (AS) Indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis.

Crohn's disease (CD) Indicated for the treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older.

Ulcerative Colitis (UC) Indicated for the treatment of moderately to severely active ulcerative colitis in adult patients. Limitations of use: The effectiveness of adalimumab products has not been established in patients who have lost response to or were intolerant to TNF-blockers.

Hidradenitis Suppurativa (HS) Indicated for the treatment of moderate to severe hidradenitis suppurativa in adult patients.

Off Label Uses: Uveitis (UV) Adalimumab may be used for the treatment of non-infectious intermediate, posterior and panuveitis in adults and pediatric patients 2 years of age and older.

2 . Criteria

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active RA

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide
- sulfasalazine

Notes	*If NDC starts with 72511, approve at NDC list "OOADALIMUM". For all other NDC's, approve both Humira and Amjevita at NDC list “ADAL IMUMPA”.

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Notes	*If NDC starts with 72511, approve at NDC list "OOADALIMUM". For all other NDC's, approve both Humira and Amjevita at NDC list “ADAL IMUMPA”.

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severely active PJIA

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4]:

- leflunomide
- methotrexate

Notes	*If NDC starts with 72511, approve at NDC list "OOADALIMUM". For all other NDC's, approve both Humira and Amjevita at NDC list “ADAL IMUMPA”.

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Notes	*If NDC starts with 72511, approve at NDC list "OOADALIMUM". For all other NDC's, approve both Humira and Amjevita at NDC list “ADAL IMUMPA”.

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active PsA

AND

2 - One of the following [5]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Notes	*If NDC starts with 72511, approve at NDC list "OOADALIMUM". For all other NDC's, approve both Humira and Amjevita at NDC list “ADAL IMUMPA”.

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 5]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Notes	*If NDC starts with 72511, approve at NDC list "OOADALIMUM". For all other NDC's, approve both Humira and Amjevita at NDC list “ADAL IMUMPA”.

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe chronic plaque psoriasis

AND

2 - One of the following [6]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [7]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

Notes	*If NDC starts with 72511, approve at NDC list "OOADALIMUM". For all other NDC's, approve both Humira and Amjevita at NDC list “ADAL IMUMPA”.

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1, 6]:

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Notes	*If NDC starts with 72511, approve at NDC list "OOADALIMUM". For all other NDC's, approve both Humira and Amjevita at NDC list “ADAL IMUMPA”.

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [8]

Notes	*If NDC starts with 72511, approve at NDC list "OOADALIMUM". For all other NDC's, approve both Humira and Amjevita at NDC list “ADAL IMUMPA”.

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following [1, 8]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Notes	*If NDC starts with 72511, approve at NDC list "OOADALIMUM". For all other NDC's, approve both Humira and Amjevita at NDC list “ADAL IMUMPA”.

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*	
Diagnosis	Crohn’s disease (CD)

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - One of the following [9, 10]:

- Frequent diarrhea and abdominal pain
- At least 10% weight loss
- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values (e.g., C-reactive protein [CRP])
- CD Activity Index (CDAI) greater than 220

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies: [9, 10]

- 6-mercaptopurine
- azathioprine
- corticosteroids (e.g., prednisone)
- methotrexate

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	*If NDC starts with 72511, approve at NDC list "OOADALIMUM". For all other NDC's, approve both Humira and Amjevita at NDC list "ADAL IMUMPA".

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*	
Diagnosis	Crohn's disease (CD)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 9, 10]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

Notes	*If NDC starts with 72511, approve at NDC list "OOADALIMUM". For all other NDC's, approve both Humira and Amjevita at NDC list “ADAL IMUMPA”.

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 Week(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [11, 12]:

- Greater than 6 stools per day
- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers
- Abnormal lab values (e.g., hemoglobin, ESR, CRP)

- Dependent on, or refractory to, corticosteroids

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies: [11, 12]

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine
- Corticosteroids (e.g., prednisone)

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	*If NDC starts with 72511, approve at NDC list "OOADALIMUM". For all other NDC's, approve both Humira and Amjevita at NDC list “ADAL IMUMPA”.

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 For patients who initiated Humira therapy within the past 12 weeks: Documentation of clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy

OR

1.2 For patients who have been maintained on Humira therapy for longer than 12 weeks, documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 11, 12]:

• Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline • Reversal of high fecal output state

Notes	*If NDC starts with 72511, approve at NDC list "OOADALIMUM". For all other NDC's, approve both Humira and Amjevita at NDC list “ADAL IMUMPA”.

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*	
Diagnosis	Hidradenitis Suppurativa (HS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley Stage II or III) **AND** **2** - Prescribed by or in consultation with a dermatologist	
Notes	*If NDC starts with 72511, approve at NDC list "OOADALIMUM". For all other NDC's, approve both Humira and Amjevita at NDC list “ADAL IMUMPA”.

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*	
Diagnosis	Hidradenitis Suppurativa (HS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Documentation of positive clinical response to therapy

Notes	*If NDC starts with 72511, approve at NDC list "OOADALIMUM". For all other NDC's, approve both Humira and Amjevita at NDC list “ADAL IMUMPA”.

Product Name: Humira*, Amjevita (Tier 2 or Preferred)* (off-label)	
Diagnosis	Uveitis (UV)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-infectious uveitis

AND

2 - Uveitis is classified as one of the following:

- intermediate
- posterior
- panuveitis

AND

3 - Prescribed by or in consultation with one of the following:

- ophthalmologist
- rheumatologist

Notes	*If NDC starts with 72511, approve at NDC list "OOADALIMUM". For all other NDC's, approve both Humira and Amjevita at NDC list “ADAL IMUMPA”.

Product Name: Humira*, Amjevita (Tier 2 or Preferred)* (off-label)

Diagnosis	Uveitis (UV)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	
Notes	*If NDC starts with 72511, approve at NDC list "OOADALIMUM". For all other NDC's, approve both Humira and Amjevita at NDC list “ADAL IMUMPA”.

3 . References

1. Humira Prescribing Information. Abbvie Inc. North Chicago, IL. February 2021.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.
3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.
4. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Rheumatol. 2019;71(6):846-863.
5. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
6. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
7. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.
8. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613.
9. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018;113:481-517.
10. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508.
11. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.

12. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterol. 2020;158:1450-1461.
13. Amjevita Prescribing Information. Amgen Inc. Thousand Oaks, CA. April 2023.

4 . Revision History

Date	Notes
5/3/2023	Updated Amjevita indication for HS to remove off-label reference

Prior Authorization Guideline

Guideline Name	Administrative Non-Formulary & Excluded Drug Exceptions Process

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	2/19/2013
P&T Revision Date:	11/14/2019 ; 11/12/2020 ; 01/20/2021 ; 03/17/2021 ; 05/20/2021 ; 06/16/2021 ; 11/18/2021 ; 08/18/2022 ; 11/17/2022

Note:

The purpose of this guideline is to establish policies and procedures on how to handle non-formulary and excluded drugs. This guideline will not apply to drugs with step therapy edits, drugs that require quantity limit review only, or drugs that are not reviewed for prior authorization. ** Please consult client-specific resources to confirm whether benefit exclusions should be reviewed for medical necessity **

1 . Criteria

Product Name: A non-formulary or excluded* contraceptive drug	
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria	

1 - One of the following:

1.1 Both of the following:

- Patient is using the requested product for contraception or other FDA-approved condition**
- The requested product is medically necessary***

OR

1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

Notes	*Please consult client-specific resources to confirm whether benefit exclusions should be reviewed for medical necessity. **Examples of non-contraception uses: (1) Abnormal or excessive bleeding disorders (eg, amenorrhea, oligomenorrhea, menorrhagia, dysfunctional uterine bleeding); (2) Acne; (3) Decrease in bone mineral density; (4) Dysmenorrhea; (5) Endometriosis; (6) Hirsutism; (7) Irregular menses / cycles; (8) Ovarian cysts; (9) Perimenopausal symptoms; (10) History of Pelvic Inflammatory Disease (PID); (11) Polycystic Ovarian Syndrome (PCO or PCOS); (12) Premenstrual Syndrome (PMS); (13) Premenstrual Dysphoric Disorder (PMDD); (14) Prevention of endometrial and/or ovarian cancer; (15) Prevention of menstrual migraines; (16) Turner's syndrome; (17) Uterine fibroids or adenomyosis. ***Any justification of medical necessity/appropriateness provided by the prescriber is adequate to approve access.

Product Name: A non-formulary or excluded* drug	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - Both of the following:

1.1 One of the following:

1.1.1 Patient has failed or has contraindications or intolerance to at least three equivalent formulary drugs. If only one or only two equivalents are available, the patient must have failed or had contraindications or intolerance to all available equivalent formulary drugs. The

clinician's judgment should be used to determine equivalent formulary drugs for the indication provided.

OR

1.1.2 Both of the following:

1.1.2.1 Only over-the-counter (OTC) equivalents are available

AND

1.1.2.2 Patient has tried and failed or has contraindications or intolerance to 3 OTC equivalents. If only one or only two equivalents are available, the patient must have failed or had contraindications or intolerance to all available OTC equivalents [document drug(s), dose, duration of trial] The clinician's judgment should be used to determine equivalent formulary drugs for the indication provided.

OR

1.1.3 No formulary or OTC drug is appropriate to treat the patient's condition

AND

1.2 One of the following:

1.2.1 Both of the following:

1.2.1.1 Requested drug is FDA-approved for the condition being treated

AND

1.2.1.2 Additional requirements listed in the "Indications and Usage" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.)

OR

1.2.2 If requested for an off-label indication, the off-label guideline approval criteria have been met	
Notes	*Please consult client-specific resources to confirm whether benefit exclusions should be reviewed for medical necessity. *For Premium Drug Exclusion on Premium formulary, if the target drug is listed on the PREMVDL grid, the patient must try and fail, or have specific medical reason(s) for why the number of alternatives specified by the grid is not appropriate.

2 . Revision History

Date	Notes
11/2/2022	Annual review: No updates required.

Prior Authorization Guideline

Guideline Name	Afinitor, Afinitor Disperz (everolimus) - PA, NF

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	8/18/2009
P&T Revision Date:	02/13/2020 ; 05/15/2020 ; 05/20/2021 ; 11/18/2021 ; 01/19/2022 ; 05/19/2022 ; 5/18/2023

1 . Indications

Drug Name: Afinitor (everolimus tablet)
Advanced Neuroendocrine Tumors of Pancreatic Origin (PNET) Indicated for the treatment of progressive PNET in patients with unresectable, locally advanced or metastatic disease. Afinitor is not indicated for the treatment of patients with functional carcinoid tumors. **Advanced Renal Cell Carcinoma (RCC)** Indicated for the treatment of patients with advanced RCC after failure of treatment with sunitinib or sorafenib. **Renal Angiomyolipoma with Tuberous Sclerosis Complex (TSC)** Indicated for the treatment of adult patients with renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery. **Subependymal Giant Cell Astrocytoma (SEGA)** Indicated for the treatment of adult and pediatric patients aged 1 year and older with TSC who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected. **Advanced Hormone Receptor-Positive, HER2-Negative Breast Cancer (Advanced HR + BC)** Indicated for the treatment of postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer (advanced HR+ BC) in combination with exemestane, after failure of treatment with letrozole or anastrozole.

Neuroendocrine Tumors of Gastrointestinal or Lung Origin Indicated for the treatment of adults with progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin that are unresectable, locally advanced or metastatic. AFINITOR is not indicated for the treatment of patients with functional carcinoid tumors.

Drug Name: Afinitor Disperz (everolimus tablet for oral suspension)

Subependymal Giant Cell Astrocytoma (SEGA) Indicated for the treatment of adult and pediatric patients aged 1 year and older with TSC who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected. The effectiveness of Afinitor Disperz is based on demonstration of durable objective response, as evidenced by reduction in SEGA tumor volume. Improvement in disease-related symptoms and overall survival in patients with SEGA and TSC has not been demonstrated.

Tuberous Sclerosis Complex (TSC) Associated Partial-onset Seizures Indicated for the adjunctive treatment of adult and pediatric patients aged 2 years and older with TSC-associated partial-onset seizures

2 . Criteria

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Advanced Neuroendocrine Tumors of Pancreatic Origin (PNET)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of progressive neuroendocrine tumors of pancreatic origin

AND

2 - Disease is one of the following:

- Unresectable, locally advanced
- Metastatic

AND

3 - Trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Advanced Neuroendocrine Tumors of Pancreatic Origin (PNET)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Advanced Neuroendocrine Tumors of Pancreatic Origin (PNET)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of progressive neuroendocrine tumors of pancreatic origin

AND

2 - Disease is one of the following:

- Unresectable, locally advanced

- Metastatic

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Advanced Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced renal cell carcinoma

AND

2 - Trial and failure with one of the following*:

- Sutent (sunitinib)
- Nexavar (sorafenib)

AND

3 - Trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

AND

4 - Prescribed by or in consultation with an oncologist	
Notes	*Criterion is part of the FDA-approved label.

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Advanced Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Advanced Renal Cell Carcinoma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of advanced renal cell carcinoma

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure with one of the following*:

- Sutent (sunitinib)
- Nexavar (sorafenib)

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

AND

4 - Prescribed by or in consultation with an oncologist

Notes	*Criterion is part of the FDA-approved label.

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Renal Angiomyolipoma with Tuberous Sclerosis Complex (TSC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of renal angiomyolipoma and tuberous sclerosis complex (TSC)

AND

2 - Trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

AND

3 - Prescribed by or in consultation with a nephrologist

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Renal Angiomyolipoma with Tuberous Sclerosis Complex (TSC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Renal Angiomyolipoma with Tuberous Sclerosis Complex (TSC)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of renal angiomyolipoma and tuberous sclerosis complex (TSC)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

AND

3 - Prescribed by or in consultation with a nephrologist

Product Name: Brand Afinitor, Generic everolimus tablet, Brand Afinitor Disperz, Generic everolimus tablet for oral suspension	
Diagnosis	Subependymal Giant Cell Astrocytoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS)

AND

2 - Patient is 1 year of age or older

AND

3 - One of the following:

3.1 Trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

OR

3.2 Trial and failure or intolerance to generic everolimus tablet for oral suspension (applies to Brand Afinitor Disperz only)

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Brand Afinitor, Generic everolimus tablet, Brand Afinitor Disperz, Generic everolimus tablet for oral suspension	
Diagnosis	Subependymal Giant Cell Astrocytoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Brand Afinitor, Generic everolimus tablet, Brand Afinitor Disperz, Generic everolimus tablet for oral suspension	
Diagnosis	Subependymal Giant Cell Astrocytoma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS)

AND

2 - Patient is 1 year of age or older

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic everolimus tablet for oral suspension (applies to Brand Afinitor Disperz only)

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Breast cancer
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hormone receptor positive, HER-2 negative advanced breast cancer

AND

2 - Trial and failure, contraindication, or intolerance to one of the following*:

- Femara (letrozole)
- Arimidex (anastrozole)

AND

3 - Trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

AND

4 - Prescribed by or in consultation with an oncologist

Notes	*Criterion is part of the FDA-approved label.

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Breast cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Breast cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of hormone receptor positive, HER-2 negative advanced breast cancer

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one of the following*:

- Femara (letrozole)
- Arimidex (anastrozole)

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

AND

4 - Prescribed by or in consultation with an oncologist

Notes	*Criterion is part of the FDA-approved label.

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Neuroendocrine tumors of gastrointestinal or lung origin
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of progressive, well-differentiated, non-functional neuroendocrine tumors of gastrointestinal or lung origin

AND

2 - One of the following:

- Unresectable, locally advanced disease
- Metastatic disease

AND

3 - Trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Neuroendocrine tumors of gastrointestinal or lung origin
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Neuroendocrine tumors of gastrointestinal or lung origin
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of progressive, well-differentiated, non-functional neuroendocrine tumors of gastrointestinal or lung origin

AND

2 - One of the following:

- Unresectable, locally advanced disease
- Metastatic disease

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Brand Afinitor Disperz, Generic everolimus tablet for oral suspension	
Diagnosis	TSC-associated Partial-onset Seizures
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of TSC-associated partial-onset seizures

AND

2 - Patient is 2 years of age or older

AND

3 - Trial and failure or intolerance to generic everolimus tablet for oral suspension (applies to Brand Afinitor Disperz only)

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Brand Afinitor Disperz, Generic everolimus tablet for oral suspension	
Diagnosis	TSC-associated Partial-onset Seizures
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient shows reduction in seizure frequency while on therapy

Product Name: Brand Afinitor Disperz, Generic everolimus tablet for oral suspension	
Diagnosis	TSC-associated Partial-onset Seizures
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of TSC-associated partial-onset seizures

AND

2 - Patient is 2 years of age or older

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic everolimus tablet for oral suspension (applies to Brand Afinitor Disperz only)

AND

4 - Prescribed by or in consultation with a neurologist

3 . References

1. Afinitor and Afinitor Disperz Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. February 2022.

4 . Revision History

Date	Notes
5/11/2023	Program update to remove requirement that patient is not a candidate for curative surgical resection, patient does not require immediate surgery, patient is post menopausal, and used in combination with Aromasin (exemestane) for their respective indications

Prior Authorization Guideline

Guideline Name	Afrezza (insulin human, inhalation powder) - PA, NF

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	8/20/2014
P&T Revision Date:	02/13/2020 ; 02/13/2020 ; 02/18/2021 ; 05/20/2021 ; 02/17/2022 ; 2/16/2023

1 . Indications

Drug Name: Afrezza (insulin human, inhalation powder)
Diabetes Mellitus Indicated to improve glycemic control in adult patients with diabetes mellitus. Limitations of Use: Afrezza is not a substitute for long-acting insulin. Afrezza must be used in combination with long-acting insulin in patients with type 1 diabetes mellitus. Afrezza is not recommended for the treatment of diabetic ketoacidosis. The safety and efficacy of Afrezza in patients who smoke has not been established. The use of Afrezza is not recommended in patients who smoke or who have recently stopped smoking.

2 . Criteria

Product Name: Afrezza	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of type 1 diabetes mellitus

AND

1.1.2 Used in combination with a long-acting insulin (e.g., Lantus, Levemir)

OR

1.2 Diagnosis of type 2 diabetes mellitus

AND

2 - Unable to self-inject short-acting insulin multiple times daily due to one of the following: [4]

- Physical impairment
- Visual impairment
- Lipohypertrophy

AND

3 - Documented FEV1 within the last 60 days greater than or equal to 70% of expected normal as determined by the physician [A]

AND

4 - Prescribed by or in consultation with an endocrinologist

AND

5 - Afrezza will NOT be approved in patients:

- Who smoke cigarettes
- Who recently quit smoking (within the past 6 months) [B]
- With chronic lung disease (e.g., asthma, chronic obstructive pulmonary disease [COPD]) [C]

Product Name: Afrezza	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Repeat pulmonary function test confirms that the patient has NOT experienced a decline of 20% or more in FEV1 from baseline [1]

AND

2 - Documentation of positive clinical response to therapy

AND

3 - Both of the following: [1]

- Patient does NOT have chronic lung disease (e.g., asthma, chronic obstructive pulmonary disease [COPD])
- Patient does not smoke cigarettes

Product Name: Afrezza	
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of type 1 diabetes mellitus

AND

1.1.2 Used in combination with a long-acting insulin (e.g., Lantus, Levemir)

OR

1.2 Diagnosis of type 2 diabetes mellitus

AND

2 - Submission of medical records (e.g., chart notes) documenting that patient is unable to self-inject short-acting insulin multiple times daily due to one of the following: [4]

- Physical impairment
- Visual impairment
- Lipohypertrophy

AND

3 - Submission of medical records (e.g., chart notes) documenting FEV1 within the last 60 days greater than or equal to 70% of expected normal as determined by the physician [A]

AND

4 - Prescribed by or in consultation with an endocrinologist

AND

5 - Afrezza will NOT be approved in patients:

- Who smoke cigarettes
- Who recently quit smoking (within the past 6 months) [B]
- With chronic lung disease (e.g., asthma, chronic obstructive pulmonary disease [COPD]) [C]

3 . Endnotes

A. The inclusion criteria for the phase III trial includes the following parameters: Forced expiratory volume in 1 second (FEV1) = 70% of predicted values. [2, 3]
B. The exclusion criteria for the phase III trial excludes current smokers or smoking history within the past 6 months. [2, 3]
C. Afrezza (insulin human) is contraindicated in patients with chronic lung disease such as asthma or chronic obstructive pulmonary disease (COPD).

4 . References

1. Afrezza Prescribing Information. MannKind Corporation. Danbury, CT. February 2020.
2. Bode BW, McGill JB, Lorber DL, et al. Inhaled Technosphere Insulin Compared With Injected Prandial Insulin in Type 1 Diabetes: A Randomized 24-Week Trial. Diabetes Care. 2015 Dec;38(12):2266-73.
3. Rosenstock J, Franco D, Korpachev V, et al. Inhaled Technosphere Insulin Versus Inhaled Technosphere Placebo in Insulin-Naïve Subjects With Type 2 Diabetes Inadequately Controlled on Oral Antidiabetes Agents. Diabetes Care. 2015 Dec;38(12):2274-81.
4. Per clinical consult with endocrinologist, August 6, 2014.

5 . Revision History

Date	Notes
1/24/2023	2023 UM Annual Review. Updated NF criteria to require submission of medical records to align with NF SOP.

Prior Authorization Guideline

Guideline Name	Aldurazyme (laronidase)

Guideline Note:

Effective Date:	8/1/2022
P&T Approval Date:	2/2/2004
P&T Revision Date:	06/17/2020 ; 06/16/2021 ; 6/15/2022

1 . Indications

Drug Name: Aldurazyme (laronidase)
Mucopolysaccharidosis I (MPS I) Indicated for adult and pediatric patients with Hurler and Hurler-Scheie forms of Mucopolysaccharidosis I (MPS I) and for patients with the Scheie form who have moderate to severe symptoms. The risks and benefits of treating mildly affected patients with the Scheie form have not been established. Aldurazyme has not been evaluated for effects of the central nervous system manifestations of the disorder.

2 . Criteria

Product Name: Aldurazyme	
Approval Length	60 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of Hurler and Hurler-Scheie forms of Mucopolysaccharidosis I (MPS I)

OR

1.2 Diagnosis of Scheie form of Mucopolysaccharidosis I (MPS I) in patients with moderate to severe symptoms

3 . References

1. Aldurazyme Prescribing Information, BioMarin Pharmaceutical Inc. Novato, CA. December 2019.

4 . Revision History

Date	Notes
6/8/2022	Annual Review

Prior Authorization Guideline

Guideline Name	Alecensa (alectinib)

Guideline Note:

Effective Date:	7/1/2022
P&T Approval Date:	2/25/2016
P&T Revision Date:	08/13/2020 ; 08/19/2021 ; 08/19/2021 ; 5/19/2022

1 . Indications

Drug Name: Alecensa (alectinib)
Non-small cell lung cancer Indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.

2 . Criteria

Product Name: Alecensa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of metastatic non-small cell lung cancer **AND** **2** - Patient has anaplastic lymphoma kinase (ALK)-positive disease as detected with an FDA-approved test or test performed at a Clinical Laboratory Improvement Amendments (CLIA)-approved facility* **AND** **3** - Prescribed by or in consultation with an oncologist	
Notes	*CLIA-certified laboratories: https://wwwn.cdc.gov/clia/Resources/LabSearch.aspx

Product Name: Alecensa	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has not experienced disease progression	

3 . References

1. Alecensa prescribing information. Genentech. South San Francisco, CA. September 2021.

4 . Revision History

Date	Notes

4/28/2022	Annual review - no criteria changes, background update

Prior Authorization Guideline

Guideline Name	Alfa Interferons

Guideline Note:

Effective Date:	8/1/2022
P&T Approval Date:	3/17/2000
P&T Revision Date:	06/17/2020 ; 06/16/2021 ; 6/15/2022

1 . Indications

Drug Name: Intron A (interferon alfa-2b)
Hairy Cell Leukemia Indicated for the treatment of patients 18 years of age or older with hairy cell leukemia. **Malignant Melanoma** Indicated as adjuvant to surgical treatment in patients 18 years of age or older with malignant melanoma who are free of disease but at high risk for systemic recurrence, within 56 days of surgery. **Follicular Lymphoma** Indicated for the initial treatment of clinically aggressive follicular Non-Hodgkin's Lymphoma in conjunction with anthracycline-containing combination chemotherapy in patients 18 years of age or older. Efficacy of Intron A therapy in patients with low-grade, low-tumor burden follicular Non-Hodgkin's Lymphoma has not been demonstrated. **Condylomata Acuminata** Indicated for intralesional treatment of selected patients 18 years of age or older with condylomata acuminata involving external surfaces of the genital and perianal areas. The use of this product in adolescents has not been studied. **AIDS-Related Kaposi's Sarcoma** Indicated for the treatment of selected patients 18 years of age or older with AIDS-Related Kaposi's Sarcoma. The likelihood of response to Intron A therapy is greater in patients who are without systemic symptoms, who have limited lymphadenopathy and who have a relatively intact immune system as indicated by total CD4

count.

Chronic Hepatitis C Indicated for the treatment of chronic hepatitis C in patients 18 years of age or older with compensated liver disease who have a history of blood or blood-product exposure and/or are HCV antibody positive. Studies in these patients demonstrated that Intron A therapy can produce clinically meaningful effects on this disease, manifested by normalization of serum alanine aminotransferase (ALT) and reduction in liver necrosis and degeneration. A liver biopsy should be performed to establish the diagnosis of chronic hepatitis. Patients should be tested for the presence of antibody to HCV. Patients with other causes of chronic hepatitis, including autoimmune hepatitis, should be excluded. Prior to initiation of Intron A therapy, the physician should establish that the patient has compensated liver disease. The following patient entrance criteria for compensated liver disease were used in the clinical studies and should be considered before Intron A treatment of patients with chronic hepatitis C: - No history of hepatic encephalopathy, variceal bleeding, ascites, or other clinical signs of decompensation - Bilirubin less than or equal to 2 mg/dL - Albumin stable and within normal limits - Prothrombin time less than 3 seconds prolonged - WBC greater than or equal to 3,000/mm3 - Platelets greater than or equal to 70,000/mm3. Serum creatinine should be normal or near normal. Prior to initiation of Intron A therapy, CBC and platelet counts should be evaluated in order to establish baselines for monitoring potential toxicity. These tests should be repeated at Weeks 1 and 2 following initiation of Intron A therapy, and monthly thereafter. Serum ALT should be evaluated at approximately 3-month intervals to assess response to treatment. Patients with preexisting thyroid abnormalities may be treated if thyroid-stimulating hormone (TSH) levels can be maintained in the normal range by medication. TSH levels must be within normal limits upon initiation of Intron A treatment and TSH testing should be repeated at 3 and 6 months. Intron A in combination with Rebetol is indicated for the treatment of chronic hepatitis C in patients 3 years of age and older with compensated liver disease previously untreated with alpha interferon therapy and in patients 18 years of age and older who have relapsed following alpha interferon therapy. See Rebetol prescribing information for additional information.

Chronic Hepatitis B Indicated for the treatment of chronic hepatitis B in patients 1 year of age or older with compensated liver disease. Patients who have been serum HBsAg positive for at least 6 months and have evidence of HBV replication (serum HBeAg positive) with elevated serum ALT are candidates for treatment. Studies in these patients demonstrated that Intron A therapy can produce virologic remission of this disease (loss of serum HBeAg), and normalization of serum aminotransferases. Intron A therapy resulted in the loss of serum HBsAg in some responding patients. Prior to initiation of Intron A therapy, it is recommended that a liver biopsy be performed to establish the presence of chronic hepatitis and the extent of liver damage. The physician should establish that the patient has compensated liver disease. The following patient entrance criteria for compensated liver disease were used in the clinical studies and should be considered before Intron A treatment of patients with chronic hepatitis B: - No history of hepatic encephalopathy, variceal bleeding, ascites, or other signs of clinical decompensation - Bilirubin normal - Albumin stable and within normal limits - Prothrombin Time - adults < 3 seconds prolonged, pediatrics less than or equal to 2 seconds prolonged - WBC greater than or equal to 4,000/mm^3 - Platelets - adults greater than or equal to 100,000/mm^3, pediatrics greater than or equal to 150,000/mm^3. Patients with causes of chronic hepatitis other than chronic hepatitis B or chronic hepatitis C should not be treated with Intron A. CBC and platelet counts should be evaluated prior to initiation of Intron A therapy in order to establish baselines for monitoring potential toxicity. These tests should be repeated at treatment Weeks 1, 2, 4, 8, 12, and 16. Liver function tests, including serum

ALT, albumin, and bilirubin, should be evaluated at treatment Weeks 1, 2, 4, 8, 12, and 16. HBeAg, HBsAg, and ALT should be evaluated at the end of therapy, as well as 3- and 6-months post-therapy, since patients may become virologic responders during the 6-month period following the end of treatment. In clinical studies in adults, 39% (15/38) of responding patients lost HBeAg 1 to 6 months following the end of Intron A therapy. Of responding patients who lost HBsAg, 58% (7/12) did so 1 to 6 months post-treatment. A transient increase in ALT greater than or equal to 2 x baseline value (flare) can occur during Intron A therapy for chronic hepatitis B. In clinical trials in adults and pediatrics, this flare generally occurred 8 to 12 weeks after initiation of therapy and was more frequent in Intron A responders (adults 63%, 24/38; pediatrics 59%, 10/17) than in non-responders (adults 27%, 13/48; pediatrics 35%, 19/55). However, in adults and pediatrics, elevations in bilirubin 3 mg/dL (2 times ULN) occurred infrequently (adults 2%, 2/86; pediatrics 3%, 2/72) during therapy. When ALT flare occurs, in general, Intron A therapy should be continued unless signs and symptoms of liver failure are observed. During ALT flare, clinical symptomatology and liver function tests including ALT, prothrombin time, alkaline phosphatase, albumin, and bilirubin, should be monitored at approximately 2-week intervals.

Drug Name: Pegasys (peginterferon alfa-2a)

Chronic Hepatitis C As part of a combination regimen with other hepatitis C virus (HCV) antiviral drugs, is indicated for the treatment of adults with chronic hepatitis C (CHC) with compensated liver disease. For information about the safe and effective use of other HCV antiviral drugs to be used in combination with Pegasys, refer to their prescribing information. Pegasys in combination with ribavirin is indicated for treatment of pediatric patients 5 years of age and older with CHC and compensated liver disease. Pegasys monotherapy is only indicated for the treatment of patients with CHC with compensated liver disease if there are contraindications or significant intolerance to other HCV antiviral drugs. Limitations of use: - Pegasys alone or in combination with ribavirin without additional HCV antiviral drugs is not recommended for treatment of patients with CHC who previously failed therapy with an interferon-alfa. - Pegasys is not recommended for treatment of patients with CHC who have had solid organ transplantation.

Chronic Hepatitis B Indicated for the treatment of adult patients with HBeAg-positive and HBeAg-negative chronic hepatitis B infection who have compensated liver disease and evidence of viral replication and liver inflammation. Indicated for the treatment of HBeAg-positive CHB in non-cirrhotic pediatric patients 3 years of age and older with evidence of viral replication and elevations in serum alanine aminotransferase (ALT).

Drug Name: PegIntron (peginterferon alfa-2b)

Chronic Hepatitis C As part of a combination regimen, is indicated for the treatment of Chronic Hepatitis C (CHC) in patients with compensated liver disease. PegIntron in combination with ribavirin and an approved Hepatitis C Virus (HCV) NS3/4A protease inhibitor is indicated in adult patients with HCV genotype 1 infection (see labeling of the specific HCV NS3/4A protease inhibitor for further information). PegIntron in combination with ribavirin is indicated in patients with genotypes other than 1, pediatric patients (3-17 years of age), or in patients with genotype 1 infection where use of an HCV NS3/4A protease inhibitor is not warranted based on tolerability, contraindications or other clinical factors. PegIntron monotherapy should only be used in the treatment of CHC in patients with compensated liver disease if there are contraindications to or significant intolerance of ribavirin and is indicated

for use only in previously untreated adult patients. Combination therapy provides substantially better response rates than monotherapy.

2 . Criteria

Product Name: Intron A	
Diagnosis	Chronic Hepatitis C
Approval Length	48 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C

AND

2 - Patients without decompensated liver disease**

AND

3 - For patients who have not previously been treated with interferon

AND

4 - One of the following:

- Contraindication or intolerance to ribavirin
- Used in combination with ribavirin

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

Notes	**Defined as Child-Pugh Class B or C

Product Name: Intron A or Pegasys	
Diagnosis	Chronic Hepatitis B
Approval Length	48 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis B infection

AND

2 - Patients without decompensated liver disease**

Notes	**Defined as Child-Pugh Class B or C

Product Name: Pegasys or PegIntron	
Diagnosis	Chronic Hepatitis C
Approval Length	28 Week(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C infection

AND

2 - Patient without decompensated liver disease**

AND

3 - One of the following:

3.1 Used in combination with one of the following:

- Sovaldi (sofosbuvir)
- Ribavirin

OR

3.2 Contraindication or intolerance to all other HCV agents (e.g., Sovaldi [sofosbuvir], ribavirin)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

Notes	**Defined as Child-Pugh Class B or C

Product Name: Pegasys or PegIntron	
Diagnosis	Chronic Hepatitis C
Approval Length	20 Week(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has an undetectable HCV RNA at week 24

AND

2 - Additional treatment weeks of peginterferon are required to complete treatment regimen

AND

3 - Patient has not exceeded 48 weeks of therapy with peginterferon

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

Product Name: Intron A	
Diagnosis	Condylomata acuminata
Approval Length	6 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of condylomata acuminata (genital or perianal)

Product Name: Intron A	
Diagnosis	Diagnoses other than hepatitis and condylomata acuminata
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of hairy cell leukemia

OR

1.2 Diagnosis of AIDS-related Kaposi's sarcoma

OR

1.3 All of the following:

1.3.1 Diagnosis of metastatic renal cell carcinoma

AND

1.3.2 Used in combination with Avastin (bevacizumab)

AND

1.3.3 Prescribed by or in consultation with an oncologist

OR

1.4 Diagnosis of malignant melanoma

OR

1.5 Diagnosis of Stage III or IV follicular Non-Hodgkin's Lymphoma

OR

1.6 As maintenance therapy for the treatment of multiple myeloma (non-FDA approved indication)

3 . References

1. Pegasys Prescribing Information. Genentech, Inc. South San Francisco, CA. March 2021.
2. PegIntron Prescribing Information. Merck & Co. Whitehouse Station, NJ. August 2019.
3. Intron A Prescribing Information. Merck & Co. Whitehouse Station, NJ. November 2021.
4. Avastin Prescribing Information. Genentech, Inc. South San Francisco, CA. January 2021.
5. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com/. Accessed May 5, 2022.
6. Sovaldi Prescribing Information. Gilead Sciences, Inc. Foster City, CA. September 2019.

4 . Revision History

Date	Notes
6/8/2022	Annual Review

Prior Authorization Guideline

Guideline Name	Alpha-1 Proteinase Inhibitors

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	2/25/2016
P&T Revision Date:	03/18/2020 ; 01/20/2021 ; 03/17/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Aralast NP (alpha-1-proteinase inhibitor [human])
Alpha-1 proteinase inhibitor deficiency (also known as alpha-1-antitrypsin (AAT) deficiency) Indicated for chronic augmentation therapy in adults with clinically evident emphysema due to severe congenital deficiency of Alpha1-PI (alpha1-antitrypsin deficiency). Aralast NP increases antigenic and functional (anti-neutrophil elastase capacity, ANEC) serum levels and antigenic lung epithelial lining fluid levels of Alpha1-PI. The effect of augmentation therapy with Alpha1-PI, including Aralast NP, on pulmonary exacerbations and on the progression of emphysema in alpha-1-antitrypsin deficiency has not been conclusively demonstrated in randomized, controlled clinical trials. Clinical data demonstrating the long-term effects of chronic augmentation and maintenance therapy with Aralast NP or Aralast are not available. Aralast NP is not indicated as therapy for lung disease patients in whom severe congenital Alpha-1-PI deficiency has not been established.
Drug Name: Glassia (alpha-1-proteinase inhibitor [human])
Alpha-1 proteinase inhibitor deficiency (also known as alpha-1-antitrypsin (AAT) deficiency) Indicated for chronic augmentation and maintenance therapy in individuals with clinically evident emphysema due to severe hereditary deficiency of Alpha1-PI, also known as alpha1-antitrypsin (AAT) deficiency. Glassia increases antigenic and functional (anti-neutrophil elastase capacity, ANEC) serum levels and antigenic lung epithelial lining fluid levels of Alpha1-PI. Limitations of Use: The effect of augmentation therapy with Glassia or

any Alpha1-PI product on pulmonary exacerbations and on the progression of emphysema in Alpha1-PI deficiency has not been conclusively demonstrated in randomized, controlled clinical trials. Clinical data demonstrating the long-term effects of chronic augmentation and maintenance therapy of individuals with Glassia are not available. Glassia is not indicated as therapy for lung disease in patients in whom severe Alpha1-PI deficiency has not been established.
Drug Name: Prolastin-C (alpha-1-proteinase inhibitor [human]), Prolastin-C liquid (alpha-1-proteinase inhibitor [human])
Alpha-1 proteinase inhibitor deficiency (also known as alpha-1-antitrypsin (AAT) deficiency) Indicated for chronic augmentation and maintenance therapy in adults with clinical evidence of emphysema due to severe hereditary deficiency of Alpha1-PI (alpha1-antitrypsin deficiency). Prolastin-C increases antigenic and functional (anti-neutrophil elastase capacity, ANEC) serum levels and antigenic lung epithelial lining fluid levels of Alpha1-PI. Limitations of Use: The effect of augmentation therapy with any Alpha-1-PI product on pulmonary exacerbations and on the progression of emphysema in Alpha1-PI deficiency has not been conclusively demonstrated in randomized, controlled clinical trials. Clinical data demonstrating the long-term effects of chronic augmentation or maintenance therapy with Prolastin-C are not available. Prolastin-C is not indicated as therapy for lung disease in patients in whom severe Alpha-1-PI deficiency has not been established.
Drug Name: Zemaira (alpha-1-proteinase inhibitor [human])
Alpha-1 proteinase inhibitor deficiency (also known as alpha-1-antitrypsin (AAT) deficiency) Indicated for chronic augmentation and maintenance therapy in adults with Alpha1-PI deficiency and clinical evidence of emphysema. Zemaira increases antigenic and functional (ANEC) serum levels and lung epithelial lining fluid levels of Alpha1-PI. Clinical data demonstrating the long-term effects of chronic augmentation therapy of individuals with Zemaira are not available. The effect of augmentation therapy with Zemaira or any Alpha1-PI product on pulmonary exacerbations and on the progression of emphysema in Alpha1-PI deficiency has not been demonstrated in randomized, controlled clinical trials. Zemaira is not indicated as therapy for lung disease patients in whom severe Alpha1-PI deficiency has not been established.

2 . Criteria

Product Name: Aralast NP, Glassia, Prolastin-C, Prolastin-C liquid, or Zemaira	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of congenital alpha-1 antitrypsin (AAT) deficiency

AND

2 - Diagnosis of emphysema [A]

AND

3 - One of the following:

3.1 Pi*ZZ, Pi*Z(null) or Pi*(null)(null) protein phenotypes (homozygous) [6]

OR

3.2 Other rare AAT disease genotypes associated with pre-treatment serum alpha1-antitrypsin (AAT) level less than 11 micromole per liter [e.g., Pi(Malton, Malton), Pi(SZ)] [B]

AND

4 - One of the following:

4.1 Circulating pre-treatment serum alpha1-antitrypsin (AAT) level less than 11 micromole per liter (which corresponds to less than 80 mg/dL if measured by radial immunodiffusion or less than 57 mg/dL if measured by nephelometry) [B, 10]

OR

4.2 Patient has a concomitant diagnosis of necrotizing panniculitis

AND

5 - Continued optimal conventional treatment for emphysema (e.g., bronchodilators)

AND

6 - One of the following: [8, 9, 10]

6.1 The FEV1 level is less than or equal to 65% of predicted

OR

6.2 Patient has experienced a rapid decline in lung function (i.e., reduction of FEV1 more than 120 mL/year) that warrants treatment [9]

OR

6.3 Patient has a concomitant diagnosis of necrotizing panniculitis

AND

7 - Patient is NOT a current smoker [C]

Product Name: Aralast NP, Glassia, Prolastin-C, Prolastin-C liquid, or Zemaira	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Continued optimal conventional treatment for emphysema (e.g., bronchodilators)

3 . Endnotes

A. Currently, augmentation therapy is not recommended for patients without emphysema. [3, 8] Some individuals with AAT deficiency will not go on to develop panacinar emphysema, only those with evidence of such disease should be considered for augmentation therapy.
B. Population studies suggest a minimum plasma threshold of 11 µmol/L (corresponding to 80 mg/dL in some assays and ~57 mg/dL by nephelometry), below which there is insufficient AAT to protect the lung, leading to a risk of developing emphysema. [3, 6-9]
C. The GOLD report recommends reserving alpha-1 antitrypsin augmentation therapy for those with evidence of continued and rapid progression following smoking cessation. [8]

4 . References

1. Aralast NP Prescribing Information. Baxalta US Inc. Westlake Village, CA. December 2022.
2. Zemaira Prescribing Information. CSL Behring LLC. Kankakee, IL. September 2022.
3. American Thoracic Society/European Respiratory Society Statement: Standards for diagnosis and management of individuals with alpha-1 antitrypsin deficiency. Am J Resp Care Med 2003; 168:818-900.
4. Prolastin-C Prescribing Information. Grifols Therapeutics, Inc. Research Triangle Park, NC. January 2022.
5. Glassia Prescribing Information. Baxalta US Inc. Lexington, MA. September 2022.
6. Marciniuk DD, Hernandez P, Balter M, et al. Alpha-1 antitrypsin deficiency targeted testing and augmentation therapy: A Canadian Thoracic Society clinical practice guideline. Canadian Respiratory Journal 2012;19(2):109-116.
7. Stoller JK. Treatment of of alpha-1 antitrypsin deficiency. UpToDate. Accessed March 12, 2019.
8. Vogelmeir C, Agusti A, et al. The global strategy for diagnosis, management and prevention of COPD (2020 Report). Global Initiative for Chronic Obstructive Lung Disease. Accessed January 21, 2020.
9. Brantly ML, Lascano JE, Shahmohammadi A. Intravenous alpha-1 antitrypsin therapy for alpha-1 antitrypsin deficiency: the current state of the evidence. Chronic Obstr Pulm Dis. 2019;6(1):100-114.
10. Sandhaus RA, Turino G, Brantly ML, et al. The diagnosis and management of alpha-1 antitrypsin deficiency in the adult. Chronic Obstr Pulm Dis. 2016; 3(3): 668-682.

5 . Revision History

Date	Notes

2/22/2023	2023 UM Annual Review. No changes to criteria. Updated references

Prior Authorization Guideline

Guideline Name	Ampyra (dalfampridine) - PA, NF

Guideline Note:

Effective Date:	9/1/2022
P&T Approval Date:	4/6/2010
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 05/19/2022 ; 7/20/2022

1 . Indications

Drug Name: Ampyra (dalfampridine)
Improvement in walking in patients with multiple sclerosis Indicated as a treatment to improve walking in adult patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed.

2 . Criteria

Product Name: Brand Ampyra, Generic dalfampridine extended-release	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis [A]

AND

2 - Physician confirmation that patient has difficulty walking (e.g., timed 25-foot walk test) [B]

AND

3 - One of the following:

- Patient has an expanded disability status scale (EDSS) score less than or equal to 7
- Patient is not restricted to using a wheelchair (if EDSS is not measured)

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Brand Ampyra, Generic dalfampridine extended-release	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Physician confirmation that the patient's walking improved with therapy

AND

2 - One of the following:

- Patient has an expanded disability status scale (EDSS) score less than or equal to 7
- Patient is not restricted to using a wheelchair (if EDSS is not measured)

Product Name: Brand Ampyra	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of multiple sclerosis [A]

AND

2 - Submission of medical records (e.g., chart notes) documenting physician confirmation that patient has difficulty walking (e.g., timed 25-foot walk test) [B]

AND

3 - Submission of medical records (e.g., chart notes) documenting one of the following:

- Patient has an expanded disability status scale (EDSS) score less than or equal to 7
- Patient is not restricted to using a wheelchair (if EDSS is not measured)

AND

4 - Prescribed by or in consultation with a neurologist

3 . Endnotes

A. Patients with clinically definite MS of any type were included in the pivotal trials for Ampyra. [2, 3]
B. Inclusion criteria in the Ampyra pivotal trials included patients who were able to walk (with or without an assistive device) 25 feet in 8-45 seconds and 8-60 seconds in the two studies, respectively. [2, 3]

4 . References

1. Ampyra Prescribing Information. Acorda Therapeutics, Inc. Ardsley, NY. November 2021.
2. Goodman AD, Brown TR, Krupp LB, et al. Sustained-release oral fampridine in multiple sclerosis: a randomised, double-blind, controlled trial. Lancet 2009;373:732-738.
3. Goodman AD, Brown TR, Cohen JA, et al. Dose comparison trial of sustained-release fampridine in multiple sclerosis. Neurology. 2008;1134-1141.

5 . Revision History

Date	Notes
7/5/2022	Addition of NF criteria for Brand Ampyra only

Prior Authorization Guideline

Guideline Name	Anti-Parkinson’s Agents

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	5/22/1998
P&T Revision Date:	03/18/2020 ; 06/17/2020 ; 03/17/2021 ; 04/21/2021 ; 01/19/2022 ; 03/16/2022 ; 03/15/2023 ; 5/18/2023

1 . Indications

Drug Name: Rytary (carbidopa and levodopa) extended-release capsules
Parkinson’s disease Indicated for the treatment of Parkinson's disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication
Drug Name: Duopa (carbidopa and levodopa) enteral suspension
Advanced Parkinson's disease Indicated for the treatment of motor fluctuations in patients with advanced Parkinson’s disease.
Drug Name: Xadago (safinamide) tablets
Parkinson’s disease Indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes.
Drug Name: Gocovri (amantadine) extended-release capsules
Dyskinesia in Parkinson's disease Indicated for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications.

"Off" Episodes in Parkinson's Disease Indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes.
Drug Name: Osmolex ER (amantadine) extended-release tablets
Parkinson's Disease Indicated for the treatment of Parkinson's disease. **Drug-Induced Extrapyramidal Reactions** Indicated for the treatment of drug-induced extrapyramidal reactions in adult patients.
Drug Name: Dhivy (carbidopa-levodopa)
Parkinson's Disease Indicated for the treatment of Parkinson's disease, post-encephalitic parkinsonism, and symptomatic parkinsonism that may follow carbon monoxide intoxication or manganese intoxication.

2 . Criteria

Product Name: Rytary	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply) of ONE of the following:

- Generic carbidopa-levodopa immediate release
- Generic carbidopa-levodopa extended release

Product Name: Xadago

Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply) of BOTH of the following:

- rasagiline mesylate
- selegiline

Product Name: Duopa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Patient is levodopa-responsive [A, B]

AND

3 - Patient experiences disabling “Off” periods for a minimum of 3 hours/day [B]

AND

4 - Disabling “Off" periods occur despite therapy with both of the following: [A, C]

- Oral levodopa-carbidopa
- One drug from a different class of anti-Parkinson's disease therapy (e.g., COMT inhibitor [entacapone, tolcapone], MAO-B inhibitor [selegiline, rasagiline], dopamine agonist [pramipexole, ropinirole])

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Duopa	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Gocovri	
Diagnosis	Dyskinesia in Parkinson’s Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Patient is experiencing dyskinesia

AND

3 - Patient is receiving concurrent levodopa-based therapy [5, D]

AND

4 - Trial and failure or intolerance to amantadine immediate release

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Gocovri	
Diagnosis	"Off" Episodes in Parkinson's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Patient is experiencing "off" episodes [E, 6]

AND

3 - Used in combination with levodopa/carbidopa therapy [1]

AND

4 - Both of the following:

4.1 Trial and failure, or intolerance to amantadine immediate release

AND

4.2 Trial and failure, contraindication or intolerance to one of the following:

- MAO-B inhibitor (e.g., rasagiline, selegiline)
- Dopamine Agonist (e.g., pramipexole, ropinirole)
- COMT inhibitor (e.g., entacapone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Gocovri	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., decreased "off" periods, decreased "on" time with troublesome dyskinesia) [D]

Product Name: Osmolex ER	
Diagnosis	Parkinson's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Trial and failure, contraindication or intolerance to BOTH of the following:

2.1 amantadine immediate release

AND

2.2 ONE of the following: [9]

- carbidopa-levodopa
- MAO-B Inhibitor (e.g., rasagiline, selegiline)
- Dopamine Agonist (e.g., pramipexole, ropinirole)

AND

3 - Prescribed by or in consultation with a neurologist

Product Name: Osmolex ER	
Diagnosis	Drug-Induced Extrapyramidal Reactions
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is experiencing drug-induced extrapyramidal reactions

AND

2 - One of the following: [10]

2.1 Patient has persistent extrapyramidal symptoms despite a trial of dose reduction, tapering, or discontinuation of the offending medication

OR

2.2 Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication

AND

3 - Trial and failure or intolerance to amantadine immediate release

AND

4 - Prescribed by or in consultation with one of the following:

- Neurologist
- Psychiatrist

Product Name: Osmolex ER	
Diagnosis	Parkinson's Disease, Drug-Induced Extrapyramidal Reactions
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Dhivy	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply) of both of the following:

- Generic carbidopa-levodopa immediate release (IR)
- Generic carbidopa-levodopa oral disintegraing tablet (ODT)

3 . Endnotes

A. The efficacy of Duopa was established in a randomized, double-blind, double-dummy, active controlled, parallel group, 12-week study in patients with advanced Parkinson's disease who were levodopa-responsive and had persistent motor fluctuations while on treatment with oral immediate-release carbidopa-levodopa and other Parkinson's disease medications. [2, 3]
B. Patients were eligible for participation in the studies if they were experiencing 3 hours or more of “Off” time on their current Parkinson's disease drug treatment and they demonstrated a clear responsiveness to treatment with levodopa. [2, 3]
C. Most patients (89%) were taking at least one concomitant medication for Parkinson’s disease (e.g., dopaminergic agonist, COMT-inhibitor, MAO B inhibitor) in addition to oral immediate-release carbidopa-levodopa. [2, 3]
D. The efficacy of Gocovri was established in two Phase III randomized, double-blind, placebo-controlled trials, a 12 week and 24 week study in patients with Parkinson's disease were treated with levodopa. Both studies demonstrate statistically significant

and clinically relevant reduction in dyskinesia compared to placebo. Also, both studies showed that Gocovri-treated patients experienced an increase in functional time daily (defined as ON time without troublesome dyskinesia) compared to placebo-treated patients. [6, 7]

E. “Off” time is defined as the amount of time the Parkinson’s Disease medication was not controlling motor symptoms. [6]

4 . References

1. Duopa Prescribing Information. AbbVie Inc. North Chicago, IL. December 2019.
2. Olanow CW, Kieburtz K, Odin P, et al. Continuous intrajejunal infusion of levodopa-carbidopa intestinal gel for patients with advanced Parkinson’s disease: a randomised, controlled, double-blind, double-dummy study. Lancet Neurol. 2014 Feb;13(2):141-9.
3. Rytary Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. December 2019.
4. Xadago Prescribing Information. US WorldMeds, LLC. Louisville, KY. August 2021.
5. Gocovri Prescribing Information. Adamas Pharma, LLC. Emeryville, CA. January 2021.
6. Pahwa R, Tanner CM, Hauser RA, et al. ADS-5102 (Amantadine) Extended- Release Capsules for Levodopa-Induced Dyskinesia in Parkinson Disease (EASE LID Study): A Randomized Clinical Trial. JAMA Neurol. 2017 Aug:1;74(8): 941-949.
7. Pahwa R, Tanner CM, Hauser Ra, et al. Amantadine Extended Release for Levodopa-Induced Dyskinesia in Parkinson’s Disease (EASED Study). Mov Disorder. 2015 May; 30(6):788-95.
8. Osmolex ER Prescribing Information. Vertical Pharmaceuticals, LLC. Bridgewater, NJ. March 2021.
9. National Institute of Health and Clinical Excellence (NICE). Parkinson's disease in adults. NICE guideline [NG71]. July 2017. Available at: https://www.nice.org.uk/guidance/ng71/chapter/Recommendations. Accessed January 28, 2021.
10. Muench J, Hamer AM. Adverse effects of antipsychotic medications. Am Fam Physician. 2010 Mar 1;81(5):617-622.
11. Oertel W, Eggert K, Pahwa R, et al. Randomized, placebo-controlled trial of ADS-5102 (amantadine) extended-release capsules for levodopa-induced dyskinesia in Parkinson's disease (EASE LID 3). Mov Disord. 2017;32(12):1701-1709.
12. Dhivy Prescribing Information. Riverside Pharmaceuticals Corporation. Washington, DC. November 2021.

5 . Revision History

Date	Notes
5/16/2023	update guideline

Prior Authorization Guideline

Guideline Name	Anticonvulsants

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	11/19/1999
P&T Revision Date:	12/18/2019 ; 03/18/2020 ; 03/17/2021 ; 10/20/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Briviact (brivaracetam)
Partial-Onset Seizures Indicated for the treatment of partial-onset seizures in patients 1 month of age and older.

2 . Criteria

Product Name: Briviact tablet, oral solution	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria	

1 - One of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.2 Trial and failure, contraindication or intolerance to one of the following generics:

- lamotrigine immediate-release (IR)
- levetiracetam IR
- levetiracetam extended-release (ER)
- oxcarbazepine IR
- topiramate IR

OR

2 - For continuation of prior therapy

3 . References

1. Briviact Prescribing Information. UCB, Inc. Smyrna, GA. September 2021.

4 . Revision History

Date	Notes
2/27/2023	Annual Review - no criteria changes

Prior Authorization Guideline

Guideline Name	Antidepressants

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	9/28/1998
P&T Revision Date:	03/20/2019 ; 03/18/2020 ; 03/17/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Trintellix (vortioxetine)
Major Depressive Disorder Indicated for the treatment of major depressive disorder (MDD) in adults.
Drug Name: Fetzima (levomilnacipran extended-release)
Major Depressive Disorder Indicated for the treatment of major depressive disorder (MDD) in adults. Limitation of Use: Fetzima is not approved for the management of fibromyalgia. The efficacy and safety of Fetzima for the management of fibromyalgia have not been established.
Drug Name: Emsam (selegiline patch)
Major Depressive Disorder Indicated for the treatment of adults with major depressive disorder (MDD)

2 . Criteria

Product Name: Fetzima or Fetzima Pack	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Both of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.2 Trial and failure, contraindication, or intolerance to any two of the following generics:

- desvenlafaxine succinate extended-release (ER)
- duloxetine
- venlafaxine or venlafaxine ER

OR

2 - For continuation of prior therapy

Product Name: Trintellix, Emsam	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Both of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.2 Trial and failure, contraindication, or intolerance to any two of the following generics:

- bupropion
- citalopram
- desvenlafaxine succinate extended-release (ER)
- duloxetine
- escitalopram
- fluoxetine
- mirtazapine
- paroxetine or paroxetine ER
- sertraline
- venlafaxine or venlafaxine ER

OR

2 - For continuation of prior therapy

3 . References

1. Emsam Prescribing Information. Somers et Pharmaceuticals, Inc. Morgantown, WV. July 2017.
2. American Psychiatric Association. Practice guideline for the treatment of patients with major depressive disorder, third edition. Oct. 2010. http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf . Accessed January 21, 2022.
3. Soleimani L, Lapidus KA, Losifescu DV. Diagnosis and treatment of major depressive disorder. Neurol Clin. 2011;29(1):177-93.
4. American Geriatrics Society. American Geriatrics Society 2015 updated Beers Criteria for potentially inappropriate medication use in older adults. J Am Geriatr Soc. 2015;63:2227-46.
5. Trintellix Prescribing Information. Takeda Pharmaceuticals America, Inc. Lexington, MA. September 2021.
6. Fetzima Prescribing Information. Allergan USA, Inc. Madison, NJ. September 2021.

4 . Revision History

Date	Notes
2/28/2023	Annual Review - removal of Aplenzin and Paxil oral solution. Addition of Emsam

Prior Authorization Guideline

Guideline Name	Antiemetics Quantity Limit Overrides

Guideline Note:

Effective Date:	12/1/2022
P&T Approval Date:	2/25/2016
P&T Revision Date:	05/14/2020 ; 08/13/2020 ; 10/20/2021 ; 10/19/2022

1 . Indications

Drug Name: Akynzeo (netupitant/palonosetron)
Chemotherapy-induced nausea and vomiting Indicated in combination with dexamethasone in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. Akynzeo is an oral fixed combination of palonosetron and netupitant: palonosetron prevents nausea and vomiting during the acute phase and netupitant prevents nausea and vomiting during both the acute and delayed phase after cancer chemotherapy.
Drug Name: Anzemet (dolasetron)
Chemotherapy-induced nausea and vomiting Indicated for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy, including initial and repeat courses in adults and children 2 years and older. **Off Label Uses: Radiotherapy-induced nausea and vomiting** Used for the prevention and treatment of nausea and vomiting induced by radiation therapy. [11, 12] **Postoperative nausea and vomiting** Used orally for the prevention of postoperative nausea and vomiting. [13]

Drug Name: Emend (aprepitant)
Chemotherapy-induced nausea and vomiting Indicated, in combination with other antiemetic agents, in patients 6 months of age and older for oral suspension, or 12 years of age and older for the capsules, for the prevention of: (1) acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin; (2) nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC). Limitations of Use: (1) Emend has not been studied for the treatment of established nausea and vomiting; (2) Chronic continuous administration of Emend is not recommended because it has not been studied, and because the drug interaction profile may change during chronic continuous use. **Postoperative Nausea and Vomiting - capsules only** Indicated in adults for the prevention of postoperative nausea and vomiting. Limitations of Use: (1) Emend has not been studied for the treatment of established nausea and vomiting; (2) Chronic continuous administration of Emend is not recommended because it has not been studied, and because the drug interaction profile may change during chronic continuous use.
Drug Name: Granisetron
Chemotherapy-induced nausea vomiting Indicated for the prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer therapy, including high-dose cisplatin. **Radiation-induced nausea and vomiting** Indicated for the prevention of nausea and vomiting associated with radiation, including total body irradiation and fractionated abdominal radiation. **Off Label Uses: Postoperative nausea and vomiting** Used for the prevention of postoperative nausea and vomiting. [14, 15]
Drug Name: Marinol (dronabinol)
Chemotherapy-induced nausea and vomiting Indicated in adults for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments. **Anorexia in patients with AIDS** Indicated in adults for the treatment of anorexia associated with weight loss in patients with AIDS.
Drug Name: Sancuso (granisetron transdermal system)
Chemotherapy-induced nausea and vomiting Indicated for the prevention of nausea and vomiting in patients receiving moderately and/or highly emetogenic chemotherapy regimens of up to 5 consecutive days duration.
Drug Name: Sustol (granisetron injection)
Chemotherapy-induced nausea and vomiting Indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated

with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens.
Drug Name: Varubi (rolapitant)
Chemotherapy-induced nausea and vomiting Indicated in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy.
Drug Name: Zofran (ondansetron), Zuplenz (ondansetron oral soluble film)
Chemotherapy-induced nausea and vomiting Indicated for the prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy, including cisplatin greater than or equal to 50 mg/m2. Also indicated for the prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy. **Radiotherapy-induced nausea and vomiting** Indicated for the prevention of nausea and vomiting associated with radiotherapy in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen. **Postoperative nausea and vomiting** Indicated for the prevention of postoperative nausea and/or vomiting. As with other antiemetics, routine prophylaxis is not recommended for patients in whom there is little expectation that nausea and/or vomiting will occur postoperatively. In patients where nausea and/or vomiting must be avoided postoperatively, Zofran Tablets, Zofran ODT Orally Disintegrating Tablets, Zofran Oral Solution, and Zuplenz are recommended even where the incidence of postoperative nausea and/or vomiting is low. **Off Label Uses: Hyperemesis gravidarum** Used in the management of hyperemesis gravidarum. [10, 16]

2 . Criteria

Product Name: Akynzeo, Anzemet, Generic dronabinol, Brand Emend, Generic aprepitant, granisetron, Brand Marinol, Generic ondansetron 24 mg tablet, Generic ondansetron oral solution, Generic ondansetron ODT, Sancuso, Sustol, Varubi, Brand Zofran oral solution, or Zuplenz	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Diagnosis of chemotherapy-induced nausea and vomiting

AND

2 - Patient is receiving moderately to highly emetogenic chemotherapy

AND

3 - Provider attests that a higher quantity is needed due to the number of chemotherapy sessions

Product Name: Anzemet, granisetron, Generic ondansetron 24 mg tablet, Generic ondansetron oral solution, Generic ondansetron ODT, Brand Zofran oral solution, or Zuplenz	
Diagnosis	Radiotherapy-induced nausea and vomiting
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Diagnosis of radiotherapy-induced nausea and vomiting

AND

2 - Patient is receiving radiotherapy consisting of total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen

AND

3 - Provider attests that a higher quantity is needed due to the number of radiation sessions

Product Name: Generic ondansetron 24 mg tablet, Generic ondansetron oral solution, Generic ondansetron ODT, Brand Zofran oral solution, or Zuplenz

Diagnosis	Hyperemesis gravidarum
Approval Length	6 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Diagnosis of nausea and vomiting due to pregnancy (i.e., hyperemesis gravidarum) [10, 16]

AND

2 - History of failure, contraindication, or intolerance to at least one of the following: [A]

- doxylamine
- metoclopramide (Reglan)
- prochlorperazine (Compazine)
- promethazine (Phenergan)
- pyridoxine (Vitamin B6)

AND

3 - Patient has had at least a partial response to therapy at a dose within the quantity limit

3 . Background

Benefit/Coverage/Program Information
Quantity Limit These products are subject to a standard quantity limit. The quantity limit may vary from the standard limit based upon plan-specific benefit design. Please refer to your benefit materials.

4 . Endnotes

A. Treatment of nausea and vomiting of pregnancy with vitamin B6 or vitamin B6 plus doxylamine is safe and effective and should be considered first-line pharmacotherapy (Level A Evidence). Treatment of nausea and vomiting of pregnancy with ginger has shown beneficial effects and can be considered as a nonpharmacologic option (Level B Evidence). Several types of dopamine antagonists can be used for the treatment of nausea and vomiting of pregnancy such as promethazine, prochlorperazine, and metoclopramide. Antihistamines (such as dimenhydrinate and diphenhydramine) have been shown to be effective in controlling nausea and vomiting symptoms of pregnancy and are frequently used. Evidence is limited on the safety or efficacy of the 5-HT3 inhibitors (e.g. ondansetron) for nausea and vomiting of pregnancy. The ACOG recommends discussing the available data with patients as well as weighing the risks and benefits in women less than 10 weeks of gestation. Because of their limited data, they should not be advocated for first-line use until agents with established safety and efficacy have been tried and have failed. Treatment of severe nausea and vomiting of pregnancy or hyperemesis gravidarum with methylprednisolone may be efficacious in refractory cases; however, the risk profile of methylprednisolone suggests it should be a treatment of last resort (Level B Evidence). [16]

5 . References

1. Akynzeo prescribing information. Helsinn Therapeutics (U.S.), Inc. Iselin, NJ. October 2020.
2. Anzemet prescribing information. Validus Pharmaceuticals LLC. Parsippany, NJ. September 2021.
3. Emend prescribing information. Merck Sharp & Dohme Corp. Whitehouse Station, NJ. February 2021.
4. Granisetron prescribing information. Ascend Laboratories. Montvale, NJ. March 2011.
5. Marinol prescribing information. AbbVie Inc. North Chicago, IL. October 2019.
6. Sancuso prescribing information. Kyowa Kirin, Inc. Bedminster, NJ. June 2020.
7. Varubi prescribing information. TerSera Therapeutics LLC. Deerfield, IL. August 2020.
8. Zofran prescribing information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. June 2020.
9. Zuplenz prescribing information. Fortovia Therapeutics, Inc. Raleigh, NC. May 2020.
10. Micromedex Healthcare Series [database on the Internet]. Greenwood Village (CO): Thomson Reuters (Healthcare) Inc.; Updated periodically. Available by subscription at: http://www.thomsonhc.com/. Accessed September 9, 2021.
11. Fauser AA, Russ W, Bischoff M. Oral dolasetron mesilate (MDL 73,147EF) for the control of emesis during fractionated total-body irradiation and high-dose cyclophosphamide in patients undergoing allogeneic bone marrow transplantation. Support Care Cancer. 1997 May;5(3):219-22.
12. Basch E, Prestrud AA, Hesketh PJ, et al. Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. J Clinic Oncol. 2011;29(31):4189-98.
13. AHFS Drug Information website. Available at: https://online.lexi.com/lco/action/doc/retrieve/docid/250/413041. Accessed September 9, 2021.
14. Fujii Y, Tanaka H, Kawasaki T. Preoperative oral granisetron for the prevention of postoperative nausea and vomiting after breast surgery. Eur J Surg. 2001 Mar;167(3):184-7.

15. Fujii Y, Tanaka H, Kawasaki T. Prophylaxis with oral granisetron for the prevention of nausea and vomiting after laparoscopic cholecystectomy: a prospective randomized study. Arch Surg. 2001 Jan;136(1):101-4.
16. ACOG Practice Bulletin. Nausea and vomiting of pregnancy. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2018; 103(1):15-30.
17. Sustol prescribing information. Heron Therapeutics. San Diego, CA. May 2017.

6 . Revision History

Date	Notes
8/31/2022	2022 Annual Review

Prior Authorization Guideline

Guideline Name	Antigout Agents

Guideline Note:

Effective Date:	10/1/2022
P&T Approval Date:	9/28/2016
P&T Revision Date:	10/17/2018 ; 10/16/2019 ; 10/21/2020 ; 12/01/2021 ; 8/18/2022

1 . Indications

Drug Name: Uloric (febuxostat)
Gout A xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in adult patients with gout who have an inadequate response to a maximally titrated dose of allopurinol, who are intolerant to allopurinol, or for whom treatment with allopurinol is not advisable. Uloric is not recommended for the treatment of asymptomatic hyperuricemia.

2 . Criteria

Product Name: generic febuxostat	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure, contraindication, or intolerance to allopurinol

3 . References

1. Uloric Prescribing Information. Takeda Pharmaceuticals America, Inc. Deerfield, IL. April 2021.

4 . Revision History

Date	Notes
8/3/2022	Annual Review, added FDA approved dx requirement to criteria.

Prior Authorization Guideline

Guideline Name	Antimalarial Agents

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	8/24/2001
P&T Revision Date:	02/13/2020 ; 06/17/2020 ; 07/21/2021 ; 05/19/2022 ; 5/18/2023

1 . Indications

Drug Name: Qualaquin (quinine sulfate)
Malaria Indicated only for treatment of uncomplicated Plasmodium falciparum malaria. Quinine sulfate has been shown to be effective in geographical regions where resistance to chloroquine has been documented. Oral capsules are not approved for patients with severe or complicated P. falciparum malaria. Oral capsules are not approved for prevention of malaria. Oral capsules are not approved for the treatment or prevention of nocturnal leg cramps.

2 . Criteria

Product Name: Brand Qualaquin, Generic quinine sulfate	
Diagnosis	Nocturnal Leg Cramps*
Guideline Type	Prior Authorization

Approval Criteria **1** - Requests for coverage when used solely for the treatment or prevention of nocturnal leg cramps are not authorized and will not be approved [1, C]	
Notes	*Nocturnal leg cramp is an off-label use.

Product Name: Brand Qualaquin, Generic quinine sulfate	
Diagnosis	Malaria
Approval Length	7 days [1]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of uncomplicated malaria

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Treatment in areas of chloroquine-sensitive malaria [2-4, A]*

AND

2.1.2 Trial and failure, contraindication or intolerance to one of the following:

- chloroquine
- hydroxychloroquine

OR

2.2 Treatment in areas of chloroquine-resistant malaria [2-4, B]*

Notes	*Call the Malaria Hotline (770-488-7788) for additional information if n eeded.

3 . Endnotes

A. Areas of chloroquine-sensitive malaria include: Central America west of the Panama Canal, Haiti, the Dominican Republic, and most of the Middle East. [2-4]
B. Areas of chloroquine-resistant malaria include: Southeast Asia, and all malarious regions except those specified as chloroquine-sensitive listed in Endnote A. [2-4]
C. Quinine is not approved for and should not be used for the prophylaxis or treatment of nocturnal leg cramps. Quinine may cause unpredictable serious and life-threatening hematologic reactions including thrombocytopenia and hemolytic-uremic syndrome/thrombotic thrombocytopenic purpura (HUS/TTP) in addition to hypersensitivity reactions, QT prolongation, serious cardiac arrhythmias including torsades de pointes, and other serious adverse events requiring medical intervention and hospitalization. Chronic renal impairment associated with the development of TTP, and fatalities have also been reported. The risk associated with the use of quinine in the absence of evidence of its effectiveness for treatment or prevention of nocturnal leg cramps, outweighs any potential benefit in treating and/or preventing this benign, self-limiting condition. [1]

4 . References

1. Qualaquin Prescribing Information. Sun Pharmaceutical Industries, Inc. Cranbury, NJ. August 2019.
2. Center for Disease Control Traveler's Health - Yellow Book 2020 edition. Chapter 4: Infectious diseases related to travel - malaria. Available at: https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/malaria. Accessed April 6, 2023.
3. Center for Disease Control. Guideline for treatment of malaria in the United States. Available at: http://www.cdc.gov/malaria/diagnosis_treatment/treatment.html. Accessed April 6, 2023.
4. Griffith KS, Lewis LS, Mali S, Parise ME. Treatment of malaria in the United States. A systematic review. JAMA. 2007;297(20):2264-77.

5 . Revision History

Date	Notes
5/3/2023	Annual review - updated references.

Prior Authorization Guideline

Guideline Name	Apokyn

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	10/2/2004
P&T Revision Date:	05/20/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Apokyn (apomorphine injection)
Parkinson's Disease Indicated for the acute, intermittent treatment of hypomobility, "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes) in patients with advanced Parkinson's disease. Apokyn has been studied as an adjunct to other medications.

2 . Criteria

Product Name: Generic apomorphine hydrochloride inj	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Patient is experiencing intermittent OFF episodes

AND

3 - One of the following:

3.1 Patient is receiving drug in combination with carbidopa/levodopa at a maximally tolerated dose

OR

3.2 Patient has a contraindication or intolerance to carbidopa/levodopa

AND

4 - Trial and failure (of a minimum 30 day supply), contraindication or intolerance to two of the following: [A]

- MAO-B Inhibitor (e.g., rasagiline, selegiline)
- Dopamine Agonist (e.g., pramipexole, ropinirole)
- COMT Inhibitor (e.g., entacapone)

AND

5 - Not used with any 5-HT3 antagonist (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron)

AND

6 - Prescribed by or in consultation with a neurologist

Product Name: Generic apomorphine hydrochloride inj	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	

3 . References

1. Apokyn prescribing information. US WorldMeds, LLC. Louisville, KY. June 2022.
2. Obering CD, Chen JJ, Swope DM. Update on apomorphine for the rapid treatment of hypomobility ("off") episodes in Parkinson's disease. Pharmacotherapy. 2006;26(6):840-852.
3. Per clinical consult with neurologist, March 27, 2019.

4 . Revision History

Date	Notes
3/16/2023	2023 Annual Review.

Prior Authorization Guideline

Guideline Name	Atypical Antipsychotics

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	3/22/1998
P&T Revision Date:	03/18/2020 ; 10/21/2020 ; 02/18/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Fanapt (iloperidone)
Schizophrenia Indicated for the treatment of adults with schizophrenia. When deciding among the alternative treatments available for this condition, the prescriber should consider the finding that Fanapt is associated with prolongation of the QTc interval. Prolongation of the QTc interval is associated in some other drugs with the ability to cause torsade de pointes-type arrhythmia, a potentially fatal polymorphic ventricular tachycardia which can result in sudden death. In many cases this would lead to the conclusion that other drugs should be tried first. Whether Fanapt will cause torsade de pointes or increase the rate of sudden death is not yet known. Patients must be titrated to an effective dose of Fanapt. Thus, control of symptoms may be delayed during the first 1 to 2 weeks of treatment compared to some other antipsychotic drugs that do not require a similar titration. Prescribers should be mindful of this delay when selecting an antipsychotic drug for the treatment of schizophrenia.

2 . Criteria

Product Name: Fanapt or Fanapt Titration Pack

Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Both of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.2 Trial and failure (to a minimum 30 day supply), contraindication, or intolerance to two of the following:

- aripiprazole
- olanzapine
- quetiapine IR/ER
- risperidone
- clozapine
- ziprasidone
- paliperidone
- asenapine

OR

2 - For continuation of prior therapy

3 . Background

Benefit/Coverage/Program Information
Quantity Limit These products are subject to a standard quantity limit. The quantity limit may vary from the standard limit based upon plan-specific benefit design. Please refer to your benefit materials.

4 . References

1. Fanapt prescribing information. Vanda Pharmaceuticals Inc. Washington, D.C. January 2016.

5 . Revision History

Date	Notes
2/27/2023	Annual review - no criteria change

Prior Authorization Guideline

Guideline Name	Authorized Brand Alternative (ABA) Policy

Guideline Note:

Effective Date:	3/9/2023
P&T Approval Date:	2/13/2020
P&T Revision Date:	03/18/2020 ; 02/18/2021 ; 02/17/2022 ; 06/15/2022 ; 10/19/2022 ; 01/18/2023 ; 02/16/2023 ; 3/15/2023

1 . Indications

Drug Name: Budesonide and Formoterol inhalation aerosol
Asthma Indicated for the treatment of asthma in patients 6 years of age and older. Budesonide and formoterol fumarate dihydrate inhalation aerosol should be used for patients not adequately controlled on a long-term asthma-control medication such as an inhaled corticosteroid (ICS) or whose disease warrants initiation of treatment with both an inhaled corticosteroid and long-acting beta2-adrenergic agonist (LABA). Limitations of Use: Budesonide and formoterol fumarate dihydrate inhalation aerosol is NOT indicated for the relief of acute bronchospasm. **Chronic Obstructive Pulmonary Disease** Indicated for the maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/or emphysema. Budesonide and formoterol fumarate dihydrate inhalation aerosol 160/4.5 is also indicated to reduce exacerbations of COPD. Budesonide and formoterol fumarate dihydrate inhalation aerosol 160/4.5 is the only strength indicated for the treatment of COPD. Limitations of Use: Budesonide and formoterol fumarate dihydrate inhalation aerosol is NOT indicated for the relief of acute bronchospasm.
Drug Name: Fluticasone and Vilanterol inhalation powder

Asthma Indicated for once-daily treatment of asthma in patients aged 18 years and older.

Chronic Obstructive Pulmonary Disease Indicated for long-term, once-daily, maintenance treatment of airflow obstruction and reducing exacerbations in patients with chronic obstructive pulmonary disease (COPD).

Drug Name: Fluticasone Propionate HFA inhalation aerosol

Asthma Indicated for maintenance treatment of asthma as prophylactic therapy in adult and pediatric patients aged 4 years and older.

Drug Name: Fluticasone and Salmeterol HFA inhalation aerosol

Asthma For treatment of asthma in adult and adolescent patients aged 12 years and older.

Drug Name: Insulin Glargine Injection Solution, Insulin Glargine Solostar Injection

Diabetes Mellitus Indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus. Limitations of use: Insulin glargine is not recommended for the treatment of diabetic ketoacidosis.

Drug Name: Insulin Degludec Injection Solution, Insulin Degludec Flextouch Injection

Diabetes Mellitus Indicated to improve glycemic control in patients 1 year of age and older with diabetes mellitus. Limitations of Use: Not recommended for the treatment of diabetic ketoacidosis.

Drug Name: Insulin Aspart Injection Solution, Insulin Aspart Flexpen, Insulin Aspart Penfill, Insulin Aspart 70/30 Injection Solution, Insulin Aspart 70/30 Flexpen, Novolog Relion, Novolog Relion Flexpen, Novolog Relion 70/30, Novolog Relion 70/30 Flexpen

Diabetes Mellitus Indicated to improve glycemic control in adults and children with diabetes mellitus. Limitations of Use: 1) Insulin Aspart Protamine and Insulin Aspart Injectable Suspension Mix 70/30 is not recommended for the treatment of diabetic ketoacidosis. 2) The proportions of rapid-acting and long-acting insulins in Insulin Aspart Protamine and Insulin Aspart Injectable Suspension Mix 70/30 are fixed and do not allow for basal versus prandial dose adjustments.

Drug Name: Insulin Lispro Injection Solution, Insulin Lispro Kwikpen, Insulin Lispro Jr Kwikpen, Insulin Lispro 75/25 Kwikpen

Diabetes Mellitus Indicated to improve glycemic control in adults and children with diabetes mellitus. Limitations of Use: the proportions of rapid-acting and intermediate-acting insulins in Insulin Lispro Protamine and Insulin Lispro Injectable Suspension Mix75/25 are fixed and do not allow for basal versus prandial dose adjustments.

2 . Criteria

Product Name: Brand Budesonide-Formoterol, Brand Insulin Glargine, Brand Insulin Glargine Solostar, Brand Fluticasone-Vilanterol, Brand Fluticasone HFA, Brand Insulin Degludec, Brand Insulin Aspart, Brand Insulin Lispro, Novolog Relion, Brand Fluticasone-Salmeterol HFA	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Requested drug is FDA-approved for the condition being treated

OR

1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

AND

2 - At least 6 months use of the Brand product* within the previous 365 days (document drug, duration, dose and date of use)

AND

3 - Both of the following:

3.1 Documentation provided stating the Brand product has not been effective

AND

3.2 Justification provided for why the authorized brand alternative (ABA) is expected to provide benefit when the Brand product has not been shown to be effective

Notes	*See table in background section for a list of the target ABAs and their associated Brand products.

3 . Background

Benefit/Coverage/Program Information

Authorized Brand Alternative (ABA) and their respective Brand products

Authorized Brand Alternative (ABA)	Brand product
Budesonide-Formoterol	Symbicort
Insulin Glargine	Lantus
Fluticasone-Vilanterol	Breo Ellipta
Fluticasone HFA	Flovent HFA
Insulin Degludec	Tresiba
Insulin Lispro	Humalog
Insulin Aspart, Novolog Relion	Novolog
Fluticasone-Salmeterol HFA	Advair HFA

4 . References

1. Budesonide-Formoterol Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. December 2020.
2. Insulin Glargine/Insulin Glargine Solostar. Winthrop U.S. Bridgewater, New Jersey. January 2021.
3. Fluticasone-Vilanterol Prescribing Information. Prasco Laboratories. Mason, Ohio. February 2022.
4. Fluticasone HFA Prescribing Information. Prasco Laboratories. Mason, Ohio. May 2022.
5. Insulin Degludec/Insulin Degludec Flextouch Prescribing Information. Novo Nordisk Pharma, Inc. Plainsboro, NJ. July 2022.
6. Insulin Aspart Protamine & Insulin Aspart Mix 70/30. Novo Nordisk Pharma, Inc. Plainsboro, New Jersey. October 2020.
7. Insulin Aspart Injection/Flexpen/Penfill. Novo Nordisk Pharma, Inc. Plainsboro, New Jersey. November 2019.

8. Insulin Lispro Injection/Kwikpen/Jr Kwikpen. Eli Lilly and Company. Indianapolis, IN. February 2020.
9. Insulin Lispro Protamine & Insulin Lispro Mix 75/25 Kwikpen. Eli Lilly and Company. Indianapolis, IN. February 2020.
10. Fluticasone and Salmeterol HFA Prescribing Information. Prasco Laboratories. Mason, Ohio. August 2022.

5 . Revision History

Date	Notes
3/9/2023	Added new ABA for Advair HFA.

Prior Authorization Guideline

Guideline Name	Azole Antifungals - PA, NF

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	10/20/1998
P&T Revision Date:	11/14/2019 ; 02/13/2020 ; 02/18/2021 ; 02/18/2021 ; 08/19/2021 ; 06/16/2021 ; 02/17/2022 ; 07/20/2022 ; 01/18/2023 ; 2/16/2023

1 . Indications

Drug Name: Sporanox (itraconazole) capsules
Blastomycosis Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Blastomycosis, pulmonary and extrapulmonary **Histoplasmosis** Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis **Aspergillosis** Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or refractory to amphotericin B therapy **Onychomycosis of the toenail** Indicated for the treatment of the following fungal infection in non-immunocompromised patients: Onychomycosis of the toenail, with or without fingernail involvement, due to dermatophytes (Tinea unguium) **Onychomycosis of the fingernail** Indicated for the treatment of the following fungal infection

in non-immunocompromised patients: Onychomycosis of the fingernail due to dermatophytes (Tinea unguium)

Drug Name: Sporanox Pulse Pak (itraconazole)

Onychomycosis of the fingernail Indicated for the treatment of the following fungal infection in non-immunocompromised patients: Onychomycosis of the fingernail due to dermatophytes (Tinea unguium)

Drug Name: Sporanox (itraconazole) oral solution

Oropharyngeal and esophageal candidiasis Indicated for the treatment of oropharyngeal and esophageal candidiasis.

Drug Name: Tolsura (itraconazole) capsules

Blastomycosis Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Blastomycosis, pulmonary and extrapulmonary.

Histoplasmosis Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis.

Aspergillosis Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or refractory to amphotericin B therapy.

Drug Name: Noxafil (posaconazole) tablets

Prophylaxis of Aspergillus infection Indicated for prophylaxis of invasive Aspergillus infections in adult and pediatric patients 2 years of age and older who weigh greater than 40 kg, who are at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

Prophylaxis of Candida infection Indicated for prophylaxis of invasive Candida infections in adult and pediatric patients 2 years of age and older who weigh greater than 40kg, who are at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

Treatment of Invasive Aspergillosis Indicated for the treatment of invasive aspergillosis in adults and pediatric patients 13 years of age and older.

Drug Name: Noxafil (posaconazole) oral suspension

Prophylaxis of Aspergillus infection Indicated for prophylaxis of invasive Aspergillus infections in patients 13 years of age and older, who are at high risk of developing these

infections due to being severely immunocompromised, such as HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

Prophylaxis of Candida infection Indicated for prophylaxis of invasive Candida infections in patients 13 years of age and older, who are at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

Oropharyngeal candidiasis Indicated for treatment of oropharyngeal candidiasis (OPC), including OPC refractory (rOPC) to itraconazole and/or fluconazole in adults and pediatric patients 13 years of age and older.

Drug Name: Noxafil PowderMix (posaconazole) for delayed-release oral suspension

Prophylaxis of Invasive Aspergillus and Candida Infections Indicated for the prophylaxis of invasive Aspergillus and Candida infections in pediatric patients 2 years of age and older who weigh 40 kg or less, who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

Drug Name: Vfend (voriconazole) oral suspension, Vfend (voriconazole) tablets

Invasive Aspergillosis Indicated in adults and pediatric patients (2 years of age and older) for the treatment of invasive aspergillosis (IA). In clinical trials, the majority of isolates recovered were Aspergillus fumigatus. There was a small number of cases of culture-proven disease due to species of Aspergillus other than A. fumigatus.

Candidemia in Non-neutropenic Patients and Other Deep Tissue Candida Infections Indicated in adults and pediatric patients (2 years of age and older) for the treatment of candidemia in non-neutropenic patients and the following Candida infections: disseminated infections in skin and infections in abdomen, kidney, bladder wall, and wounds.

Esophageal Candidiasis Indicated in adults and pediatric patients (2 years of age and older) for the treatment of esophageal candidiasis (EC) in adults and pediatric patients 2 years of age and older.

Scedosporiosis and Fusariosis Indicated for the treatment of serious fungal infections caused by Scedosporium apiospermum (asexual form of Pseudallescheria boydii) and Fusarium spp. including Fusarium solani, in adults and pediatric patients (2 years of age and older) intolerant of, or refractory to, other therapy.

Drug Name: Cresemba (isavuconazonium sulfate) capsules

Invasive Aspergillosis Indicated for patients 18 years of age and older for the treatment of invasive aspergillosis.

Invasive Mucormycosis Indicated for patients 18 years of age and older for the treatment of invasive mucormycosis.

2 . Criteria

Product Name: Brand Sporanox capsules or generic itraconazole capsules	
Diagnosis	Systemic and topical fungal infections
Approval Length	6 months [5, 10-12, B-D]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis)

OR

2 - All of the following:

2.1 One of the following diagnoses:

- Tinea corporis (ring worm)
- Tinea cruris (jock itch)
- Tinea pedis (athlete's foot)
- Tinea capitis (scalp ringworm)
- Pityriasus versicolor

AND

2.2 One of the following:

2.2.1 The tinea infection is resistant to topical antifungal treatment

OR

2.2.2 Trial and failure, contraindication, or intolerance to oral terbinafine [3]

Product Name: Brand Sporanox capsules, generic itraconazole capsules, or Sporanox Pulse Pak	
Diagnosis	Fingernail Onychomycosis
Approval Length	1 Month [A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of fingernail onychomycosis as confirmed by one of the following:

- Positive potassium hydroxide (KOH) preparation
- Fungal culture
- Nail biopsy

AND

2 - The patient's condition is causing debility or a disruption in their activities of daily living (e.g., limitations to manual dexterity, wearing shoes, or appropriately manicuring nails) [4]

AND

3 - Trial and failure (of a minimum 6-week supply), contraindication, or intolerance to oral terbinafine

Product Name: Brand Sporanox capsules or generic itraconazole capsules	
Diagnosis	Toenail Onychomycosis
Approval Length	3 Month [A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of toenail onychomycosis as confirmed by one of the following:

- Positive potassium hydroxide (KOH) preparation
- Fungal culture

- Nail biopsy

AND

2 - The patient's condition is causing debility or a disruption in their activities of daily living (e.g., limitations to manual dexterity, walking, standing, wearing shoes, or appropriately manicuring nails) [4]

AND

3 - Trial and failure (of a minimum 12-week supply), contraindication, or intolerance to oral terbinafine

Product Name: Brand Sporanox oral solution or generic itraconazole oral solution	
Diagnosis	Candidiasis (esophageal or oropharyngeal)
Approval Length	1 month [E, F]
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of esophageal candidiasis

OR

1.2 Diagnosis of oropharyngeal candidiasis (OPC)

AND

2 - One of the following:

- Trial and failure, contraindication, or intolerance to fluconazole
- Susceptibility results demonstrate resistance to fluconazole

Product Name: Tolsura	
Approval Length	6 months [5, 10-12, B-D]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following fungal infections:

- Blastomycosis
- Histoplasmosis
- Aspergillosis

AND

2 - Trial and failure or intolerance to generic itraconazole capsules

Product Name: Noxafil oral suspension	
Diagnosis	Oropharyngeal Candidiasis
Approval Length	1 Month [E]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of oropharyngeal candidiasis (OPC)

AND

2 - Patient is 13 years of age and older

AND

3 - One of the following:

- Trial and failure, contraindication, or intolerance to fluconazole

- Susceptibility results demonstrate resistance to fluconazole

Product Name: Noxafil oral suspension	
Diagnosis	Oropharyngeal Candidiasis
Approval Length	1 Month [E]
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of oropharyngeal candidiasis (OPC)

AND

2 - Patient is 13 years of age and older

AND

3 - One of the following:

- Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to fluconazole
- Submission of medical records (e.g., chart notes) documenting susceptibility results demonstrate resistance to fluconazole

Product Name: Brand Noxafil oral tablet, generic posaconazole oral tablet, Noxafil oral suspension, Noxafil PowderMix	
Diagnosis	Prophylaxis of systemic fungal infections
Approval Length	6 Months [B-D]
Guideline Type	Prior Authorization

Approval Criteria

1 - Used as prophylaxis of invasive fungal infections caused by one of the following:

- Aspergillus
- Candida

AND

2 - One of the following:

2.1 For Noxafil (posaconazole) oral tablet, both of the following:

- Patient is 2 years of age and older
- Patient weighs greater than 40 kg

OR

2.2 For Noxafil oral suspension, patient is 13 years of age and older

OR

2.3 For Noxafil PowderMix, both of the following:

- Patient is 2 years of age and older
- Patient weighs 40 kg or less

AND

3 - One of the following:

3.1 Patient is at high risk of infections due to severe immunosuppression from one of the following conditions:

- Hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD)
- Hematologic malignancies with prolonged neutropenia from chemotherapy

OR

3.2 Patient has a prior fungal infection requiring secondary prophylaxis [15, G]

Product Name: Brand Noxafil oral tablet, generic posaconazole oral tablet, Noxafil oral suspension, Noxafil PowderMix	
Diagnosis	Prophylaxis of systemic fungal infections
Approval Length	6 Months [B-D]
Guideline Type	Non Formulary

Approval Criteria

1 - Used as prophylaxis of invasive fungal infections caused by one of the following:

- Aspergillus
- Candida

AND

2 - One of the following:

2.1 For Noxafil (posaconazole) oral tablet, both of the following:

- Patient is 2 years of age and older
- Patient weighs greater than 40kg

OR

2.2 For Noxafil oral suspension, patient is 13 years of age and older

OR

2.3 For Noxafil PowderMix, both of the following:

- Patient is 2 years of age and older
- Patient weighs 40 kg or less

AND

3 - Submission of medical records (e.g., chart notes) documenting one of the following:

3.1 Patient is at high risk of infections due to severe immunosuppression from one of the following conditions:

- Hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD)
- Hematologic malignancies with prolonged neutropenia from chemotherapy

OR

3.2 Patient has a prior fungal infection requiring secondary prophylaxis [15, G]

Product Name: Brand Noxafil oral tablet, generic posaconazole oral tablet	
Diagnosis	Treatment of systemic fungal infections
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of invasive aspergillosis

AND

2 - Patient is 13 years of age and older

Product Name: Brand Noxafil oral tablet, generic posaconazole oral tablet	
Diagnosis	Treatment of systemic fungal infections
Approval Length	3 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of invasive aspergillosis

AND

2 - Patient is 13 years of age and older

Product Name: Brand Vfend oral tablet, generic voriconazole oral tablet, Brand Vfend oral suspension, generic voriconazole oral suspension	
Diagnosis	Invasive Aspergillosis
Approval Length	6 Months [16, B-D]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of invasive aspergillosis

AND

2 - Patient is 2 years of age and older

Product Name: Brand Vfend oral tablet, generic voriconazole oral tablet, Brand Vfend oral suspension, generic voriconazole oral suspension	
Diagnosis	Serious Fungal Infections
Approval Length	6 Months [16, B-D]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of serious fungal infections (e.g., Scedosporium apiospermum, Fusarium species including Fusarium solani)

AND

2 - Patient is 2 years of age and older

AND

3 - Patient is intolerant of, or refractory to, other therapy (e.g., amphotericin B)

Product Name: Brand Vfend oral tablet, generic voriconazole oral tablet, Brand Vfend oral suspension, generic voriconazole oral suspension	
Diagnosis	Candidemia in non-neutropenic patients and other deep tissue Candida infections
Approval Length	1 Month [H, 16]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Candidemia
- Deep tissue Candida infection (e.g., disseminated in skin, infection in abdomen, kidney, bladder wall, and wounds)

AND

2 - Patient is non-neutropenic

AND

3 - Patient is 2 years of age and older

AND

4 - One of the following:

- Trial and failure, contraindication or intolerance to fluconazole [I]

- Susceptibility results demonstrate resistance to fluconazole [K]

Product Name: Brand Vfend oral tablet, generic voriconazole oral tablet, Brand Vfend oral suspension, generic voriconazole oral suspension	
Diagnosis	Esophageal Candidiasis
Approval Length	1 Month [H, 16]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of esophageal candidiasis

AND

2 - Patient is 2 years of age and older

AND

3 - One of the following:

- Trial and failure, contraindication, or intolerance to fluconazole
- Susceptibility results demonstrate resistance to fluconazole

Product Name: Cresemba oral capsule	
Approval Length	6 Months [17, B-D]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following fungal infections: [17]

- Invasive aspergillosis

- Invasive mucormycosis

AND

2 - Patient is 18 years of age and older

3 . Endnotes

A. Fingernail infections are usually reevaluated 18 weeks or longer after completion of therapy. Toenail infections are usually reevaluated 6-9 months after completion of therapy. [5] Indeed, considering that toenails can take 12 to 18 months to grow out, many clinicians consider that 1 year is too short to assess clinical effectiveness. [6] Reports of long-term follow-up of treated patients have recently been presented, suggesting that positive mycology at 12 and 24 weeks after commencement of therapy are poor prognostic signs and may indicate a need for retreatment or for a change of drug. [8]

B. The optimal duration of therapy for aspergillosis has not been defined. Most clinicians treat infections (pulmonary) until resolution or stabilization of clinical and radiographic manifestations. The IDSA recommends a minimal treatment period of 6 – 12 weeks in immunocompetent patients for invasive conditions. [11]

C. According to the IDSA guidelines for aspergillosis, duration of therapy for most conditions for aspergillosis has not been optimally defined. Most experts attempt to treat pulmonary infection until resolution or stabilization of all clinical and radiographic manifestations. Other factors include site of infection (e.g., osteomyelitis), level of immunosuppression, and extent of disease. Reversal of immunosuppression, if feasible, is important for a favorable outcome for invasive aspergillosis." [11]

D. According to the IDSA guidelines for the treatment of aspergillosis, both Amphotericin B and itraconazole are listed as second line treatment options for the treatment of invasive disease. [11]

E. For fluconazole-refractory OPC, either itraconazole or posaconazole for up to 28 days is recommended. For fluconazole-refractory esophageal candidiasis, itraconazole or voriconazole for 14 to 21 days is recommended. [3, 5]

F. Patients may be expected to relapse shortly after discontinuing therapy with Sporanox oral solution. Limited data on the safety of long-term use (> 6 months) of Sporanox Oral Solution are available at this time. [2]

G. NCCN recommends secondary prophylaxis with an appropriate antifungal agent in patients with prior chronic disseminated candidiasis or with invasive filamentous fungal infection during subsequent cycles of chemotherapy or HSCT. In patients with invasive aspergillosis before HSCT, antifungal therapy for more than a month and resolution of radiologic abnormalities correlate with a lower likelihood of post-transplant recurrence of infection. Secondary prophylaxis with a mold-active agent is advised for the entire period of immunosuppression. Secondary prophylaxis is generally administered for the duration of immunosuppression. Per recommendation from an infectious disease specialist, posaconazole is used for secondary prophylaxis of prior fungal infections. [15]

H. Voriconazole prescribing information states that for candidemia in non-neutropenic patients and other deep tissue Candida infections, patients should be treated for at least 14 days following resolution of symptoms or following last positive culture, whichever is long. For esophageal candidiasis, patients should be treated for a minimum of 14 days and for at least 7 days following resolution of symptoms. [16]
I. According to the 2016 IDSA guideline for candidemia in nonneutropenic patients, fluconazole, intravenous or oral, is an acceptable alternative to an echinocandin (e.g., caspofungin, micafungin, anidulafungin) in patients who are not critically ill and who are considered unlikely to have fluconazole-resistant Candida species. Voriconazole is effective for candidemia, however, offers little advantage over fluconazole as the initial therapy. [5]
J. According to the 2016 IDSA guideline for the treatment of esophageal candidiasis, oral fluconazole 200-400 mg for 14 to 21 days is strongly recommended (high-quality evidence). Intravenous fluconazole may be used in patients who cannot tolerate oral therapy. For fluconazole-refractory disease, voriconazole either intravenous or oral is recommended. [5]
K. Of the Candida species, C. krusei and C. glabrata are the two species with higher likelihood of fluconazole-resistance for serious candida infections due to widespread azole treatment. In these cases, voriconazole may be used as oral therapy in patients with infections due to C. krusei or fluconazole-resistant, voriconazole-susceptible C. glabrata infections. [5]

4 . References

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11. Wheat LJ, Freifeld AG, Kleiman MB, et al. Clinical practice guidelines for the management of patients with histoplasmosis: 2007 update by the Infectious Diseases Society of America. Clin Infect Dis. 2007;45:807-825.
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13. Tolsura Prescribing Information. Mayne Pharma; Greenville, NC. April 2022.
14. Noxafil Prescribing Information. Merck Sharp & Dohme Corp.; Whitehouse Station, NJ. September 2022.
15. Per Clinical Consultation with an Infectious Disease Specialist. January 24, 2014.
16. Voriconazole Tablet Prescribing Information. Ajanta Pharma Limited.; Bridgewater, NJ. November 2022.
17. Cresemba Prescribing Information. Astellas Pharma US., Inc. Northbrook, IL. November 2022.
18. Vfend Prescribing Information.Roerig. New York, NY. October 2022.

5 . Revision History

Date	Notes
1/24/2023	2023 UM Annual Review. Updated NF criteria to require submission of medical records to align with NF SOP.

Prior Authorization Guideline

Guideline Name	Banzel (rufinamide)

Guideline Note:

Effective Date:	8/1/2022
P&T Approval Date:	6/19/2019
P&T Revision Date:	06/17/2020 ; 12/16/2020 ; 12/16/2020 ; 06/16/2021 ; 07/21/2021 ; 6/15/2022

1 . Indications

Drug Name: Banzel (rufinamide) tablets and oral suspension
Lennox-Gastaut Syndrome (LGS) Indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome in pediatric patients 1 year of age and older and in adults.

2 . Criteria

Product Name: Brand Banzel	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of seizures associated with Lennox-Gaustaut Syndrome (LGS)

AND

2 - Used as adjunctive therapy

AND

3 - Patient is 1 year of age or older

AND

4 - One of the following:

4.1 Trial of and inadequate response to, contraindication, or intolerance to ONE generic formulary anticonvulsant (e.g., topiramate, lamotrigine, valproate)

OR

4.2 For continuation of prior therapy if the patient is established on Brand Banzel

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: generic rufinamide	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of seizures associated with Lennox-Gaustaut Syndrome (LGS)

AND

2 - Used as adjunctive therapy

AND

3 - Patient is 1 year of age or older

AND

3 - One of the following:

3.1 Trial of and inadequate response to, contraindication, or intolerance to ONE generic formulary anticonvulsant (e.g., topiramate, lamotrigine, valproate) other than generic rufinamide

OR

3.2 For continuation of prior therapy if the patient is established on generic rufinamide

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Brand Banzel, generic rufinamide	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

3 . References

1. Banzel Prescribing Information. Eisai Inc. Woodcliff, NJ. April 2020.

4 . Revision History

Date	Notes
6/2/2022	Annual review - addition of age criteria

Prior Authorization Guideline

Guideline Name	Bavencio (avelumab) injection

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	
P&T Revision Date:	05/14/2020 ; 08/13/2020 ; 05/20/2021 ; 05/19/2022 ; 5/18/2023

1 . Indications

Drug Name: Bavencio (avelumab) injection
Merkel Cell Carcinoma (MCC) Indicated for the treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (MCC). This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. **Urothelial Carcinoma (UC)** Indicated for the maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) that has not progressed with first-line platinum-containing chemotherapy. Indicated for the treatment of patients with locally advanced or metastatic UC who: 1) have disease progression during or following platinum-containing chemotherapy, or 2) have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. **Renal Cell Carcinoma (RCC)** Indicated for use in combination with axitinib for the first-line treatment of patients with advanced renal cell carcinoma (RCC).

2 . Criteria

Product Name: Bavencio injection	
Diagnosis	Merkel Cell Carcinoma (MCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic Merkel cell carcinoma

AND

2 - Patient is 12 years of age or older

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Bavencio injection	
Diagnosis	Urothelial Carcinoma (UC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of urothelial carcinoma

AND

2 - Disease is one of the following:

- Locally advanced
- Metastatic

AND

3 - One of the following:

3.1 Patient has disease progression during or following platinum-containing chemotherapy (e.g., cisplatin, carboplatin)

OR

3.2 Patient has disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin)

OR

3.3 Both of the following:

3.3.1 Used as maintenance treatment

AND

3.3.2 Patient has not progressed with first-line platinum-containing chemotherapy (e.g., cisplatin, carboplatin)

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Bavencio injection	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced renal cell carcinoma

AND

2 - Used as first-line treatment in combination with Inlyta (axitinib)

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Bavencio injection	
Diagnosis	Merkel Cell Carcinoma (MCC), Urothelial Carcinoma (UC), Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Bavencio Prescribing Information. EMD Serono, Inc. Rockland, MA. July 2022.

4 . Revision History

Date	Notes

4/4/2023	Annual Review - No criteria changes

Prior Authorization Guideline

Guideline Name	Beleodaq (belinostat)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	10/14/2014
P&T Revision Date:	02/18/2021 ; 02/17/2022 ; 3/15/2023

1 . Indications

Drug Name: Beleodaq (belinostat)
Peripheral T-Cell Lymphoma (PTCL) Indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL). This indication is approved under accelerated approval based on tumor response rate and duration of response. An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial.

2 . Criteria

Product Name: Beleodaq	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of peripheral T-cell lymphoma (PTCL) [2]

AND

2 - Disease is relapsed or refractory

AND

3 - Trial and failure, contraindication, or intolerance to at least one prior therapy (e.g., conventional chemotherapy, stem cell transplant)

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Beleodaq	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Beleodaq Prescribing Information. Spectrum Pharmaceuticals, Inc.; Irvine, CA. December 2022.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. T-cell Lymphomas. v.1.2021. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed February 27, 2023.

4 . Revision History

Date	Notes
2/27/2023	2023 Annual Review, updated references

Prior Authorization Guideline

Guideline Name	Bendamustine Agents - PA, NF

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	9/18/2019
P&T Revision Date:	04/15/2020 ; 08/13/2020 ; 08/19/2021 ; 01/19/2022 ; 07/20/2022 ; 02/16/2023 ; 03/15/2023 ; 5/18/2023

1 . Indications

Drug Name: Belrapzo
Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with chronic lymphocytic leukemia. Efficacy relative to first line therapies other than chlorambucil has not been established. **Non-Hodgkin Lymphoma (NHL)** Indicated for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

Drug Name: Bendamustine
Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with chronic lymphocytic leukemia. Efficacy relative to first line therapies other than chlorambucil has not been established. **Non-Hodgkin Lymphoma (NHL)** Indicated for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

Drug Name: Bendeka
Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with chronic lymphocytic leukemia. Efficacy relative to first line therapies other than chlorambucil has not been established. **Non-Hodgkin Lymphoma (NHL)** Indicated for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.
Drug Name: Treanda
Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with chronic lymphocytic leukemia. Efficacy relative to first line therapies other than chlorambucil has not been established. **Non-Hodgkin Lymphoma (NHL)** Indicated for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.
Drug Name: Vivimusta
Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with chronic lymphocytic leukemia. Efficacy relative to first line therapies other than chlorambucil has not been established. **Non-Hodgkin Lymphoma (NHL)** Indicated for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

2 . Criteria

Product Name: Bendeka, Belrapzo, Brand Bendamustine, Brand Treanda, Vivimusta	
Diagnosis	Chronic lymphocytic leukemia (CLL)
Approval Length	6 Month(s) [A, C]
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic lymphocytic leukemia (CLL)	

AND

2 - One of the following:

2.1 Trial and failure, or intolerance to generic bendamustine

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Bendeka, Belrapzo, Brand Bendamustine, Brand Treanda, Vivimusta	
Diagnosis	Chronic lymphocytic leukemia (CLL)
Approval Length	6 Month(s) [A, C]
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia (CLL)

AND

2 - One of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic bendamustine

OR

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy for patients currently in the midst of an ongoing prescribed treatment regimen

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Bendeka, Belrapzo, Brand Bendamustine, Brand Treanda, Vivimusta	
Diagnosis	Non-Hodgkin lymphoma (NHL)
Approval Length	6 Month(s) [B, D]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of indolent B-cell non-Hodgkin lymphoma (NHL)

AND

2 - Disease has progressed during or within 6 months of treatment with rituximab or a rituximab-containing regimen

AND

3 - One of the following:

3.1 Trial and failure, or intolerance to generic bendamustine

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Bendeka, Belrapzo, Brand Bendamustine, Brand Treanda, Vivimusta	
Diagnosis	Non-Hodgkin lymphoma (NHL)
Approval Length	6 Month(s) [B, D]
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of indolent B-cell non-Hodgkin lymphoma (NHL)

AND

2 - Disease has progressed during or within 6 months of treatment with rituximab or a rituximab-containing regimen

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic bendamustine

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy for patients currently in the midst of an ongoing prescribed treatment regimen

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Generic bendamustine	
Diagnosis	Chronic lymphocytic leukemia (CLL)
Approval Length	6 Month(s) [C]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia (CLL)

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Generic bendamustine	
Diagnosis	Non-Hodgkin lymphoma (NHL)
Approval Length	6 Month(s) [D]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of indolent B-cell non-Hodgkin lymphoma (NHL)

AND

2 - Disease has progressed during or within 6 months of treatment with rituximab or a rituximab-containing regimen

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

3 . Endnotes

A. For Bendeka: The recommended dose for chronic lymphocytic leukemia (CLL) is 100 mg/m2 administered intravenously over 10 minutes on Days 1 and 2 of a 28-day cycle, up to 6 cycles. [3]
B. For Bendeka: The recommended dose for non-Hodgkin lymphoma (NHL) is 120 mg/m2 administered intravenously over 10 minutes on Days 1 and 2 of a 21-day cycle, up to 8 cycles. [3]
C. For Belrapzo, Bendamustine, Treanda: The recommended dose for chronic lymphocytic leukemia (CLL) is 100 mg/m2 administered intravenously over 30 minutes on Days 1 and 2 of a 28-day cycle, up to 6 cycles. [1, 2, 4]
D. For Belrapzo, Bendamustine, Treanda: The recommended dose for non-Hodgkin lymphoma (NHL) is 120 mg/m2 administered intravenously over 60 minutes on Days 1 and 2 of a 21-day cycle, up to 8 cycles. [1, 2, 4]
E. For Vivimusta: The recommended dose for chronic lymphocytic leukemia (CLL) is 100 mg/m2 administered intravenously over 20 minutes on Days 1 and 2 of a 28-day cycle for up to 6 cycles. [5]
F. For Vivimusta: The recommended dose for non-Hodgkin lymphoma (NHL) is 20 mg/m2 administered intravenously over 20 minutes on Days 1 and 2 of a 21-day cycle for up to 8 cycles. [5]

4 . References

1. Belrapzo prescribing information. Eagle Pharmaceuticals, Inc. Woodcliff Lake, NJ. June 2022.
2. Bendamustine prescribing information. Eagle Pharmaceuticals, Inc. Woodcliff Lake, NJ. May 2019.
3. Bendeka prescribing information. Teva Pharmaceuticals USA, Inc. North Wales, PA. October 2021.
4. Treanda prescribing information. Teva Pharmaceuticals USA, Inc. North Wales, PA. June 2021.
5. Vivimusta prescribing information. Slayback Pharma LLC. Princeton, NJ. December 2022.

5 . Revision History

Date	Notes

5/4/2023	update guideline

Prior Authorization Guideline

Guideline Name	Benlysta (belimumab)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	7/12/2011
P&T Revision Date:	10/16/2019 ; 08/13/2020 ; 02/18/2021 ; 08/19/2021 ; 12/15/2021 ; 08/18/2022 ; 09/21/2022 ; 4/19/2023

1 . Indications

Drug Name: Benlysta (belimumab IV), Benlysta (belimumab SC)
Systemic Lupus Erythematosus (SLE) Indicated for the treatment of patients aged 5 years and older with active, autoantibody-positive, systemic lupus erythematosus (SLE) who are receiving standard therapy. Limitations of Use: The efficacy of Benlysta has not been evaluated in patients with severe active central nervous system lupus. Use of Benlysta is not recommended in these situations. **Lupus Nephritis** Indicated for the treatment of patients aged 5 years and older with active lupus nephritis who are receiving standard therapy. Limitations of Use: The efficacy of Benlysta has not been evaluated in patients with severe active central nervous system lupus. Use of Benlysta is not recommended in these situations.

2 . Criteria

Product Name: Benlysta IV or Benlysta SC

Diagnosis	Systemic lupus erythematosus
Approval Length	6 months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active systemic lupus erythematosus (SLE)

AND

2 - Autoantibody positive (i.e., anti-nuclear antibody [ANA] titer greater than or equal to 1:80 or anti-dsDNA level greater than or equal to 30 IU/mL) [2, 3]

AND

3 - One of the following:

- For Benlysta IV, patient is 5 years of age or older
- For Benlysta SC, patient is 18 years of age or older

AND

4 - Trial and failure, contraindication, or intolerance to two standard of care treatments for active SLE (e.g., antimalarials [e.g., Plaquenil (hydroxychloroquine)], corticosteroids [e.g., prednisone], or immunosuppressants [e.g., methotrexate, Imuran (azathioprine)]) [5]

AND

5 - Currently receiving at least one standard of care treatment for active SLE (e.g., antimalarials [e.g., Plaquenil (hydroxychloroquine)], corticosteroids [e.g., prednisone], or immunosuppressants [e.g., methotrexate, Imuran (azathioprine)]) [2, 3]

AND

6 - Prescribed by or in consultation with a rheumatologist

Product Name: Benlysta IV or Benlysta SC	
Diagnosis	Lupus nephritis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active lupus nephritis

AND

2 - One of the following:

- For Benlysta IV, patient is 5 years of age or older
- For Benlysta SC, patient is 18 years of age or older

AND

3 - Currently receiving standard of care treatment for active lupus nephritis (e.g., corticosteroids [e.g., prednisone] with mycophenolate or cyclophosphamide) [1, 4]

AND

4 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Rheumatologist

Product Name: Benlysta IV or Benlysta SC	
Diagnosis	All indications listed above

Approval Length	6 months [2, A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., decrease or stabilization of symptoms, improvement in functional impairment, decrease of corticosteroid dose, decrease in pain medications)

Product Name: Benlysta IV	
Diagnosis	Systemic lupus erythematosus
Approval Length	6 months [A]
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of active systemic lupus erythematosus (SLE)

AND

2 - Autoantibody positive (i.e., anti-nuclear antibody [ANA] titer greater than or equal to 1:80 or anti-dsDNA level greater than or equal to 30 IU/mL) [2, 3]

AND

3 - Patient is 5 years of age or older

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to two standard of care treatments for active SLE (e.g., antimalarials [e.g., Plaquenil (hydroxychloroquine)], corticosteroids [e.g., prednisone], or immunosuppressants [e.g., methotrexate, Imuran (azathioprine)]) [5]

AND

5 - Currently receiving at least one standard of care treatment for active SLE (e.g., antimalarials [e.g., Plaquenil (hydroxychloroquine)], corticosteroids [e.g., prednisone], or immunosuppressants [e.g., methotrexate, Imuran (azathioprine)]) [2, 3]

AND

6 - Prescribed by or in consultation with a rheumatologist

Product Name: Benlysta IV	
Diagnosis	Lupus nephritis
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of active lupus nephritis

AND

2 - Patient is 5 years of age or older

AND

3 - Currently receiving standard of care treatment for active lupus nephritis (e.g., corticosteroids [e.g., prednisone] with mycophenolate or cyclophosphamide) [1, 4]

AND

4 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Rheumatologist

3 . Endnotes

A. SLE is a disease that fluctuates. The undulating course of typical lupus patients requires frequent reassessment. A 6-month authorization period is reasonable. [2]

4 . References

1. Benlysta Prescribing Information. GlaxoSmithKline LLC. Philadelphia, PA. July 2022.
2. Per clinical consult with rheumatologist, October 4, 2017.
3. American College of Rheumatology Ad Hoc Committee on Systemic Lupus Erythematosus Guidelines. Guidelines for referral and management of systemic lupus erythematosus. Arthritis Rheum. 1999 Sep;42(9):1785-96.
4. American College of Rheumatology Guidelines for Screening, Case Definition, Treatment and Management of Lupus Nephritis. Arthritis Care Res (Hoboken). 2012 Jun; 64(6): 797-808.
5. Fanouriakis A, Kostopoulou M, Alunno A, et al. Ann Rheum Dis 2019;78:736–745.

5 . Revision History

Date	Notes
3/31/2023	Update to age criteria

Prior Authorization Guideline

Guideline Name	Bevacizumab - PA, NF

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	6/19/2019
P&T Revision Date:	02/13/2020 ; 03/18/2020 ; 08/13/2020 ; 02/18/2021 ; 01/19/2022 ; 02/17/2022 ; 07/20/2022 ; 03/15/2023 ; 4/19/2023

1 . Indications

Drug Name: Avastin (bevacizumab)
Metastatic Colorectal Cancer (mCRC) Indicated for the first- or second-line treatment of patients with metastatic carcinoma of the colon or rectum in combination with intravenous 5-fluorouracil-based chemotherapy. Bevacizumab, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy, is also indicated for second-line treatment of patients with metastatic colorectal cancer who have progressed on a first-line bevacizumab-containing regimen. Limitation of use: Bevacizumab is not indicated for adjuvant treatment of colon cancer. **Non-Squamous Non–Small Cell Lung Cancer (NSCLC)** Indicated for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer in combination with carboplatin and paclitaxel. **Glioblastoma** Indicated for the treatment of recurrent glioblastoma in adults. **Metastatic Renal Cell Carcinoma (mRCC)** Indicated for the treatment of metastatic renal cell carcinoma in combination with interferon alfa. **Persistent, Recurrent, or Metastatic Carcinoma of the Cervix** Indicated for the treatment of persistent, recurrent, or metastatic carcinoma of the cervix when used in combination with

paclitaxel and cisplatin or paclitaxel and topotecan.

Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Indicated, in combination with carboplatin and paclitaxel, followed by bevacizumab as a single agent, for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial resection. Indicated, in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than 2 prior chemotherapy regimens. Indicated, in combination with carboplatin and paclitaxel, or with carboplatin and gemcitabine, followed by bevacizumab as a single agent, for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

Hepatocellular Carcinoma Indicated, in combination with atezolizumab, for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy.

Drug Name: Mvasi (bevacizumab-awwb), Zirabev (bevacizumab-bvzr)

Metastatic Colorectal Cancer (mCRC) Indicated for the first- or second-line treatment of patients with metastatic carcinoma of the colon or rectum in combination with intravenous 5-fluorouracil-based chemotherapy. Bevacizumab, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy, is also indicated for second-line treatment of patients with metastatic colorectal cancer who have progressed on a first-line bevacizumab-containing regimen. Limitation of use: Bevacizumab is not indicated for adjuvant treatment of colon cancer.

Non-Squamous Non–Small Cell Lung Cancer (NSCLC) Indicated for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer in combination with carboplatin and paclitaxel.

Glioblastoma Indicated for the treatment of recurrent glioblastoma in adults.

Metastatic Renal Cell Carcinoma (mRCC) Indicated for the treatment of metastatic renal cell carcinoma in combination with interferon alfa.

Persistent, Recurrent, or Metastatic Carcinoma of the Cervix Indicated for the treatment of persistent, recurrent, or metastatic carcinoma of the cervix when used in combination with paclitaxel and cisplatin or paclitaxel and topotecan.

Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Indicated, in combination with carboplatin and paclitaxel, followed by bevacizumab as a single agent, for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial resection. Indicated, in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than 2 prior chemotherapy regimens. Indicated, in combination with carboplatin and paclitaxel, or with carboplatin and gemcitabine, followed by bevacizumab as a single agent, for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

Off Label Uses: **Hepatocellular Carcinoma** Indicated, in combination with atezolizumab, for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy. [4, A]

Drug Name: Alymsys (bevacizumab-maly)

Metastatic Colorectal Cancer (mCRC) Indicated for the first- or second-line treatment of patients with metastatic carcinoma of the colon or rectum in combination with intravenous 5-fluorouracil-based chemotherapy. Bevacizumab, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy, is also indicated for second-line treatment of patients with metastatic colorectal cancer who have progressed on a first-line bevacizumab-containing regimen. Limitation of use: Bevacizumab is not indicated for adjuvant treatment of colon cancer.

Non-Squamous Non–Small Cell Lung Cancer (NSCLC) Indicated for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer in combination with carboplatin and paclitaxel.

Glioblastoma Indicated for the treatment of recurrent glioblastoma in adults.

Metastatic Renal Cell Carcinoma (mRCC) Indicated for the treatment of metastatic renal cell carcinoma in combination with interferon alfa.

Persistent, Recurrent, or Metastatic Carcinoma of the Cervix Indicated for the treatment of persistent, recurrent, or metastatic carcinoma of the cervix when used in combination with paclitaxel and cisplatin or paclitaxel and topotecan.

Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Indicated, in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than 2 prior chemotherapy regimens.

Off Label Uses: **Hepatocellular Carcinoma** Indicated, in combination with atezolizumab, for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy. [4, A]

Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Indicated, in combination with carboplatin and paclitaxel, followed by bevacizumab as a single agent, for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial resection. [4, A] Indicated, in combination with carboplatin and paclitaxel, or with carboplatin and gemcitabine, followed by bevacizumab as a single agent, for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer. [4, A]

Drug Name: Vegzelma (bevacizumab-adcd)

Metastatic Colorectal Cancer Indicated for the first- or second-line treatment of patients with metastatic colorectal cancer (mCRC) in combination with intravenous fluorouracil-based chemotherapy. Vegzelma, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-

oxaliplatin-based chemotherapy, is also indicated for second-line treatment of patients with mCRC who have progressed on a first-line bevacizumab-containing regimen. Limitation of use: Vegzelma is not indicated for adjuvant treatment of colon cancer.

Non-Squamous Non–Small Cell Lung Cancer (NSCLC) Indicated for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer in combination with carboplatin and paclitaxel.

Glioblastoma Indicated for the treatment of recurrent glioblastoma in adults.

Metastatic Renal Cell Carcinoma (mRCC) Indicated for the treatment of metastatic renal cell carcinoma in combination with interferon alfa.

Persistent, Recurrent, or Metastatic Carcinoma of the Cervix Indicated for the treatment of persistent, recurrent, or metastatic cervical cancer when used in combination with paclitaxel and cisplatin or paclitaxel and topotecan.

Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Indicated, in combination with carboplatin and paclitaxel, followed by Vegzelma as a single agent, for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial surgical resection. Indicated, in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than 2 prior chemotherapy regimens. Indicated, in combination with carboplatin and paclitaxel, or with carboplatin and gemcitabine, followed by Vegzelma as a single agent, for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

Off Label Uses: Hepatocellular Carcinoma Indicated, in combination with atezolizumab, for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy. [4, A]

2 . Criteria

Product Name: Avastin, Mvasi, Zirabev, Alymsys, Vegzelma	
Diagnosis	Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of metastatic colorectal cancer

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Used as first- or second-line treatment

AND

2.1.2 Used in combination with an intravenous 5-fluorouracil-based chemotherapy

OR

2.2 All of the following:

2.2.1 Used as second-line treatment

AND

2.2.2 Used in combination with one of the following:

- fluoropyrimidine-irinotecan-based chemotherapy [e.g., capecitabine, floxuridine, and fluorouracil (5-FU)]
- fluoropyrimidine-oxaliplatin-based chemotherapy [e.g., capecitabine, floxuridine, and fluorouracil (5-FU)]

AND

2.2.3 Patient has progressed on a first-line bevacizumab-containing regimen

AND

3 - Prescribed by or in consultation with an oncologist

AND

4 - One of the following (applies to Avastin, Alymsys and Vegzelma only):

4.1 Trial and failure, or intolerance to both of the following:

- Mvasi
- Zirabev

OR

4.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Avastin, Mvasi, Zirabev, Alymsys, Vegzelma	
Diagnosis	Non-Small Cell Lung Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is one of the following:

- Unresectable
- Locally advanced
- Recurrent
- Metastatic

AND

3 - Used as first-line treatment

AND

4 - Used in combination with both of the following:

- Paclitaxel
- Carboplatin

AND

5 - Patient does not have squamous cell histology

AND

6 - Prescribed by or in consultation with an oncologist

AND

7 - One of the following (applies to Avastin, Alymsys and Vegzelma only):

7.1 Trial and failure, or intolerance to both of the following:

- Mvasi
- Zirabev

OR

7.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Avastin, Mvasi, Zirabev, Alymsys, Vegzelma	
Diagnosis	Renal Cell Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic renal cell cancer

AND

2 - Used in combination with interferon-alfa

AND

3 - Prescribed by or in consultation with an oncologist

AND

4 - One of the following (applies to Avastin, Alymsys and Vegzelma only):

4.1 Trial and failure, or intolerance to both of the following:

- Mvasi
- Zirabev

OR

4.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Avastin, Mvasi, Zirabev, Alymsys, Vegzelma	
Diagnosis	Cervical Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of carcinoma of the cervix

AND

2 - Disease is one of the following:

- Persistent
- Recurrent
- Metastatic

AND

3 - Used in combination with one of the following:

- Paclitaxel and cisplatin
- Paclitaxel and topotecan

AND

4 - Prescribed by or in consultation with an oncologist

AND

5 - One of the following (applies to Avastin, Alymsys and Vegzelma only):

5.1 Trial and failure, or intolerance to both of the following:

- Mvasi
- Zirabev

OR

5.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Avastin, Mvasi, Zirabev, Alymsys, Vegzelma	
Diagnosis	Glioblastoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent glioblastoma

AND

2 - Prescribed by or in consultation with an oncologist

AND

3 - One of the following (applies to Avastin, Alymsys and Vegzelma only):

3.1 Trial and failure, or intolerance to both of the following:

- Mvasi
- Zirabev

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Avastin, Mvasi, Zirabev, Alymsys, Vegzelma	
Diagnosis	Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Epithelial ovarian cancer
- Fallopian tube cancer
- Primary peritoneal cancer

AND

2 - One of the following:

2.1 All of the following:

2.1.1 Disease is stage 3 or 4

AND

2.1.2 Patient has been treated with bevacizumab as a single agent

AND

2.1.3 Treatment is following surgical resection

AND

2.1.4 Used in combination with both of the following:

- Carboplatin
- Paclitaxel

OR

2.2 All of the following:

2.2.1 Disease is platinum-resistant recurrent

AND

2.2.2 Patient has received no more than two prior chemotherapy regimens

AND

2.2.3 Used in combination with one of the following:

- Paclitaxel
- Pegylated liposomal doxorubicin
- Topotecan

OR

2.3 All of the following:

2.3.1 Disease is platinum-sensitive recurrent

AND

2.3.2 Patient has been treated with bevacizumab as a single agent

AND

2.3.3 Used in combination with one of the following:

- Carboplatin and paclitaxel
- Carboplatin and gemcitabine

AND

3 - Prescribed by or in consultation with an oncologist

AND

4 - One of the following (applies to Avastin, Alymsys and Vegzelma only):

4.1 Trial and failure, or intolerance to both of the following:

- Mvasi
- Zirabev

OR

4.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Avastin, Mvasi (off-label), Zirabev (off-label), Alymsys (off-label), Vegzelma (off-label) [4, A]	
Diagnosis	Hepatocellular Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hepatocellular carcinoma

AND

2 - Disease is one of the following:

- Unresectable
- Metastatic

AND

3 - Used in combination with Tecentriq (atezolizumab)

AND

4 - Patient has not received prior systemic therapy

AND

5 - Prescribed by or in consultation with an oncologist

AND

6 - One of the following (applies to Avastin, Alymsys and Vegzelma only):

6.1 Trial and failure, or intolerance to both of the following:

- Mvasi
- Zirabev

OR

6.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Avastin, Mvasi, Zirabev, Alymsys, Vegzelma	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - One of the following (applies to Avastin, Alymsys and Vegzelma only):

2.1 Trial and failure, or intolerance to both of the following:

- Mvasi
- Zirabev

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Alymsys	
Diagnosis	Colorectal Cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of metastatic colorectal cancer

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

2.1 Both of the following:

2.1.1 Used as first- or second-line treatment

AND

2.1.2 Used in combination with an intravenous 5-fluorouracil-based chemotherapy

OR

2.2 All of the following:

2.2.1 Used as second-line treatment

AND

2.2.2 Used in combination with one of the following:

- fluoropyrimidine-irinotecan-based chemotherapy [e.g., capecitabine, floxuridine, and fluorouracil (5-FU)]
- fluoropyrimidine-oxaliplatin-based chemotherapy [e.g., capecitabine, floxuridine, and fluorouracil (5-FU)]

AND

2.2.3 Patient has progressed on a first-line bevacizumab-containing regimen

AND

3 - Prescribed by or in consultation with an oncologist

AND

4 - One of the following:

4.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to both of the following:

- Mvasi
- Zirabev

OR

4.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Alymsys	
Diagnosis	Non-Small Cell Lung Cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is one of the following:

- Unresectable
- Locally advanced
- Recurrent
- Metastatic

AND

3 - Used as first-line treatment

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming medication is being used in combination with both of the following:

- Paclitaxel
- Carboplatin

AND

5 - Patient does not have squamous cell histology

AND

6 - Prescribed by or in consultation with an oncologist

AND

7 - One of the following:

7.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to both of the following:

- Mvasi
- Zirabev

OR

7.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Alymsys	
Diagnosis	Renal Cell Cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of metastatic renal cell cancer

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming medication is being used in combination with interferon-alfa

AND

3 - Prescribed by or in consultation with an oncologist

AND

4 - One of the following:

4.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to both of the following:

- Mvasi
- Zirabev

OR

4.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Alymsys	
Diagnosis	Cervical Cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of carcinoma of the cervix

AND

2 - Disease is one of the following:

- Persistent
- Recurrent

- Metastatic

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming medication is being used in combination with one of the following:

- Paclitaxel and cisplatin
- Paclitaxel and topotecan

AND

4 - Prescribed by or in consultation with an oncologist

AND

5 - One of the following:

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to both of the following:

- Mvasi
- Zirabev

OR

5.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Alymsys	
Diagnosis	Glioblastoma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of recurrent glioblastoma

AND

2 - Prescribed by or in consultation with an oncologist

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to both of the following:

- Mvasi
- Zirabev

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Alymsys	
Diagnosis	Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following diagnoses:

- Epithelial ovarian cancer
- Fallopian tube cancer
- Primary peritoneal cancer

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

2.1 All of the following:

2.1.1 Disease is stage 3 or 4

AND

2.1.2 Patient has been treated with bevacizumab as a single agent

AND

2.1.3 Treatment is following surgical resection

AND

2.1.4 Used in combination with both of the following:

- Carboplatin
- Paclitaxel

OR

2.2 All of the following:

2.2.1 Disease is platinum-resistant recurrent

AND

2.2.2 Patient has received no more than two prior chemotherapy regimens

AND

2.2.3 Used in combination with one of the following:

- Paclitaxel
- Pegylated liposomal doxorubicin
- Topotecan

OR

2.3 All of the following:

2.3.1 Disease is platinum-sensitive recurrent

AND

2.3.2 Patient has been treated with bevacizumab as a single agent

AND

2.3.3 Used in combination with one of the following:

- Carboplatin and paclitaxel
- Carboplatin and gemcitabine

AND

3 - Prescribed by or in consultation with an oncologist

AND

4 - One of the following:

4.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to both of the following:

- Mvasi
- Zirabev

OR

4.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Alymsys (off-label) [4, A]	
Diagnosis	Hepatocellular Carcinoma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of hepatocellular carcinoma

AND

2 - Disease is one of the following:

- Unresectable
- Metastatic

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming medication is being used in combination with Tecentriq (atezolizumab)

AND

4 - Patient has not received prior systemic therapy

AND

5 - Prescribed by or in consultation with an oncologist

AND

6 - One of the following:

6.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to both of the following:

- Mvasi
- Zirabev

OR

6.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

3 . Endnotes

A. The FDA defines biosimilar as a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. [4]

4 . References

1. Avastin Prescribing Information. Genentech Inc. South San Francisco, CA. September 2022.
2. Mvasi Prescribing Information. Amgen Inc. Thousand Oaks, CA. November 2021.
3. Zirabev Prescribing Information. Pfizer Inc. New York, NY. May 2021.
4. U.S. Food and Drug Administration (FDA). Biosimilar and Interchangeable Products. Silver Spring, MD: FDA; October 23, 2017. Available at: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580419.htm#biosimilar. Accessed February 21, 2023.
5. Alymsys Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. April 2022.
6. Vegzelma Prescribing Information. Celltrion USA, Inc. Jersey City, NJ. November 2022.

5 . Revision History

Date	Notes
4/3/2023	Added Vegzelma to guideline

Prior Authorization Guideline

Guideline Name	Blood Glucose Monitor & Test Strips - ST, QL, NF

Guideline Note:

Effective Date:	2/1/2023
P&T Approval Date:	4/6/2010
P&T Revision Date:	06/17/2020 ; 08/14/2020 ; 03/17/2021 ; 07/21/2021 ; 09/15/2021 ; 06/15/2022 ; 09/21/2022 ; 1/18/2023

Note:

This guideline does not apply to continuous glucose monitors.

1 . Indications

Drug Name: Blood glucose monitoring systems
Quantitative measurements of glucose Intended to be used for quantitative measurements of glucose in fresh capillary and/or venous whole blood. Various devices are designed for testing by persons with diabetes or by health care professionals in the home or health care facilities.

2 . Criteria

Product Name: Non-preferred test strip products	
Approval Length	12 month(s)

Guideline Type	Step Therapy

Approval Criteria

1 - Requested product is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - One of the following:

2.1 Trial to a minimum 90 day supply of both Contour Next and OneTouch test strips within the last 180 days

OR

2.2 The non-preferred test strip is required because it is the only product that will interface with the member's insulin pump

Product Name: Non-Formulary or Excluded test strip products	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming that the non-formulary/excluded test strip is required because it is the only product that will interface with the member's insulin pump

Product Name: Preferred or non-preferred test strip products	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Physician confirmation that the patient requires a greater quantity because of more frequent blood glucose testing (e.g., patients on intravenous insulin infusions) [A]

Product Name: Non-Formulary or Excluded meter products	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming that the non-formulary/excluded meter is required because it is the only product that will interface with the member's insulin pump

Product Name: Non-preferred meter products	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested product is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - One of the following:

2.1 Minimum 90 day trial of both a Contour Next Blood Glucose Monitoring System (e.g. Contour Next EZ Blood Glucose Monitoring System) and a OneTouch Blood Glucose Monitoring System within the last 180 days

OR

2.2 The non-preferred meter is required because it is the only product that will interface with the member's insulin pump

3 . Endnotes

A. The evidence regarding the utility and optimal frequency of self-monitoring of blood glucose (SMBG) is not well defined for patients who do not use intensive insulin regimens, such as those with type 2 diabetes using oral agents and/or basal insulin [1]. However for most patients using intensive insulin regimens (multiple-dose insulin or insulin pump therapy) SMBG should be performed prior to meals and snacks, at bedtime, occasionally postprandially, prior to exercise, when they suspect low blood glucose, after treating low blood glucose until they are normoglycemic, and prior to critical tasks such as driving.

4 . References

1. American Diabetes Association (ADA). Diabetes Technology: Standards of Medical Care in Diabetes - 2022. Diabetes Care. 2022;45(suppl 1):S97-S112.

5 . Revision History

Date	Notes
1/19/2023	Addition of non-preferred meter product, Tempo Kit

Prior Authorization Guideline

Guideline Name	Bonjesta, Diclegis (doxylamine/pyridoxine)

Guideline Note:

Effective Date:	10/1/2022
P&T Approval Date:	2/25/2016
P&T Revision Date:	07/17/2019 ; 04/15/2020 ; 06/17/2020 ; 08/19/2021 ; 8/18/2022

1 . Indications

Drug Name: Bonjesta, Diclegis (doxylamine succinate and pyridoxine hydrochloride)
Nausea and vomiting of pregnancy Indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management. Limitations of Use: Bonjesta and Diclegis have not been studied in women with hyperemesis gravidarum.

2 . Criteria

Product Name: Bonjesta, Brand Diclegis, Generic doxylamine/pyridoxine delayed-release	
Approval Length	9 Months
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of nausea and vomiting of pregnancy

AND

2 - Trial and failure or intolerance to generic doxylamine and generic pyridoxine (Vitamin B6) taken together [5, 7]

3 . Endnotes

A. Bonjesta and Diclegis (doxylamine succinate/pyridoxine hydrochloride) are contraindicated in women who are taking monoamine oxidase inhibitors (MAOIs), which prolong and intensify the anticholinergic (drying) effects of antihistamines. [1, 6]

4 . References

1. Diclegis prescribing information. Duchesnay USA, Inc. Bryn Mawr, PA. November 2020.
2. ACOG Practice Bulletin. Nausea and vomiting of pregnancy. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2004 (reaffirmed 2013); 103(4): 803-14. (Practice Bulletin No. 153)
3. Arsenault MY, Lane CA. The Management of Nausea and Vomiting in Pregnancy. J Obstet Gynaecol Can 2002; 24(10):817-23.
4. Ebrahimi N, Maltepe C, Einarson A. Optimal management of nausea and vomiting of pregnancy. Int J Womens Health. 2010; 2: 241–248.
5. Matthews A, Haas DM, O'Mathúna DP, et al. Interventions for nausea and vomiting in early pregnancy. Cochrane Database Syst Rev. 2015 Sep 8; 9:CD007575.
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5 . Revision History

Date	Notes
8/2/2022	2022 Annual Review, no criteria changes.

Prior Authorization Guideline

Guideline Name	Bortezomib

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	10/2/2004
P&T Revision Date:	06/17/2020 ; 06/16/2021 ; 06/15/2022 ; 07/20/2022 ; 09/21/2022 ; 10/19/2022 ; 03/15/2023

1 . Indications

Drug Name: Velcade (bortezomib)
Multiple Myeloma Indicated for the treatment of patients with multiple myeloma. **Mantle Cell Lymphoma** Indicated for the treatment of patients with mantle cell lymphoma.
Drug Name: Bortezomib (bortezomib)
Multiple Myeloma Indicated for the treatment of patients with multiple myeloma. **Mantle Cell Lymphoma** Indicated for the treatment of adult patients with mantle cell lymphoma.

2 . Criteria

Product Name: Brand Velcade, Generic bortezomib, Bortezomib

Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma [1, 2, 5]

AND

2 - Trial and failure, contraindication or intolerance to generic bortezomib (Applies to Brand Velcade Only)

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Brand Velcade, Generic bortezomib, Bortezomib	
Diagnosis	Mantle Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mantle cell lymphoma [1, 3, 4, 5]

AND

2 - Trial and failure, contraindication or intolerance to generic bortezomib (Applies to Brand Velcade Only)

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Brand Velcade, Generic bortezomib, Bortezomib	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Velcade Prescribing Information. Millennium Pharmaceuticals, Inc. Cambridge, MA. November 2021.
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8. Bortezomib Prescribing Information. Dr Reddy’s Laboratories, Inc. Princeton, NJ. December 2022.
9. Bortezomib Prescribing Information. Hikma Pharmaceuticals USA, Inc. Berkeley Heights, NJ. November 2021.
10. Bortezomib Prescribing Information. Fosun Pharma USA. Princeton, NJ. August 2022.

4 . Revision History

Date	Notes
3/31/2023	Updated GPIs

Prior Authorization Guideline

Guideline Name	Bosulif (bosutinib)

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	11/13/2012
P&T Revision Date:	12/18/2019 ; 04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Bosulif (bosutinib)
Resistant or intolerant Chronic Myelogenous/Myeloid Leukemia Indicated for the treatment of adult patients with chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) with resistance or intolerance to prior therapy. **Newly-diagnosed Chronic Myelogenous Leukemia** Indicated for the treatment of adult patients with newly-diagnosed chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML).

2 . Criteria

Product Name: Bosulif	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome-positive chronic myelogenous/myeloid leukemia (Ph+ CML) [1,2]

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - One of the following:

3.1 Trial and failure or intolerance to generic imatinib

OR

3.2 Continuation of prior therapy

Product Name: Bosulif	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Bosulif Prescribing Information. Pfizer. New York, NY. May 2021.

2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed on March 18, 2020.

4 . Revision History

Date	Notes
3/20/2023	Annual Review - no criteria changes

Prior Authorization Guideline

Guideline Name	Botox (onabotulinumtoxinA)

Guideline Note:

Effective Date:	9/1/2022
P&T Approval Date:	3/17/2000
P&T Revision Date:	10/16/2019 ; 12/18/2019 ; 07/15/2020 ; 09/16/2020 ; 12/16/2020 ; 04/21/2021 ; 07/21/2021 ; 04/20/2022 ; 7/20/2022

1 . Indications

Drug Name: Botox (onabotulinumtoxin A)
Overactive Bladder Indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication. **Detrusor Overactivity associated with a Neurologic Condition** Indicated for the treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) in adults who have an inadequate response to or are intolerant of an anticholinergic medication. **Neurogenic Detrusor Overactivity (NDO)** Indicated for the treatment of neurogenic detrusor overactivity (NDO) in pediatric patients 5 years of age and older who have an inadequate response to or are intolerant of anticholinergic medications. **Chronic Migraine** Indicated for the prophylaxis of headaches in adult patients with chronic migraine (greater than or equal to 15 days per month with headache lasting 4 hours a day or longer). Important Limitations: Safety and effectiveness have not been established for the prophylaxis of episodic migraine (14 headache days or fewer per month) in seven placebo-controlled studies.

Spasticity Indicated for the treatment of spasticity in patients 2 years of age and older. Limitations of use: Botox has not been shown to improve upper extremity functional abilities, or range of motion at a joint affected by a fixed contracture.

Cervical Dystonia (Spasmodic Torticollis) Indicated for the treatment of cervical dystonia in adults to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.

Primary Axillary Hyperhidrosis Indicated for the treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents. Limitations: The safety and effectiveness of Botox for hyperhidrosis in other body areas have not been established. Weakness of hand muscles and blepharoptosis may occur in patients who receive Botox for palmar hyperhidrosis and facial hyperhidrosis, respectively. Patients should be evaluated for potential causes of secondary hyperhidrosis (e.g., hyperthyroidism) to avoid symptomatic treatment of hyperhidrosis without the diagnosis and/or treatment of the underlying disease. Safety and effectiveness of Botox have not been established for the treatment of axillary hyperhidrosis in pediatric patients under age 18.

Blepharospasm and strabismus Indicated for the treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders (involving muscles of the face) in patients 12 years of age and above.

Off Label Uses: **Chronic Low Back Pain [2, 3]** Used in the treatment of chronic low back pain.

Other Uses [2, 3] Used in the treatment of achalasia, chronic anal fissures, dynamic muscle contracture in pediatric cerebral palsy patients, sialorrhea, hand tremor, and oromandibular dystonia.

Drug Name: Botox Cosmetic (onabotulinumtoxin A)

Cosmetic Uses [Non-approvable Use] Indicated in adult patients for the temporary improvement in the appearance of: 1) Moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity 2) Moderate to severe lateral canthal lines associated with orbicularis oculi activity 3) Moderate to severe forehead lines associated with frontalis muscle activity **Please Note: The request for Botox (onabotulinumtoxin A) injections to treat the appearance of facial lines is not authorized given that this use is for cosmetic purposes only.

2 . Criteria

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Neuromuscular and Autonomic Disorders
Approval Length	3 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Blepharospasm associated with dystonia (e.g., benign essential blepharospasm)
- Cervical dystonia (also known as spasmodic torticollis)
- Spasticity
- Strabismus
- VII cranial nerve disorders (hemifacial spasms)

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Neuromuscular and Autonomic Disorders
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - At least 3 months have or will have elapsed since the last treatment

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Primary Axillary Hyperhidrosis
Approval Length	1 Time(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary axillary hyperhidrosis [G]

AND

2 - One of the following:

2.1 Score of 3 or 4 on the Hyperhidrosis Disease Severity Scale (HDSS) [A, 1, 4]

OR

2.2 Skin maceration with secondary infection [5]

AND

3 - Trial and failure, contraindication, or intolerance to topical prescription strength drying agents [e.g., Drysol, Hypercare, Xerac AC (aluminum chloride hexahydrate)]

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Primary Axillary Hyperhidrosis
Approval Length	1 Time(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - At least a 2-point improvement in HDSS [1, 4]

AND

2 - At least 3 months have or will have elapsed since the last series of injections [1, 4]

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Chronic Migraine
Approval Length	3 Month [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic migraines [I]

AND

2 - Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [M]

AND

3 - Patient is 18 years of age or older [N]

AND

4 - Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months [1, 13-16, L]

AND

5 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist

AND

6 - Two of the following: [H, J, O, P, Q, R]

6.1 One of the following:

- History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine)
- Patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine)

OR

6.2 One of the following:

- History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- Patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate)

OR

6.3 One of the following:

- History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol
- Patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol

OR

6.4 One of the following:

- History of failure (after at least a two month trial) or intolerance to Atacand (candesartan)
- Patient has a contraindication to Atacand (candesartan)

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Chronic Migraine
Approval Length	3 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity [19]

AND

2 - Use of acute migraine medications (e.g., NSAIDS, triptans) has decreased since the start of therapy

AND

3 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist

AND

4 - Patient continues to be monitored for medication overuse headache (MOH) [M]

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Urinary Incontinence associated with a Neurologic Condition OR Overactive Bladder with Symptoms OR Neurogenic Detrusor Overactivity (NDO)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following conditions: [1, 3, E, F]

- Urinary incontinence that is associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis)
- Overactive bladder with symptoms (e.g., urge urinary incontinence, urgency, and frequency)
- Neurogenic detrusor overactivity (NDO)

AND

2 - Prescribed by or in consultation with a urologist

AND

3 - Trial and failure, contraindication, or intolerance to at least one oral anticholinergic (antispasmodic or antimuscarinic) agent [e.g., Bentyl (dicyclomine), Donnatal (atropine/ scopolamine/ hyoscyamine/ phenobarbital), Levsin/Levsinex (hyoscyamine), Ditropan (oxybutynin), Enablex (darifenacin), or VESIcare (solifenacin)]

AND

4 - Patient is routinely performing clean intermittent self-catheterization (CIC) or is willing/able to perform CIC if he/she has post-void residual (PVR) urine volume greater than 200 mL

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Urinary Incontinence associated with a Neurologic Condition OR Overactive Bladder with Symptoms OR Neurogenic Detrusor Overactivity (NDO)
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - At least 3 months have or will have elapsed since the last treatment

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Chronic Anal Fissure (Off-Label)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic anal fissure [8, 9]

AND

2 - At least 2 months of one of the following symptoms:

- Nocturnal pain and bleeding
- Postdefecation pain

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies:

- Topical nitrates (e.g. Glyceryl trinitrate (Nitroglycerin))
- Topical calcium channel blockers (CCBs) (e.g., diltiazem, nifedipine)

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Chronic Anal Fissure (Off-Label)
Approval Length	3 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

- Incomplete healing of fissure
- Recurrence of fissure

AND

2 - Documentation of positive clinical response to therapy

AND

3 - At least 3 months have or will have elapsed since the last series of injections

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Chronic Back Pain [D] (Off-Label)
Approval Length	1 treatment session (series of injections) [K]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of low back pain

AND

2 - Low back pain has lasted for greater than or equal to six (6) months

AND

3 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Neurosurgeon
- Orthopedist
- Pain specialist

AND

4 - Trial and failure (at least 3 months), contraindication, or intolerance to both of the following conventional therapies: [10-12]

- At least one oral NSAID medication
- At least one opioid medication

AND

5 - Trial and failure or inadequate response to one of the following: [10]

- Physical therapy
- Nonpharmacologic therapy (e.g., spinal manipulation, massage therapy, transcutaneous electrical nerve stimulation (TENS), acupuncture/acupressure, and surgery)

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Chronic Back Pain [D] (Off-Label)
Approval Length	1 treatment session (series of injections) [K]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - At least 3 months have or will have elapsed since the last series of injections

Notes	Authorization will not exceed more than two treatment sessions total per year (including initial authorization).

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Achalasia (Off-Label)
Approval Length	6 Month [C]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of achalasia

AND

2 - One of the following:

2.1 High risk of complication from or failure to one of the following: [6, 7]

- Pneumatic dilation
- Myotomy

OR

2.2 Prior dilation caused esophageal perforation

OR

2.3 Patient has an increased risk of dilation-induced perforation due to one of the following:

- Epiphrenic diverticulum
- Hiatal hernia

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Achalasia (Off-Label)
Approval Length	6 Month [C]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of improvement or reduction in symptoms of achalasia (i.e., dysphagia, regurgitation, chest pain)

AND

2 - At least 6 months have or will have elapsed since the last series of injections [C]

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	All other diagnoses
Approval Length	6 months unless the FDA-approved treatment duration is less than 6 months. If FDA-approved treatment duration is less than 6 months, utilize the FDA-approved duration for authorization period.
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert)

AND

1.1.2 Additional requirements listed in the “Indications and Usage” and “Dosage and Administration” sections of the prescribing information (or package insert) have been met (e.g.: first line therapies have been tried and failed, any testing requirements have been met, etc)

OR

1.2 Meets the off-label administrative guideline criteria

AND

2 - Trial and failure, contraindication, or intolerance to two appropriate formulary alternatives (if available)

Product Name: All Products	
Diagnosis	Cosmetic Use
Guideline Type	Prior Authorization

Approval Criteria

1 - Requests for coverage of any Botox product for treating the appearance of facial lines are not authorized and will not be approved. These uses are considered cosmetic only.

3 . Endnotes

A. Hyperhidrosis Disease Severity Scale • The HDSS is a 4-point scale designed to assess the severity of hyperhidrosis in everyday clinical practice or in clinical research and the effectiveness of treatment. • The HDSS can be administered by an interviewer or self-completed by the patient. • The HDSS assess disease severity based on the extent of sweating-related impairment of daily activities. (1) Question - My (underarm) sweating is never noticeable and never interferes with my daily activities, Score - 1; (2) Question - My (underarm) sweating is tolerable but sometimes interferes with my daily activities, Score - 2; (3) Question - My (underarm) sweating is barely tolerable and frequently

interferes with my daily activities, Score - 3; (4) Question - My (underarm) sweating is intolerable and always interferes with my daily activities, Score - 4

B. This recommendation is based on results from the PREEMPT 2 trial. The primary endpoint of PREEMPT 2 was the mean change from baseline in frequency of headache days for the 28-day period ending with week 24. [13, 14]
C. Approximately 50% of achalasia patients relapse and require repeat treatments at 6 to 24-month intervals. [6]
D. An evidence-based review by the American Academy of Neurology (AAN) concluded that botulinum neurotoxin (BoNT) is possibly effective for the treatment of chronic predominantly unilateral low back pain (LBP) [one Class II study]. The AAN recommends that BoNT may be considered as a treatment option for patients with chronic predominantly unilateral LBP (Level C). [12]
E. An evidence-based review by the AAN established BoNT as safe and effective for the treatment of neurogenic detrusor overactivity (NDO) in adults (one Class I study and one Class II study). Data on the use of BoNT is probably safe and effective for the treatment of detrusor sphincter dyssynergia (DSD) in patients with spinal cord injury (2 Class II studies). On basis of one Class I study, BoNT does not provide significant benefit for the treatment of DSD in patients with multiple sclerosis (MS). The AAN recommends that BoNT should be offered as a treatment option for neurogenic detrusor overactivity (Level A), and that BoNT should be considered for DSD in patients with spinal cord injury (Level B). [12]
F. BoNT is not effective in patients with DSD due to multiple sclerosis in a multicenter, double-blind, placebo-controlled trial; however, in patients with DSD due to spinal cord injury, open-label clinical studies showed improvements in urodynamic parameters [recommendation for DSD: Adult, Class IIb, Category B]. For NDO, the use of BoNT (refractory to antispasmodics) in a randomized, double-blind, placebo-controlled clinical trial of 59 patients (n = 53 with spinal cord injury and n = 6 with multiple sclerosis) showed significant improvement in daily incontinence episodes in weeks 1 through 24 (except for weeks 12 and 18) compared to placebo [recommendation for NDO: Adult, Class IIb, Category B]. [12]
G. The safety and effectiveness of Botox for hyperhidrosis in areas other than the axillae have not been established. [1]
H. Clinical benefit from prophylactic therapy may take as long as 2 to 3 months to manifest. [17, 18] Recommended first-line agents for the prevention of migraine headache are atenolol, nadolol, propranolol, timolol, amitriptyline, venlafaxine, topiramate, divalproex sodium, and sodium valproate. [17]
I. Safety and effectiveness have not been established for the prophylaxis of episodic migraine (14 headache days or fewer per month) in seven placebo-controlled studies. [1] An evidence-based review by the American Academy of Neurology determined that, based on available evidence, Botox was probably ineffective in episodic migraine and tension-type headaches, and should not be considered in patients with these conditions. [12]
J. The effects of Botox in reducing the frequency of headache days in the PREEMPT trial and in the pooled analysis of the PREEMPT trials were very modest. Given the experience and evidence we have for other prophylactic treatments in the management of migraine, which are supported by national guidelines, it is reasonable to require failure with other prophylactic treatments before approving use of Botox. [17]
K. A single small randomized trial (n = 31) compared paravertebral injections of botulinum toxin with saline injections and found significant benefit of botulinum toxin up to eight weeks after injection. There is currently no consensus on number of injections or treatment length for low back pain. [12]

L. The International Classification of Headache Disorders, 3rd addition (beta version) distinguishes chronic and episodic migraine [20]. Chronic migraine is described as headache occurring on 15 or more days per month for more than 3 months, which has the features of migraine headache on at least 8 days per month. Episodic migraine is not clearly defined, but is applied when a patient is diagnosed with migraine but does not meet criteria for chronic migraine.
M. Medication overuse headache (MOH) is defined as headache occurring greater than or equal to 15 days per month. It develops as a consequence of regular overuse of acute or symptomatic headache medication for more than 3 months [20]. Current evidence suggests the best treatment strategy is withdrawal of the offending medication.
N. The safety and effectiveness of Botox for chronic headache in patients below the age of 18 years have not been established. In a 12-week, multicenter, double-blind, placebo-controlled clinical trial, 123 adolescent patients (ages 12 to below 18 years) with chronic migraine were randomized to receive Botox 74 Units, Botox 155 Units, or placebo, for one injection cycle. This trial did NOT establish the efficacy of Botox, compared with placebo, for the prophylaxis of headaches in adolescents with chronic migraine. [1]
O. The American Academy of Neurology supports the use of the following medications for the prevention of episodic migraine in adult patients (with level A or B evidence): antidepressants [i.e., Elavil (amitriptyline), Effexor (venlafaxine)], antiepileptics [i.e., Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], and beta-blockers [i.e., atenolol, propranolol, nadolol, timolol, metoprolol] [21]. They also support the use of Botox (onabotulinumtoxin A) as an efficacious treatment option for chronic migraine. Botox (onabotulinumtoxin A) is not however recommended for episodic migraine treatment.
P. The US Headache Consortium Consensus (Table e-1) recommends that therapy be initiated with medications that have the highest level of evidence-based therapy while also taking into account patient specific comorbidities [17]. Each medication should be given an adequate trial, it may take two to three months to achieve clinical benefit, and six months to achieve maximal benefit.
Q. The clinical team consulted with a neurologist [22]. He confirmed that preventative treatment for chronic migraine and episodic migraine are similar. The choice of preventative medication will not vary much between the episodic vs chronic subtypes. The choice of agent will largely depend more on patient specific factors.
R. The National Institute for Health and Care Excellence guidelines for the management of migraine recommend Botox (onabotulinumtoxin A) as an option in chronic migraine after failure of at least three other prophylactic medications and that the patient is being managed for medication overuse [23].

4 . References

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21. Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016 May 10;86(19):1818-26.
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23. National Institute for Health and Care Excellence. Management of migraine (with or without aura). April 17th, 2018. Available at: https://pathways.nice.org.uk/pathways/headaches/management-of-migraine-with-or-without-aura#path=view%3A/pathways/headaches/management-of-migraine-with-or-without-aura.xml&content=view-node%3Anodes-prophylactic-treatment. Accessed August 14, 2020.
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5 . Revision History

Date	Notes
7/21/2022	Annual review - updated references.

Prior Authorization Guideline

Guideline Name	Bowel Prep Agents

Guideline Note:

Effective Date:	1/1/2023

1 . Indications

Drug Name: Brand Moviprep
Colonoscopy Indicated for cleansing of the colon as a preparation for colonoscopy in adults.
Drug Name: Plenvu
Colonoscopy Indicated for cleansing of the colon in preparation for colonoscopy in adults.
Drug Name: Osmoprep
Colonoscopy Indicated for cleansing of the colon as a preparation for colonoscopy in adults.

2 . Criteria

Product Name: Brand Moviprep, Plenvu, Osmoprep	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure of a minimum 1 day supply within the last 180 days, contraindication, or intolerance to one of the following:

- Clenpiq
- Suprep

3 . References

1. Moviprep prescribing information. Salix Pharmaceuticals, Inc. Bridgewater, NJ. May 2021.
2. Plenvu prescribing information. Salix Pharmaceuticals, Inc. Bridgewater, NJ. May 2021.
3. Osmoprep prescribing information. Salix Pharmaceuticals, Inc. Bridgewater, NJ. March 2019.

4 . Revision History

Date	Notes
10/24/2022	Guideline Update

Prior Authorization Guideline

Guideline Name	Cablivi (caplacizumab-yhdp)

Guideline Note:

Effective Date:	4/1/2022
P&T Approval Date:	4/17/2019
P&T Revision Date:	02/13/2020 ; 02/18/2021 ; 2/17/2022

1 . Indications

Drug Name: Cablivi (caplacizumab-yhdp)
Acquired Thrombotic Thrombocytopenic Purpura (aTTP) Indicated for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy.

2 . Criteria

Product Name: Cablivi	
Diagnosis	Acquired Thrombotic Thrombocytopenic Purpura (aTTP)
Approval Length	3 Months [A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP)

AND

2 - First dose was/will be administered by a healthcare provider as a bolus intravenous injection

AND

3 - Used in combination with immunosuppressive therapy (e.g., rituximab, glucocorticoids) [3]

AND

4 - One of the following:

4.1 Used in combination with plasma exchange

OR

4.2 Both of the following:

- Patient has completed plasma exchange
- Less than 59 days have or will have elapsed beyond the last plasma exchange [B]

AND

5 - Prescribed by or in consultation with a hematologist or oncologist[2]

3 . Endnotes

A. Three month approval duration, based on package insert stating longest therapy in trial was 77 days.
B. Per package insert, after the plasma exchange period can use injection once daily for 30 days beyond the last plasma exchange and after the initial treatment course, if signs of

persistent underlying disease are present treatment can be extended for a maximum of 28 days, totaling 58 days of therapy after last plasma exchange.

4 . References

1. Cablivi Prescribing Information. Cambridge, MA. Genzyme Corporation. October 2021
2. Understanding TTP. https://www.understandingttp.com/patient/ttp-treatment/#overview-of-treatment. Accessed January 28, 2021.
3. FDA News Release: FDA approves first therapy for the treatment of adult patients with a rare blood clotting disorder. U.S. Food and Drug Administration; February 6, 2019. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm630851.htm. Accessed January 28, 2021.

5 . Revision History

Date	Notes
1/6/2022	2022 Annual Review - No changes to criteria, updated background in formation

Prior Authorization Guideline

Guideline Name	Cabometyx (cabozantinib)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	6/22/2016
P&T Revision Date:	03/18/2020 ; 03/17/2021 ; 11/18/2021 ; 03/16/2022 ; 5/18/2023

1 . Indications

Drug Name: Cabometyx (cabozantinib) tablets
Renal cell carcinoma (RCC) Indicated for the treatment of patients with advanced renal cell carcinoma (RCC). **Renal cell carcinoma (RCC)** Indicated, in combination with nivolumab, for the first-line treatment of patients with advanced RCC. **Hepatocellular Carcinoma (HCC)** Indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib. **Differentiated Thyroid Cancer** Indicated for the treatment of adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible.

2 . Criteria

Product Name: Cabometyx	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of renal cell carcinoma (RCC)

AND

2 - Disease is advanced

AND

3 - Prescribed by or in consultation with one of the following:

- Oncologist
- Nephrologist

Product Name: Cabometyx	
Diagnosis	Hepatocellular Carcinoma (HCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hepatocellular carcinoma (HCC)

AND

2 - Trial and failure, contraindication, or intolerance to Nexavar (sorafenib tosylate)*

AND

3 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hepatologist
- Gastroenterologist

Notes	*Criterion is part of the FDA-approved label

Product Name: Cabometyx	
Diagnosis	Differentiated Thyroid Cancer (DTC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of differentiated thyroid cancer (DTC) [A, 5]

AND

2 - Disease is one of the following:

- Locally advanced
- Metastatic

AND

3 - Patient is 12 years of age or older

AND **4** - Disease has progressed following prior VEGFR-targeted therapy (e.g., Lenvima [lenvatinib], Nexavar [sorafenib])* **AND** **5** - Disease or patient is refractory to radioactive iodine treatment or ineligible **AND** **6** - Prescribed by or in consultation with an oncologist

Notes	*Criterion is part of the FDA-approved label

Product Name: Cabometyx	
Diagnosis	All Indications Listed Above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. Differentiated thyroid carcinomas are broadly categorized as papillary thyroid carcinoma (PTC), follicular cancer (FTC), and Hurthle cell carcinoma (HCTC). [5]

4 . References

1. Cabometyx Prescribing Information. Exelixis, Inc. San Francisco, CA. January 2023.
2. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Kidney Cancer. Version 1.2021. Available at https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed January 29, 2021.
3. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Hepatocellular Carcinoma. Version 1.2023. Available at https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf Accessed May 3, 2023.
4. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed January 29, 2019.
5. Patel K, Yip L, Lubitz C et al. The American Association of Endocrine Surgeons Guidelines for the Definitive Surgical Management of Thyroid Disease in Adults. Ann Surg. 2020;271(3):e21-e93.

5 . Revision History

Date	Notes
5/3/2023	Annual review: Updated HCC criteria to remove NCCN criteria, updated DTC criteria to include age requirement, updated operational notes for HCC and DTC indications, updated references.

Prior Authorization Guideline

Guideline Name	Cabotegravir Containing Agents - PA, NF

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	3/17/2021
P&T Revision Date:	04/21/2021 ; 11/18/2021 ; 03/16/2022 ; 05/19/2022 ; 09/21/2022 ; 12/14/2022 ; 3/15/2023

1 . Indications

Drug Name: Cabenuva (cabotegravir and rilpivirine) Injection
Treatment of HIV-1 Infection Indicated as a complete regimen for the treatment of HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 35kg to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.
Drug Name: Vocabria (cabotegravir) Tablet
Treatment of HIV-1 Infection Indicated in combination with EDURANT (rilpivirine) for short-term treatment of HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 35kg who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine. Vocabria may be used as: 1) Oral lead-in to assess the tolerability of cabotegravir prior to administration of Cabenuva extended-release injectable suspension for HIV-1 treatment. 2) Oral therapy for patients who will miss planned injection dosing with Cabenuva for HIV-1 treatment. **HIV-1 Pre-Exposure Prophylaxis** Indicated in at-risk adults and adolescents weighing at

least 35 kg for short-term pre exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Vocabria may be used as: 1) Oral lead-in to assess the tolerability of cabotegravir prior to administration of Apretude extended-release injectable suspension for HIV-1 PrEP. 2) Oral therapy for patients who will miss planned injection dosing with Apretude for HIV-1 PrEP.

Drug Name: Apretude (cabotegravir) Injection

HIV-1 Pre-exposure prophylaxis (PrEP) Indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test prior to initiating Apretude (with or without an oral lead-in with oral cabotegravir) for HIV-1 PrEP.

2 . Criteria

Product Name: Vocabria*, Cabenuva*	
Diagnosis	Treatment of HIV-1 Infection
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of HIV-1 infection

AND

1.2 Patient is 12 years of age or older

AND

1.3 Patient's weight is greater than or equal to 35 kg

AND

1.4 Patient is currently virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable, uninterrupted antiretroviral regimen for at least 6 months

AND

1.5 Patient has no history of treatment failure or known/suspected resistance to either cabotegravir or rilpivirine

AND

1.6 Provider attests that patient would benefit from long-acting injectable therapy over standard oral regimens

AND

1.7 Prescribed by or in consultation with a clinician with HIV expertise

OR

2 - For continuation of prior therapy

Notes	*If patient meets criteria above, please approve both Vocabria and Ca benuva at GPI list “CABOTEGRPA”.

Product Name: Vocabria*, Cabenuva*	
Diagnosis	Treatment of HIV-1 Infection
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - All of the following:

1.1 Diagnosis of HIV-1 infection

AND

1.2 Patient is 12 years of age or older

AND

1.3 Patient's weight is greater than or equal to 35 kg

AND

1.4 Patient is currently virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable, uninterrupted antiretroviral regimen for at least 6 months

AND

1.5 Patient has no history of treatment failure or known/suspected resistance to either cabotegravir or rilpivirine

AND

1.6 Provider attests that patient would benefit from long-acting injectable therapy over standard oral regimens

AND

1.7 Prescribed by or in consultation with a clinician with HIV expertise

OR

2 - Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 70-day gap in therapy [A]

Notes	*If patient meets criteria above, please approve both Vocabria and Cabenuva at GPI list “CABOTEGRPA”.

Product Name: Vocabria**, Apretude**	
Diagnosis	HIV-1 Pre-Exposure Prophylaxis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Requested drug is being used for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection

AND

2 - Patient's weight is greater than or equal to 35 kg

AND

3 - Documentation of both of the following U.S. Food and Drug (FDA)-approved test prior to use of Vocabria or Apretude:

- Negative HIV-1 antigen/antibody test
- Negative HIV-1 RNA assay

AND

4 - One of the following:

4.1 Trial of, contraindication or intolerance to generic emtricitabine-tenofovir disoproxil fumarate 200/300mg

OR

4.2 Provider attests to both of the following:

- Patient would benefit from long-acting injectable therapy over standard oral regimens

• Patient would be adherent to testing and dosing schedule	
Notes	**If patient meets criteria above, please approve both Vocabria and A pretude at GPI list “APRETUDEPA”

Product Name: Vocabria**, Apretude**	
Diagnosis	HIV-1 Pre-Exposure Prophylaxis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Provider attests that patient is adherent to the testing appointments and scheduled injections of Apretude

AND

2 - Documentation of both of the following U.S. Food and Drug (FDA)-approved test prior to each maintenance injection of Apretude for HIV PrEP:

- Negative HIV-1 antigen/antibody test
- Negative HIV-1 RNA assay

Notes	**If patient meets criteria above, please approve both Vocabria and A pretude at GPI list “APRETUDEPA”

Product Name: Vocabria**, Apretude**	
Diagnosis	HIV-1 Pre-Exposure Prophylaxis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Requested drug is being used for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection

AND

2 - Patient's weight is greater than or equal to 35 kg

AND

3 - Submission of medical records (e.g., chart notes) confirming documentation of both the following U.S. Food and Drug (FDA)-approved test prior to use of Vocabria or Apretude:

- Negative HIV-1 antigen/antibody test
- Negative HIV-1 RNA assay

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

4.1 Trial of, contraindication or intolerance to generic emtricitabine-tenofovir disoproxil fumarate 200/300mg

OR

4.2 Both of the following:

- Patient would benefit from long-acting injectable therapy over standard oral regimens
- Patient would be adherent to testing and dosing schedule

Notes	**If patient meets criteria above, please approve both Vocabria and A pretude at GPI list “APRETUDEPA”

Product Name: Vocabria**, Apretude**	
Diagnosis	HIV-1 Pre-Exposure Prophylaxis
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Provider attests that patient is adherent to the testing appointments and scheduled injections of Apretude

AND

2 - Submission of medical records (e.g., chart notes) confirming documentation of both of the following U.S. Food and Drug (FDA)-approved test prior to each maintenance injection of Apretude for HIV PrEP:

- Negative HIV-1 antigen/antibody test
- Negative HIV-1 RNA assay

Notes	**If patient meets criteria above, please approve both Vocabria and A pretude at GPI list “APRETUDEPA”

3 . Endnotes

A. Continuation of therapy for Cabenuva and Vocabria in NF criteria will allow for a 70-day gap to account for the 2-month dosing schedule +/- 7 days. [1]

4 . References

1. Cabenuva Prescribing Information. ViiV Healthcare Company. Research Triangle Park, NC. April 2022.
2. Vocabria Prescribing Information. ViiV Healthcare Company. Research Triangle Park, NC. March 2022.
3. Apretude Prescribing information. ViiV Healthcare Company. Research Triangle Park, NC. December 2021.

5 . Revision History

Date	Notes
3/15/2023	Annual review - no changes.

Prior Authorization Guideline

Guideline Name	Cannabinoids

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	10/3/2006
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 11/18/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Marinol (dronabinol) capsule, Syndros (dronabinol) oral solution
Chemotherapy-induced nausea and vomiting Indicated in adults for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments. **Anorexia in patients with AIDS** Indicated in adults for the treatment of anorexia associated with weight loss in patients with Acquired Immune Deficiency Syndrome (AIDS)

2 . Criteria

Product Name: Brand Marinol	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving cancer chemotherapy

AND

2 - Trial and failure, contraindication, or intolerance to formulary generic dronabinol capsules*

AND

3 - Trial and failure, contraindication, or intolerance to a 5HT-3 receptor antagonist (e.g., Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]) [1]

AND

4 - Trial and failure, contraindication, or intolerance to one of the following: [1, A]

- Ativan (lorazepam)
- Compazine (prochlorperazine)
- Decadron (dexamethasone)
- Haldol (haloperidol)
- Phenergan (promethazine)
- Reglan (metoclopramide)
- Zyprexa (olanzapine)

Notes	*This product may require prior authorization.

Product Name: Syndros	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving cancer chemotherapy

AND

2 - One of the following:

2.1 Trial and failure or intolerance to formulary generic dronabinol capsules*

OR

2.2 Patient is unable to swallow capsules

AND

3 - Trial and failure, contraindication, or intolerance to a 5HT-3 receptor antagonist (e.g., Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]) [1]

AND

4 - Trial and failure, contraindication, or intolerance to one of the following: [1, A]

- Ativan (lorazepam)
- Compazine (prochlorperazine)
- Decadron (dexamethasone)
- Haldol (haloperidol)
- Phenergan (promethazine)
- Reglan (metoclopramide)
- Zyprexa (olanzapine)

Notes	*This product may require prior authorization.

Product Name: Generic dronabinol	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving cancer chemotherapy

AND

2 - Trial and failure, contraindication, or intolerance to a 5HT-3 receptor antagonist (e.g., Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]) [1]

AND

3 - Trial and failure, contraindication, or intolerance to one of the following: [1, A]

- Ativan (lorazepam)
- Compazine (prochlorperazine)
- Decadron (dexamethasone)
- Haldol (haloperidol)
- Phenergan (promethazine)
- Reglan (metoclopramide)
- Zyprexa (olanzapine)

Product Name: Brand Marinol	
Diagnosis	Anorexia in Patients with AIDS
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anorexia with weight loss in patients with AIDS

AND

2 - Patient is on antiretroviral therapy [8, 9]

AND

3 - One of the following [3-6, 9]:

3.1 Patient is 65 years of age or greater

OR

3.2 Both of the following:

- Patient is less than 65 years of age
- Trial and failure, contraindication, or intolerance to megestrol acetate oral suspension

AND

4 - Trial and failure or intolerance to formulary generic dronabinol capsules*

Notes	*This product may require prior authorization.

Product Name: Syndros	
Diagnosis	Anorexia in Patients with AIDS
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anorexia with weight loss in patients with AIDS

AND

2 - Patient is on antiretroviral therapy [8, 9]

AND

3 - One of the following [3-4, 9]:

3.1 Patient is 65 years of age or greater

OR

3.2 Both of the following:

- Patient is less than 65 years of age
- Trial and failure, contraindication, or intolerance to megestrol acetate oral suspension

AND

4 - One of the following:

4.1 Trial and failure or intolerance to formulary generic dronabinol capsules*

OR

4.2 Patient is unable to swallow capsules

Notes	*This product may require prior authorization.

Product Name: Generic dronabinol	
Diagnosis	Anorexia in Patients with AIDS
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anorexia with weight loss in patients with AIDS

AND

2 - Patient is on antiretroviral therapy [8, 9]

AND

3 - One of the following [3-6, 9]:

3.1 Patient is 65 years of age or greater

OR

3.2 Both of the following:

- Patient is less than 65 years of age
- Trial and failure, contraindication, or intolerance to megestrol acetate oral suspension

3 . Endnotes

A. Per NCCN, cannabinoids are agents that can be used for breakthrough treatment. Other agents used for breakthrough treatment include: phenothiazines (prochlorperazine, promethazine), prokinetic agents (metoclopramide), antipsychotic agents (haloperidol, olanzapine), corticosteroids (dexamethasone), benzodiazepines (lorazepam), and 5-HT3 receptor antagonists (dolasetron, granisetron, ondansetron). [1]

4 . References

1. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Antiemesis v.1.2021. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf. Accessed March 9, 2022.
2. Marinol prescribing information. Patheon Softgels, Inc. High Point, NC. March 2021.
3. The National Committee for Quality Assurance (NCQA). Use of high-risk medications in the elderly (DAE). Available at www.ncqa.org. Accessed August 22, 2016.
4. American Geriatrics Society 2019 Beers Criteria Update Expert Panel. American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc. 2019;00:1-21.
5. Pascual Lopez A, Roque i Figuls M, Urrutia Cuchi G, et al. Systematic review of megestrol acetate in the treatment of anorexia-cachexia syndrome. J Pain Symptom Manage 2004;27:360-369.
6. Per clinical consult with HIV specialist, February 4, 2013.

7. Syndros prescribing information. Benuvia Therapeutics, Inc. Chandler, AZ. January 2021.
8. Williams B, Waters D, Parker K. Evaluation and Treatment of Weight Loss in Adults with HIV Disease. Am Fam Physician. 1999;60(3):843-854.
9. Grinspoon S, Mulligan K; Department of Health and Human Services Working Group on the Prevention and Treatment of Wasting and Weight Loss. Weight loss and wasting in patients infected with human immunodeficiency virus. Clin Infect Dis. 2003;36(Suppl 2):S69-78.

5 . Revision History

Date	Notes
3/29/2023	Annual review - step criteria updated from Megace to megestrol acet ate oral suspension for Weight loss in AIDS

Prior Authorization Guideline

Guideline Name	Caprelsa (vandetanib)

Guideline Note:

Effective Date:	11/1/2022
P&T Approval Date:	7/12/2011
P&T Revision Date:	09/16/2020 ; 09/15/2021 ; 9/21/2022

1 . Indications

Drug Name: Caprelsa (vandetanib)
Medullary Thyroid Cancer (MTC) Indicated for the treatment of symptomatic or progressive MTC in patients with unresectable locally advanced or metastatic disease. Use Caprelsa in patients with indolent, asymptomatic or slowly progressing disease only after careful consideration of the treatment related risks of Caprelsa.

2 . Criteria

Product Name: Caprelsa	
Approval Length	12 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Metastatic medullary thyroid cancer (MTC)
- Unresectable locally advanced MTC

AND

2 - One of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

3 - Prescribed by or in consultation with one of the following:

- Oncologist
- Endocrinologist

Product Name: Caprelsa	
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Caprelsa prescribing information. Genzyme Corporation. Cambridge, MA. March 2022.

4 . Revision History

Date	Notes
9/7/2022	Annual review: No criteria changes. Updated references.

Prior Authorization Guideline

Guideline Name	Cayston (aztreonam for inhalation solution) - PA, NF

Guideline Note:

Effective Date:	8/1/2022
P&T Approval Date:	6/22/2010
P&T Revision Date:	06/17/2020 ; 01/20/2021 ; 06/16/2021 ; 12/15/2021 ; 6/15/2022

1 . Indications

Drug Name: Cayston (aztreonam for inhalation solution)
Cystic Fibrosis Indicated to improve respiratory symptoms in cystic fibrosis (CF) patients with Pseudomonas aeruginosa. Safety and effectiveness have not been established in pediatric patients below the age of 7 years, patients with FEV1 less than 25% or greater than 75% predicted, or patients colonized with Burkholderia cepacia. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Cayston and other antibacterial drugs, Cayston should be used only to treat patients with CF known to have Pseudomonas aeruginosa in the lungs.

2 . Criteria

Product Name: Cayston	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis

AND

2 - Patient has evidence of Pseudomonas aeruginosa in the lungs

AND

3 - Patient is seven years of age or older

AND

4 - Trial and failure, contraindication, or intolerance to TWO of the following:

- Bethkis* (tobramycin [300 mg/4 ml] inhalation solution)
- TOBI* (tobramycin [300 mg/5 ml] inhalation solution)
- Tobi Podhaler

Notes	*NOTE: Step Therapy (ST) requirements may apply for brand Bethkis and brand TOBI

Product Name: Cayston	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis

AND

2 - Patient has evidence of Pseudomonas aeruginosa in the lungs

AND

3 - Patient is benefiting from treatment (i.e., improvement in lung function [forced expiratory volume in one second {FEV1}], decreased number of pulmonary exacerbations)

Product Name: Cayston	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of cystic fibrosis

AND

2 - Patient has evidence of Pseudomonas aeruginosa in the lungs

AND

3 - Patient is seven years of age or older

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following:

- generic tobramycin [300 mg/4 ml] inhalation solution
- generic tobramycin [300 mg/5 ml] inhalation solution

- Tobi Podhaler

3 . References

1. Cayston Prescribing Information. Gilead Sciences, Inc. Foster City, CA. November 2019.
2. Retsch-Bogart GZ, Quittner AL, Gibson RL, et al. Efficacy and safety of inhaled aztreonam lysine for airway Pseudomonas in cystic fibrosis. Chest. 2009;135:1223-32.
3. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic Fibrosis Foundation Pulmonary Guideline. Pharmacologic approaches to prevention and eradication of initial Pseudomonas aeruginosa infection. Ann Am Thorac Soc. 2014;11(10):1640-50.

4 . Revision History

Date	Notes
6/1/2022	Annual review: No changes to criteria.

Prior Authorization Guideline

Guideline Name	CGRP Inhibitors - PA, NF

Guideline Note:

Effective Date:	5/4/2023
P&T Approval Date:	5/17/2018
P&T Revision Date:	07/17/2019 ; 11/14/2019 ; 01/15/2020 ; 03/18/2020 ; 05/14/2020 ; 08/13/2020 ; 12/16/2020 ; 01/20/2021 ; 07/21/2021 ; 09/15/2021 ; 11/18/2021 ; 01/19/2022 ; 03/16/2022 ; 04/20/2022 ; 07/20/2022 ; 08/18/2022 ; 02/16/2023

1 . Indications

Drug Name: Aimovig (erenumab-aooe), Ajovy (fremanezumab-vfrm), Vyepti (eptinezumab-jjmr)
Preventive Treatment of Migraine Indicated for the preventive treatment of migraine in adults.
Drug Name: Emgality (galcanezumab-gnlm)
Preventive Treatment of Migraine Indicated for the preventive treatment of migraine in adults. **Episodic Cluster Headache** Indicated for the treatment of episodic cluster headache in adults.
Drug Name: Nurtec ODT (rimegepant sulfate)
Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults.

Preventive Treatment of Episodic Migraine Indicated for the preventive treatment of episodic migraine in adults.
Drug Name: Qulipta (atogepant)
Preventive Treatment of Episodic Migraine Indicated for the preventive treatment of episodic migraine in adults.
Drug Name: Ubrelvy (ubrogepant)
Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Not indicated for the preventive treatment of migraine.

2 . Criteria

Product Name: Aimovig, Ajovy, or Vyepti	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 Months [E]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of episodic migraines

AND

1.1.2 Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month [A, B, C]

OR

1.2 All of the following:

1.2.1 Diagnosis of chronic migraines

AND

1.2.2 Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Two of the following [D, E, F, G, 10]:

3.1 One of the following:

- History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine)
- Patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine)

OR

3.2 One of the following:

- History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- Patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate)

OR

3.3 One of the following:

- History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol
- Patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, metoprolol

OR

3.4 One of the following:

- History of failure (after at least a two month trial) or intolerance to Atacand (candesartan)
- Patient has a contraindication to Atacand (candesartan)

AND

4 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Product Name: Aimovig, Ajovy, or Vyepti	
Diagnosis	Preventive Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy

AND

3 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

4 - For Chronic Migraine only: Patient continues to be monitored for medication overuse headache (MOH) [H]

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Product Name: Emgality 120 mg/mL	
Diagnosis	Preventive Treatment of Migraine
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of episodic migraines

AND

1.1.2 Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month [A, B, C]

OR

1.2 All of the following:

1.2.1 Diagnosis of chronic migraines

AND

1.2.2 Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Two of the following [D, E, F, G, 10]:

3.1 One of the following:

- History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine)
- Patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine)

OR

3.2 One of the following:

- History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- Patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate)

OR

3.3 One of the following:

- History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol
- Patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, metoprolol

OR

3.4 One of the following:

- History of failure (after at least a two month trial) or intolerance to Atacand (candesartan)
- Patient has a contraindication to Atacand (candesartan)

AND

4 - Trial and failure, contraindication, or intolerance to both of the following:

- Aimovig

- Ajovy

AND

5 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

6 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	Approval Length: 6 months [E]. *QL Override for Emgality (For new st arts only): For migraine, please enter 2 PAs with the same start date a s follows: First PA: Approve two pens or syringes per 30 days for 1 m onth with a fill count of 2 (Loading dose has a MDD of 0.067); Second PA: Approve one pen or syringe per 30 days (no overrides needed) fo r 6 months. (Emgality 120 mg/mL is hard-coded with a quantity of one prefilled pen/syringe per 30 days)

Product Name: Emgality 120 mg/mL	
Diagnosis	Preventive Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs)

(e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy

AND

3 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

4 - For Chronic Migraine only: Patient continues to be monitored for medication overuse headache (MOH) [H]

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

AND

6 - Trial and failure, contraindication, or intolerance to both of the following:

- Aimovig
- Ajovy

Product Name: Nurtec ODT	
Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	6 Months [E]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of episodic migraines

AND

1.2 Patient has 4 to 18 migraine days per month, but no more than 18 headache days per month [26]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - History of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following [D, E, F, G, 10]:

- Elavil (amitriptyline) or Effexor (venlafaxine)
- Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol)
- Atacand (candesartan)

AND

4 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	Note: For use for preventive treatment of migraine, please enter a qua lity limit override of #16 tablets per 30 days (MDD, 0.54) for 6 months.

Product Name: Qulipta	
Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	6 Months [E]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of episodic migraines

AND

1.2 Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month [28]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - History of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following [D, E, F, G, 10]:

- Elavil (amitriptyline) or Effexor (venlafaxine)
- Dapakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol)
- Atacand (candesartan)

AND

4 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Product Name: Nurtec ODT, Qulipta	
Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy

AND

3 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	Nurtec ODT: For use for preventive treatment of migraine, please ente r a quality limit override of #16 tablets per 30 days (MDD, 0.54) for 12 months.

Product Name: Emgality 100 mg/mL	
Diagnosis	Episodic Cluster Headaches
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of episodic cluster headache

AND

2 - Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months [21]

AND

3 - Patient is 18 years of age or older [I]

AND

4 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

5 - Medication will not be used in combination with another injectable CGRP inhibitor

Product Name: Emgality 100 mg/mL	
Diagnosis	Episodic Cluster Headaches
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

3 - Medication will not be used in combination with another injectable CGRP inhibitor

Product Name: Nurtec ODT	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine with or without aura

AND

2 - Will be used for the acute treatment of migraine

AND

3 - Patient has fewer than 15 headache days per month [23]

AND

4 - Patient is 18 years of age or older [I]

AND

5 - One of the following: [24]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

6 - If patient has 4 or more headache days per month, patient must be currently treated with one of the following: [D, 24]:

- Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications
- Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications

- Atacand (candesartan) unless there is a contraindication or intolerance to this medication

AND

7 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

8 - Medication will not be used in combination with another oral CGRP inhibitor

Product Name: Nurtec ODT	
Diagnosis	Acute Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)

AND

2 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

3 - Medication will not be used in combination with another oral CGRP inhibitor

Product Name: Ubrelvy	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine with or without aura

AND

2 - Will be used for the acute treatment of migraine

AND

3 - Patient has fewer than 15 headache days per month [23]

AND

4 - Patient is 18 years of age or older [I]

AND

5 - One of the following: [24]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

6 - If patient has 4 or more headache days per month, patient must be currently treated with one of the following: [D, 24]:

- Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications
- Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications
- Atacand (candesartan) unless there is a contraindication or intolerance to this medication

AND

7 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

8 - Medication will not be used in combination with another oral CGRP inhibitor

Product Name: Ubrelvy	
Diagnosis	Acute Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)

AND

2 - Will not be used for preventive treatment of migraine

AND

3 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

4 - Medication will not be used in combination with another oral CGRP inhibitor

Product Name: Emgality 120 mg/mL	
Diagnosis	Preventive Treatment of Migraine
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Submission of medical records (e.g., chart notes) confirming a diagnosis of episodic migraines

AND

1.1.2 Submission of medical records (e.g., chart notes) confirming the patient has 4 to 14 migraine days per month, but no more than 14 headache days per month [A, B, C]

OR

1.2 All of the following:

1.2.1 Submission of medical records (e.g., chart notes) confirming a diagnosis of chronic migraines

AND

1.2.2 Submission of medical records (e.g., chart notes) confirming the patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming two of the following [D, E, F, G, 10]:

3.1 One of the following:

- History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine)
- Patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine)

OR

3.2 One of the following:

- History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- Patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate)

OR

3.3 One of the following:

- History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol
- Patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, metoprolol

OR

3.4 One of the following:

- History of failure (after at least a two month trial) or intolerance to Atacand (candesartan)
- Patient has a contraindication to Atacand (candesartan)

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to both of the following:

- Aimovig
- Ajovy

AND

5 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

6 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	Approval Length: 6 months [E]. *QL Override for Emgality (For new st arts only): For migraine, please enter 2 PAs with the same start date a s follows: First PA: Approve two pens or syringes per 30 days for 1 m onth with a fill count of 2 (Loading dose has a MDD of 0.066); Second PA: Approve one pen or syringe per 30 days (no overrides needed) fo r 6 months. (Emgality 120 mg/mL is hard-coded with a quantity of one prefilled pen/syringe per 30 days)

Product Name: Qulipta	
Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	6 Months [E]
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming both of the following:

1.1 Diagnosis of episodic migraines

AND

1.2 Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month [28]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming history of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following [D, E, F, G, 10]:

- Elavil (amitriptyline) or Effexor (venlafaxine)
- Dapakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol)

- Atacand (candesartan)

AND

4 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Product Name: Nurtec ODT	
Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	6 Months [E]
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming both of the following:

1.1 Diagnosis of episodic migraines

AND

1.2 Patient has 4 to 18 migraine days per month, but no more than 18 headache days per month [26]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming history of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following [D, E, F, G, 10]:

- Elavil (amitriptyline) or Effexor (venlafaxine)
- Dapakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol)
- Atacand (candesartan)

AND

4 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	Note: For use for preventive treatment of migraine, please enter a qua lity limit override of #16 tablets per 30 days (MDD, 0.54) for 6 months.

Product Name: Nurtec ODT	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of migraine with or without aura

AND

2 - Submission of medical records (e.g., chart notes) confirming drug will be used for the acute treatment of migraine

AND

3 - Submission of medical records (e.g., chart notes) confirming patient has fewer than 15 headache days per month [23]

AND

4 - Patient is 18 years of age or older [I]

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following: [24]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming that if patient has 4 or more headache days per month, patient must be currently treated with one of the following: [D, 24]:

- Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications
- Dapakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications
- Atacand (candesartan) unless there is a contraindication or intolerance to this medication

AND

7 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

8 - Medication will not be used in combination with another oral CGRP inhibitor

Product Name: Ubrelvy	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of migraine with or without aura

AND

2 - Submission of medical records (e.g., chart notes) confirming drug will be used for the acute treatment of migraine

AND

3 - Submission of medical records (e.g., chart notes) confirming patient has fewer than 15 headache days per month [23]

AND

4 - Patient is 18 years of age or older [I]

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following: [24]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming that if patient has 4 or more headache days per month, patient must be currently treated with one of the following: [D, 24]:

- Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications
- Dapakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications
- Atacand (candesartan) unless there is a contraindication or intolerance to this medication

AND

7 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

8 - Medication will not be used in combination with another oral CGRP inhibitor

3 . Endnotes

A. The International Classification of Headache Disorders, 3rd addition (beta version) distinguishes chronic and episodic migraine [11]. Chronic migraine is described as headache occurring on 15 or more days per month for more than 3 months, which has the features of migraine headache on at least 8 days per month. Episodic migraine is not clearly defined, but is applied when a patient is diagnosed with migraine but does not meet criteria for chronic migraine.
B. While every patient with chronic migraine should receive preventive therapy, not every patient with episodic migraine needs prevention [12]. Appropriate candidates for preventative treatment include those with at least 4 days per month of headache-related disability.
C. The phase 3 inclusion criteria for the erenumab (LIBERTY, STRIVE, ARISE) and galcanezumab (EVOLVE-1, EVOLVE-2) pivotal trials in episodic migraine required that patients had 4 to 14 migraine days per month [3-9]. The LEADER trial evaluated patients who had failed two to four prior preventive migraine treatments (PMTs). At the start of the trial, 38.6%, 37.8%, and 22.8% of patients had failed two, three, and four prior PMTs, respectively [2].
D. The American Academy of Neurology supports the use of the following medications for the prevention of episodic migraine in adult patients (with level A or B evidence): antidepressants [i.e., Elavil (amitriptyline), Effexor (venlafaxine)], antiepileptics [i.e., Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], beta-blockers [i.e., atenolol, propranolol, nadolol, timolol, metoprolol], and candesartan [16, 24].
E. The US Headache Consortium Consensus (Table e-1) recommends that therapy be initiated with medications that have the highest level of evidence-based therapy while also taking into account patient specific comorbidities [15]. Each medication should be given an adequate trial, it may take two to three months to achieve clinical benefit, and six months to achieve maximal benefit.
F. The clinical team consulted with a neurologist on the prospective review of the CGPR Inhibitors [14]. He confirmed that preventative treatment for chronic migraine and episodic migraine are similar. The choice of preventative medication will not vary much between the episodic vs chronic subtypes. The choice of agent will largely depend more on patient specific factors. Also, he felt that this agent will most likely fall into a similar place in therapy as Botox (onabotulinumtoxin A).
G. The National Institute for Health and Care Excellence guidelines for the management of migraine recommend Botox (onabotulinumtoxin A) as an option in chronic migraine after failure of at least three other prophylactic medications and that the patient is being managed for medication overuse [13].
H. Medication overuse headache (MOH) is defined as headache occurring greater than or equal to 15 days per month. It develops as a consequence of regular overuse of acute or symptomatic headache medication for more than 3 months [11]. Current evidence suggests the best treatment strategy is withdrawal of the offending medication.
I. The safety and effectiveness in pediatric patients has not been established [1, 17-19, 20, 22].
J. Headache specialists are physicians certified by the United Council for Neurologic Subspecialties (UCNS). [25]

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5 . Revision History

Date	Notes
5/3/2023	Per PA team feedback, updated T/F criteria language for Nurtec OD T, Qulipta, and Ubrelvy for clarity (no changes to clinical intent).

Prior Authorization Guideline

Guideline Name	Cholbam (cholic acid)

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	7/14/2015
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Cholbam (cholic acid)
Bile acid synthesis disorders due to single enzyme defects (SEDs) Indicated for the treatment of bile acid synthesis disorders due to single enzyme defects (SEDs). Limitation of use: The safety and effectiveness of Cholbam on extrahepatic manifestations of bile acid synthesis disorders due to SEDs or PDs including Zellweger spectrum disorders have not been established. **Peroxisomal disorders including Zellweger spectrum disorders** Indicated for adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea or complications from decreased fat-soluble vitamin absorption. Limitation of use: The safety and effectiveness of Cholbam on extrahepatic manifestations of bile acid synthesis disorders due to SEDs or PDs including Zellweger spectrum disorders have not been established.

2 . Criteria

Product Name: Cholbam	
Diagnosis	Bile acid synthesis disorders
Approval Length	4 Months [F]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a bile acid synthesis disorder due to a single enzyme defect based on one of the following: [1-6,8,A,B]

- An abnormal urinary bile acid analysis by mass spectrometry
- Molecular genetic testing consistent with the diagnosis

AND

2 - Prescribed by one of the following: [2,7,E]

- Hepatologist
- Medical geneticist
- Pediatric gastroenterologist
- Other specialist that treats inborn errors of metabolism

Product Name: Cholbam	
Diagnosis	Peroxisomal disorders
Approval Length	4 Months [F]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a peroxisomal disorder based on one of the following: [2-5,8,C,D]

- An abnormal urinary bile acid analysis by mass spectrometry
- Molecular genetic testing consistent with the diagnosis

AND

2 - Patient exhibits manifestations of at least one of the following: [2-3]

- Liver disease (e.g., jaundice, elevated serum transaminases)
- Steatorrhea
- Complications from decreased fat-soluble vitamin absorption (e.g., poor growth)

AND

3 - Prescribed by one of the following: [2,7,E]

- Hepatologist
- Medical geneticist
- Pediatric gastroenterologist
- Other specialist that treats inborn errors of metabolism

AND

4 - Used as adjunctive treatment [2-3]

Product Name: Cholbam	
Diagnosis	Bile acid synthesis disorders or Peroxisomal disorders
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement in liver function (e.g., aspartate aminotransferase [AST], alanine aminotransferase [ALT])

3 . Endnotes

A. Congenital deficiencies in the enzymes responsible for catalyzing key reactions in the synthesis of primary bile acids cholic acid and chenodeoxycholic acid are referred to as bile acid synthesis disorders (BASDs) due to single enzyme defects (SEDs). [1] 3 beta-hydroxy-D5-C27-steroid oxidoreductase deficiency (3 beta-HSD) and D4-3-oxosteroid 5 beta-reductase deficiency (AKR1D1 or D4-3-oxo-R), inherited by an autosomal recessive mode, are the most frequent inborn errors of primary bile acid synthesis causing early cirrhosis and liver failure. [6] See Background Table 1 for a list of known bile acid synthesis disorders (BASDs) due to single enzyme defects (SEDs). [1]
B. 2- (or alpha-) methylacyl-CoA racemase (AMACR) deficiency is a deficiency of a single peroxisomal enzyme that may manifest secondary abnormalities of bile acid synthesis; it may thus technically be considered a BASD, as well as, a peroxisomal disorder (PD). [2-5]
C. The spectrum of diseases referred to as peroxisomal disorders (PDs) involve defects in later steps of the bile acid synthetic pathway, such as impaired side-chain oxidation; [3] PDs are therefore classified as either disorders of peroxisome biogenesis (eg, Zellweger syndrome) or deficiencies of a single peroxisomal enzyme (eg, 2- (or alpha-)methylacyl-CoA racemase [AMACR] deficiency). [3] See Background Table 2 for a list of known PDs. [5]
D. Zellweger syndrome, infantile Refsum disease, neonatal adrenoleukodystrophy and rhizomelic chondrodysplasia punctata type 1 (RCDP1) are examples of defective biogenesis in which peroxisomes are absent. [4-5] The first 3 disorders are thought to represent a clinical continuum, referred to as Zellweger spectrum disorders (ZSD), with Zellweger syndrome the most severe, infantile Refsum disease the mildest, and neonatal adrenoleukodystrophy intermediate in severity. [5]
E. As per the prescribing information [2], treatment with Cholbam should be initiated and monitored by an experienced hepatologist or pediatric gastroenterologist. At the University of California, San Francisco, medical geneticists see patients with PDs, while specialists in pediatric gastroenterology see patients with BASDs. [7]
F. Cholbam should be discontinued if liver function does not improve within 3 months of starting treatment. [2] An additional month is added to the initial authorization duration to allow for patient follow-up with the provider.

4 . References

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5 . Revision History

Date	Notes
4/22/2023	Annual review: no criteria changes.

Prior Authorization Guideline

Guideline Name	Cibinqo (abrocitinib)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	3/16/2022
P&T Revision Date:	07/20/2022 ; 3/15/2023

1 . Indications

Drug Name: Cibinqo (abrocitinib)
Atopic Dermatitis Indicated for the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable. Limitations of Use: Cibinqo is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

2 . Criteria

Product Name: Cibinqo	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe atopic dermatitis

AND

2 - One of the following:

- Involvement of at least 10% body surface area (BSA)
- SCORing Atopic Dermatitis (SCORAD) index value of at least 25 [A]

AND

3 - Patient is 12 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist/Immunologist

AND

5 - Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least ONE of the following:

- Medium or higher potency topical corticosteroid
- Pimecrolimus cream
- Tacrolimus ointment
- Eucrisa (crisaborole) ointment

AND

6 - One of the following:

6.1 Trial and failure of a minimum 12-week supply of at least one systemic drug product for the treatment of atopic dermatitis (examples include, but are not limited to, Adbry [tralokinumab-ldrm], Dupixent [dupilumab], etc.)

OR

6.2 Patient has a contraindication, intolerance, or treatment is inadvisable with the following FDA-approved atopic dermatitis therapies:

- Dupixent (dupilumab)

AND

7 - Not used in combination with other Janus kinase (JAK) inhibitors, biologic immunomodulators (e.g., Dupixent, Adbry), or other immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Cibinqo may be used with concomitant topical or inhaled corticosteroids

Product Name: Cibinqo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy as evidenced by at least ONE of the following:

- Reduction in body surface area involvement from baseline
- Reduction in SCORing Atopic Dermatitis (SCORAD) index value from baseline [A]

AND

2 - Not used in combination with other JAK inhibitors, biologic immunomodulators (e.g., Dupixent, Adbry), or other immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Cibinqo may be used with concomitant topical or inhaled corticosteroids

3 . Background

Clinical Practice Guidelines

Table 1. Relative potencies of topical corticosteroids [2]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05

	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream	0.1
	Triamcinolone acetonide	Cream, ointment	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

4 . Endnotes

A. The Scoring Atopic Dermatitis (SCORAD) index is a clinical tool for assessing the severity of atopic dermatitis lesions based on affected body area and intensity of plaque characteristics. [3, 4] The extent and severity of AD over the body area (A) and the severity of 6 specific symptoms (erythema, edema/papulation, excoriations, lichenification, oozing/crusts, and dryness) (B) are assessed and scored by the Investigator. Subjective assessment of itch and sleeplessness is scored by the patient (C). The SCORAD score is a combined score (A/5 + 7B/2 + C) with a maximum of 103. Higher scores indicate greater severity/worsened state. A score of 25 to 50 indicates moderate disease severity and greater than 50 indicates severe disease. [5]

5 . References

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6 . Revision History

Date	Notes
2/26/2023	Updated indication and age criterion to include patients 12 years of a ge or older; background updates

Prior Authorization Guideline

Guideline Name	Cimzia (certolizumab pegol)

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	5/20/2008
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 10/19/2022 ; 4/19/2023

1 . Indications

Drug Name: Cimzia (certolizumab pegol)
Rheumatoid Arthritis (RA) Indicated for the treatment of adults with moderately to severely active rheumatoid arthritis. **Psoriatic Arthritis (PsA)** Indicated for the treatment of adult patients with active psoriatic arthritis (PsA). **Plaque Psoriasis (PsO)** Indicated for the treatment of adults with moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy. **Ankylosing Spondylitis (AS)** Indicated for the treatment of adults with active ankylosing spondylitis. **Non-radiographic Axial Spondyloarthritis (nr-axSpA)** Indicated for the treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation. **Crohn’s Disease (CD)** Indicated for reducing signs and symptoms of Crohn's disease (CD) and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.

2 . Criteria

Product Name: Cimzia	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active RA

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4, 5]:

- methotrexate
- leflunomide
- sulfasalazine

Product Name: Cimzia	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4, 5]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Cimzia	
Diagnosis	Psoriatic Arthritis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [6]:

- actively inflamed joints
- dactylitis
- enthesitis
- axial disease
- active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Product Name: Cimzia	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 6]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name: Cimzia	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [8]:

- Greater than or equal to 3% body surface area involvment
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [9]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name: Cimzia	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1, 8]:

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name: Cimzia	
Diagnosis	Ankylosing Spondylitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses [7]

Product Name: Cimzia	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following [1, 7]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Product Name: Cimzia	
Diagnosis	Non-radiographic Axial Spondyloarthritis

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active non-radiographic axial spondyloarthritis

AND

2 - Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) [1, 7]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [7]

Product Name: Cimzia	
Diagnosis	Non-radiographic Axial Spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following [1, 7]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Function
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Product Name: Cimzia	
Diagnosis	Crohn's disease
Approval Length	16 Weeks [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - One of the following [2, 3]:

- Frequent diarrhea and abdominal pain
- At least 10% weight loss
- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values (e.g., C-reactive protein [CRP])
- CD Activity Index (CDAI) greater than 220

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [2, 3]:

- 6-mercaptopurine
- Azathioprine
- Corticosteroids (e.g., prednisone)
- Methotrexate

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name: Cimzia	
Diagnosis	Crohn’s disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

3 . Endnotes

A. The recommended initial adult dose of Cimzia is 400 mg (given as two subcutaneous injections of 200 mg) initially, and at Weeks 2 and 4. In patients who obtain a clinical response, the recommended maintenance regimen is 400 mg every four weeks.

4 . References

1. Cimzia Prescribing Information. UCB. Smyrna, GA. December 2022.
2. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018;113:481-517.
3. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508.
4. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.

5. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.
6. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
7. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613.
8. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
9. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.

5 . Revision History

Date	Notes
4/10/2023	2023 Annual Review - updated references

Prior Authorization Guideline

Guideline Name	Cinqair (reslizumab)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	5/19/2016
P&T Revision Date:	02/13/2020 ; 03/17/2021 ; 03/16/2022 ; 05/19/2022 ; 5/18/2023

1 . Indications

Drug Name: Cinqair (reslizumab)
Severe Eosinophilic Asthma Indicated for the add-on maintenance treatment of patients with severe asthma aged 18 years and older with an eosinophilic phenotype. Limitation of Use: Cinqair is not indicated for treatment of other eosinophilic conditions; Cinqair is not indicated for the relief of acute bronchospasm or status asthmaticus.

2 . Criteria

Product Name: Cinqair	
Approval Length	6 Months [H]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe asthma [1]

AND

2 - Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter [1, B, D]

AND

3 - One of the following:

3.1 Patient has had at least two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months [A]

OR

3.2 Prior asthma-related hospitalization within the past 12 months [D]

AND

4 - Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

4.1 Both of the following: [C, E, F]

- High-dose inhaled corticosteroid (ICS) [e.g., greater than 500 mcg fluticasone propionate equivalent/day]
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium)

OR

4.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Symbicort [budesonide/formoterol], Breo Ellipta [fluticasone/vilanterol])

AND

5 - Age greater than or equal to 18 years

AND

6 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/immunologist

Product Name: Cinqair	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications)

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications

AND

3 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

3 . Background

Clinical Practice Guidelines

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 1. Low, medium and high daily doses of inhaled corticosteroids in adolescents and adults 12 years and older [6]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	> 500-1000	> 1000
Beclometasone dipropionate (DPI or pMDI, extrafine particle*, HFA)	100-200	> 200-400	> 400
Budesonide (DPI, or pMDI, standard particle, HFA)	200-400	> 400-800	> 800
Ciclesonide (pMDI, extrafine particle*, HFA)	80-160	> 160-320	> 320
Fluticasone furoate (DPI)	100		200
Fluticasone propionate (DPI)	100-250	> 250-500	> 500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	> 250-500	> 500
Mometasone furoate (DPI)	Depends on DPI device – see product information		
Mometasone furoate (pMDI, standard particle, HFA)	200-400		> 400
DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.			

***This is not a table of equivalence**,* but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply potency equivalence. Doses may be country -specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

4 . Endnotes

A. In two duplicate 52-week Phase III studies, eligible patients were required to have experienced at least one asthma exacerbation that required a systemic corticosteroid for at least 3 days within the past 12 months. [2, 3]
B. The Institute for Clinical and Economic Review (ICER) defines eosinophilic inflammation as a blood eosinophil level greater than or equal to 150 cells per microliter at initiation of therapy. This is the lowest measured threshold for eosinophilic asthma in pivotal trials. [8]
C. The ERS/ATS guidelines define severe asthma as that which requires treatment with high-dose ICSs plus a second controller (or systemic corticosteroids [CSs]) to prevent progression to uncontrolled disease status or continuing uncontrolled disease status despite this therapy. [4]
D. Recommended per national P&T committee meeting, December 2015, regarding similar agent first-in-class IL-5 antagonist Nucala (mepolizumab) in the use of severe eosinophilic asthma.
E. In the pivotal study for Nucala (mepolizumab), another IL-5 antagonist indicated for severe eosinophilic asthma, patients met the inclusion criteria with a well-documented requirement for regular treatment with high dose ICS (i.e., greater than or equal to 880 mcg/day fluticasone propionate or equivalent daily), with or without maintenance oral corticosteroids, in the 12 months prior to Visit 1. [5]
F. The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention update lists anti-interleukin- 5 treatment or anti-interleukin 5 receptor treatment as an add on option for patients with severe eosinophilic asthma that is uncontrolled on two or more controllers plus as-needed reliever medication (Step 4-5 treatment). [6]
G. Asthma treatment can often be reduced, once good asthma control has been achieved and maintained for three months and lung function has hit a plateau. However the approach to stepping down will depend on patient specific factors (e.g., current medications, risk factors). At this time evidence for optimal timing, sequence and magnitude of treatment reductions is limited. It is feasible and safe for most patients to reduce the ICS dose by 25-50% at three month intervals, but complete cessation of ICS is associated with a significant risk of exacerbations [6].
H. The GINA Global Strategy for Asthma Management and Prevention update recommends that patients with asthma should be reviewed regularly to monitor their symptom control,

risk factors and occurrence of exacerbations, as well as to document the response to any treatment changes. Ideally, response to Type 2-targeted therapy should be re-evaluated every 3-6 months, including re-evaluation of the need for ongoing biologic therapy for patients with good response to Type 2 targeted therapy. [6]

5 . References

1. Cinqair Prescribing Information. Teva Respiratory, LLC. Frazer, PA. June 2020.
2. Castro M, Zangrilli J, Wechsler ME, et al. Reslizumab for inadequately controlled asthma with elevated blood eosinophil counts: results from two multicentre, parallel, doubleblind, randomised, placebo-controlled, phase 3 trials. Lancet Respir Med. 2015;3(5):355-366.
3. Bjermer L, Lemiere C, Maspero J, et al. A randomized phase 3 study of the efficacy and safety of reslizumab in subjects with asthma with elevated eosinophils. Eur Respir J. 2014;44(Suppl 58):P299. Paper presented at: European Respiratory Society International Congress; September 6-10, 2014; Munich, Germany.
4. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. Eur Respir J. 2014; 43:343-373.
5. Pavord ID, Korn S, Howarth P, et al. Mepolizumab for severe eosinophilic asthma (DREAM): a multicentre, double-blind, placebo-controlled trial. Lancet. 2012; 380: 651-59.
6. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention (2022 update). 2022 www.ginasthma.org. Accessed April 2023
7. Per clinical consult with allergist specialist. May 4, 2016.
8. Institute for Clinical and Economic Review (ICER). Biologic therapies for treatment of asthma associated with type 2 inflammation: effectiveness, value, and value-based price benchmarks. https://icer.org/wp-content/uploads/2020/10/ICER_Asthma-Final-Report_Unredacted_08122020.pdf. Published December 20, 2018. Accessed April 15, 2022.

6 . Revision History

Date	Notes
4/24/2023	2023 UM Annual Review. No criteria changes. Background updates

Prior Authorization Guideline

Guideline Name	Ciprofloxacin-Containing Otic Agents

Guideline Note:

Effective Date:	9/1/2022
P&T Approval Date:	5/21/1999
P&T Revision Date:	07/15/2020 ; 03/17/2021 ; 07/21/2021 ; 7/20/2022

1 . Indications

Drug Name: Cetraxal (ciprofloxacin otic solution)
Acute Otitis Externa Indicated for the treatment of acute otitis externa due to susceptible isolates of Pseudomonas aeruginosa or Staphylococcus aureus.
Drug Name: Ciprodex (ciprofloxacin and dexamethasone otic suspension)
Acute Otitis Media Indicated in pediatric patients (age 6 months and older) with tympanostomy tubes for the treatment of infections caused by susceptible isolates of Staphylococcus aureus, Streptococcus, pneumoniae, Haemophilus influenzae, Moraxella catarrhalis, and Pseudomonas aeruginosa. **Acute Otitis Externa** Indicated in pediatric (age 6 months and older), adult and elderly patients for the treatment of infections caused by susceptible isolates of Staphylococcus aureus and Pseudomonas aeruginosa.

2 . Criteria

Product Name: Brand Cetraxal, Generic ciprofloxacin otic solution	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 10-day supply) within the past 180 days, contraindication, or intolerance to generic ofloxacin otic solution

Product Name: Brand Ciprodex	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 10-day supply) within the past 180 days, contraindication, or intolerance to generic ofloxacin otic solution

AND

3 - Trial and failure (of a minimum 7-day supply) within the past 180 days, or intolerance to generic ciprofloxacin-dexamethasone otic suspension

3 . References

1. Jones RN, Milazzo J, Seidlin M. Ofloxacin otic solution for treatment of otitis externa in children and adults. Arch Otolaryngol Head Neck Surg 1997;123:1193-200.
2. Cetraxal Prescribing Information. The RiteDose Corporation. Columbia, SC. December 2017.
3. Rosenfeld RM, Schwartz SR, Cannon CR, et al. Clinical practice guideline: acute otitis externa. Otolaryngol Head Neck Surg. 2014;150(1):S1-S24.
4. Ciprodex Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. November 2020.

4 . Revision History

Date	Notes
7/7/2022	Annual review: Updated criteria and background.

Prior Authorization Guideline

Guideline Name	Clinical Duplicates Prior Authorization (PA) Program

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	10/20/2021
P&T Revision Date:	11/18/2021 ; 01/19/2022 ; 03/16/2022 ; 04/20/2022 ; 05/19/2022 ; 06/15/2022 ; 08/18/2022 ; 09/21/2022 ; 10/19/2022 ; 11/17/2022 ; 04/19/2023 ; 04/19/2023

1 . Criteria

Product Name: Acuvail, Adlarity, Ala-Scalp lotion, Alkindi Sprinkle, Brand Allzital, Alocril, Alrex, Analpram-HC lotion, Antara, Aspruzyo Sprinkle, Brand Baclofen, Brand Fenofibrate micronized capsules, Apexicon E cream, Betoptic-S, Bryhali lotion, Brand Butalbital/apap 50-300 mg capsules, Capex shampoo, Clarinex-D, Conjupri, Consensi, Cordran cream/tape, Cortisone tablets, Brand Cyclobenzaprine/Gabapentin pak 10/300, Brand Decadron, Denavir cream, Dexabliss, Brand Durezol, Durlaza, Dutoprol, Dxevo, Ecoza, Brand Epaned, Ertaczo, Exelderm, Brand Sulconazole nitrate cream/solution, Flector patch, Fleqsuvy susp, Brand Diclofenac epolamine patch, Fosamax+D, Gialax, Gilphex TR, Giltuss, Giltuss TR, Gimoti, Glycate, Brand Glycopyrrolate, Halog ointment/solution, Hemady, Hidex, Impeklo, Inderal XL, Innopran XL, Karbinal ER, Katerzia, Kristalose, Lexette foam, Brand Halobetasol foam, Brand Levamlodipine, Licart patch, Loreev XR, Brand Lotemax gel, Lotemax ointment, Luzu cream, Brand Luliconazole cream, Lyvispah, generic methocarbamol 1000 mg, Brand Mentax cream, Generic metformin 625 mg, Brand Millipred, Motofen, Naprelan, Brand Naproxen ER, Neotuss Plus, Nexiclon XR, Brand Clonidine ER (Nexiclon XR ABA), Brand Norgesic Forte, Brand Orphengesic Forte, Oravig, Ortikos, Otovel, Brand Ciprofloxacin/Fluocinolone PF soln, Oxistat, Ozobax, Pandel cream, Pliaglis cream, Brand Lidocaine/Tetracaine cream, Generic

prednisolone, Brand Psorcon cream, Qbrelis, Qmiiz ODT, Rayos, Relafen DS, Reltone, Brand Ursodiol, Sancuso, Seglentis, Semprex-D, Sitavig, Sivextro tab, Sorilux, Brand Calcipotriene Aer, Sulfamylon cream, Synera, Taperdex, Brand Trianex oint, Ultravate lotion, Brand Valsartan oral solution, Vanatol LQ, Vanatol S, VTOL, Verdeso, Veregen, Vusion, Brand Miconazole Nitrate/Zinc Oxide/White Petrolatum oint, Xolegel, Yosprala, Brand Aspirin/Omeprazole tab, Zcort, Zilretta inj, Zuplenz	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 One of the following:

1.1.1 Both of the following:

1.1.1.1 Requested drug is FDA-approved for the condition being treated

AND

1.1.1.2 Additional requirements listed in the "Indications and Usage" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.)

OR

1.1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

AND

1.2 One of the following:

1.2.1 Patient has failed or has contraindications or intolerance to at least three generic formulary drugs. If only one or only two generic drugs are available, the patient must have failed or had contraindications or intolerance to all available generic formulary drugs. The clinician's judgment should be used to determine appropriate generic formulary drugs for the indication provided.*

OR

1.2.2 Both of the following:

1.2.2.1 Only over-the-counter (OTC) equivalents are available

AND

1.2.2.2 Patient has tried and failed or has contraindications or intolerance to three OTC equivalents. If only one or only two equivalents are available, the patient must have failed or had contraindications or intolerance to all available OTC equivalents [document drug(s), dose, duration of trial] The clinician's judgment should be used to determine equivalent formulary drugs for the indication provided.*

OR

1.2.3 No formulary or OTC drug is appropriate to treat the patient's condition

Notes	*Please consult client-specific resources to determine appropriate generic formulary drugs.

Product Name: Abilify Mycite, Spritam	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 One of the following:

1.1.1 Both of the following:

1.1.1.1 Requested drug is FDA-approved for the condition being treated

AND

1.1.1.2 Additional requirements listed in the "Indications and Usage" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.)

OR

1.1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

AND

1.2 One of the following:

1.2.1 Patient has failed or has contraindications or intolerance to at least three generic formulary drugs. If only one or only two generic drugs are available, the patient must have failed or had contraindications or intolerance to all available generic formulary drugs. The clinician's judgment should be used to determine appropriate generic formulary drugs for the indication provided.*

OR

1.2.2 Both of the following:

1.2.2.1 Only over-the-counter (OTC) equivalents are available

AND

1.2.2.2 Patient has tried and failed or has contraindications or intolerance to three OTC equivalents. If only one or only two equivalents are available, the patient must have failed or had contraindications or intolerance to all available OTC equivalents [document drug(s), dose, duration of trial] The clinician's judgment should be used to determine equivalent formulary drugs for the indication provided.*

OR

1.2.3 No formulary or OTC drug is appropriate to treat the patient's condition

OR **1.2.4** For continuation of prior therapy	
Notes	*Please consult client-specific resources to determine appropriate generic formulary drugs.

2 . Revision History

Date	Notes
4/24/2023	Removed Zembrace as target drug

Prior Authorization Guideline

Guideline Name	Colony-Stimulating Factors (CSFs) - PA, NF

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	8/1/2006
P&T Revision Date:	01/15/2020 ; 04/15/2020 ; 08/13/2020 ; 02/18/2021 ; 04/21/2021 ; 12/15/2021 ; 04/20/2022 ; 11/17/2022 ; 02/16/2023 ; 03/15/2023 ; 4/19/2023

1 . Indications

Drug Name: Fulphila (pegfilgrastim-jmdb, G-CSF), Fylnetra (pegfilgrastim-pbbk), Nyvepria (pegfilgrastim-apgf, G-CSF), Stimufend (pegfilgrastim-fpgk), Ziextenzo (pegfilgrastim-bmez, G-CSF)
Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Limitations of Use: Pegfilgrastim is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. **Off Label Uses: Hematopoietic Subsyndrome of Acute Radiation Syndrome** To increase survival in patients acutely exposed to myelosuppressive doses of radiation. [1, 33, 35, M] **Treatment of High-Risk Febrile Neutropenia (FN)** For the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34, 35]
Drug Name: Granix (tbo-filgrastim, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to reduce the duration of severe neutropenia in adult and pediatric patients 1 month and older with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia.

Off Label Uses: Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Hematopoietic Subsyndrome of Acute Radiation Syndrome To increase survival in patients acutely exposed to myelosuppressive doses of radiation. [16]

Drug Name: Leukine (sargramostim, GM-CSF)

Acute Myeloid Leukemia (AML) Following Induction Chemotherapy Indicated to shorten time to neutrophil recovery and to reduce the incidence of severe, life-threatening, or fatal infections following induction chemotherapy in adult patients 55 years and older with acute myeloid leukemia (AML).

Autologous Peripheral Blood Progenitor Cell Mobilization and Collection Indicated in adult patients with cancer undergoing autologous hematopoietic stem cell transplantation for the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis.

Autologous Peripheral Blood Progenitor Cell and Bone Marrow Transplantation Indicated for the acceleration of myeloid reconstitution following autologous peripheral blood progenitor cell (PBPC) or bone marrow transplantation in adult and pediatric patients 2 years of age and older with non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL) and Hodgkin's lymphoma (HL).

Allogeneic Bone Marrow Transplantation (BMT) Indicated for the acceleration of myeloid reconstitution in adult and pediatric patients 2 years of age and older undergoing allogeneic bone marrow transplantation from HLA-matched related donors.

Allogeneic or Autologous Bone Marrow Transplantation: Treatment of Delayed Neutrophil Recovery or Graft Failure Indicated for the treatment of adult and pediatric patients 2 years and older who have undergone allogeneic or autologous bone marrow transplantation in whom neutrophil recovery is delayed or failed.

Hematopoietic Syndrome of Acute Radiation Syndrome (H-ARS) Indicated to increase survival in adult and pediatric patients from birth to 17 years of age acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]).

Off Label Uses: Febrile Neutropenia (FN), Prophylaxis Has been used in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever [11]

Human Immunodeficiency Virus (HIV)-Related Neutropenia Has been prescribed for HIV-

related neutropenia [37]

Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Drug Name: Neulasta, Neulasta Onpro (pegfilgrastim, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Neulasta is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Hematopoietic Subsyndrome of Acute Radiation Syndrome Indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Off Label Uses: Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Drug Name: Neupogen (filgrastim, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by FN, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.

Patients with Acute Myeloid Leukemia (AML) Receiving Induction or Consolidation Chemotherapy Indicated for reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of adults with AML.

Patients with Cancer Undergoing Bone Marrow Transplantation (BMT) Indicated to reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation.

Patients Undergoing Autologous Peripheral Blood Progenitor Cell (PBPC) Collection and Therapy Indicated for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.

Patients with Severe Chronic Neutropenia (SCN) Indicated for chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

Hematopoietic Syndrome of Acute Radiation Syndrome Indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Off Label Uses: **Human Immunodeficiency Virus (HIV)-Related Neutropenia** Has been prescribed for HIV-related neutropenia. [11-15, 37]

Hepatitis-C Interferon Induced Neutropenia Neupogen has been prescribed for interferon-induced neutropenia in Hepatitis C virus infected patients [4-10, 23, 24]

Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Drug Name: Nivestym (filgrastim-aafi, G-CSF), Zarxio (filgrastim-sndz, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by FN, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.

Patients with Acute Myeloid Leukemia (AML) Receiving Induction or Consolidation Chemotherapy Indicated for reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with AML.

Patients with Cancer Undergoing Bone Marrow Transplantation Indicated to reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation.

Patients Undergoing Peripheral Blood Progenitor Cell (PBPC) Collection and Therapy Indicated for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.

Patients with Severe Chronic Neutropenia (SCN) Indicated for chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

Off Label Uses: **Hematopoietic Subsyndrome of Acute Radiation Syndrome** Has been used to increase survival in patients acutely exposed to myelosuppressive doses of radiation. [1, 33, 35, M]

Hepatitis-C Interferon Induced Neutropenia Has been prescribed for interferon-induced neutropenia in Hepatitis C virus infected patients [4-10, 23, 24, M]

Human Immunodeficiency Virus (HIV)-Related Neutropenia Has been prescribed for HIV-related neutropenia. [11, 37]

Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Drug Name: Releuko (filgrastim-ayow)
Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by FN, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever. **Patients with Acute Myeloid Leukemia (AML) Receiving Induction or Consolidation Chemotherapy** Indicated for reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with AML. **Patients with Cancer Undergoing Bone Marrow Transplantation** Indicated to reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation. **Patients with Severe Chronic Neutropenia (SCN)** Indicated for chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia. **Off Label Uses: Patients Undergoing Peripheral Blood Progenitor Cell (PBPC) Collection and Therapy** Indicated for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis. **Hematopoietic Subsyndrome of Acute Radiation Syndrome** Has been used to increase survival in patients acutely exposed to myelosuppressive doses of radiation. [1, 33, 35, M] **Hepatitis-C Interferon Induced Neutropenia** Has been prescribed for interferon-induced neutropenia in Hepatitis C virus infected patients [4-10, 23, 24, M] **Human Immunodeficiency Virus (HIV)-Related Neutropenia** Has been prescribed for HIV-related neutropenia. [11, 37] **Treatment of High-Risk Febrile Neutropenia (FN)** Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]
Drug Name: Rolvedon (eflapegrastim-xnst)
Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Rolvedon is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.
Drug Name: Udenyca (pegfilgrastim-cbqv, G-CSF)
Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving

myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Limitations of Use: Udenyca is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Hematopoietic Subsyndrome of Acute Radiation Syndrome To increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Off Label Uses: Treatment of High-Risk Febrile Neutropenia (FN) For the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34, 35]

2 . Criteria

Product Name: Leukine, Neupogen, Nivestym, Releuko, or Zarxio	
Diagnosis	Bone Marrow/Stem Cell Transplant
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient has non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT)

OR

1.2 Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis

OR

1.3 Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Patient is 2 years of age or older (applies to Leukine only)

AND

4 - Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

Product Name: Neupogen	
Diagnosis	Bone Marrow/Stem Cell Transplant
Approval Length	3 months or duration of therapy
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following:

1.1 Patient has non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT)

OR

1.2 Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis

OR

1.3 Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following:

- Nivestym
- Zarxio

Product Name: Leukine	
Diagnosis	Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy
Approval Length	3 months or duration of therapy [C]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML) [A]

AND

2 - Patient has completed induction or consolidation chemotherapy [27]

AND

3 - Patient is 55 years of age or older [3, B]

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Neupogen, Nivestym, Releuko, or Zarxio	
Diagnosis	Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy
Approval Length	3 months or duration of therapy [C]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML) [A]

AND

2 - Patient has completed induction or consolidation chemotherapy [27]

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

AND

4 - Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

Product Name: Neupogen

Diagnosis	Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy
Approval Length	3 months or duration of therapy [C]
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML) [A]

AND

2 - Patient has completed induction or consolidation chemotherapy [27]

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following:

- Nivestym
- Zarxio

Product Name: Fulphila, Fylnetra, Granix, Leukine (Off-Label), Neulasta/Neulasta Onpro, Releuko, Neupogen, Nivestym, Nyvepria, Stimufend, Udenyca, Zarxio, or Ziextenzo	
Diagnosis	Febrile Neutropenia Prophylaxis
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient will be receiving prophylaxis for febrile neutropenia (FN) due to one of the following:

1.1 Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer (see Table 1 in Background section) [16-19, 34, D, E]

OR

1.2 Patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown [E]

OR

1.3 One of the following:

1.3.1 Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN (see Table 2 in Background section) [16, 17, 34, I]

OR

1.3.2 Both of the following:

1.3.2.1 Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN (see Table 3 in Background section) [16, J]

AND

1.3.2.2 Patient has one or more risk factors associated with chemotherapy induced infection, FN, or neutropenia [16, 17, 34, K]

OR

1.4 Both of the following:

1.4.1 Patient is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [L]

AND

1.4.2 Patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis) [16, 17, 34]

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - One of the following:

3.1 Trial and failure or intolerance to both of the following (applies to Neupogen, Releuko, and Granix only):

- Nivestym
- Zarxio

OR

3.2 Trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, Stimufend, and Udenyca only):

- Neulasta/Neulasta Onpro
- Ziextenzo

Product Name: Fulphila, Fylnetra, Granix, Neupogen, Nyvepria, Udenyca	
Diagnosis	Febrile Neutropenia Prophylaxis
Approval Length	3 months or duration of therapy
Guideline Type	Non Formulary

Approval Criteria

1 - Patient will be receiving prophylaxis for febrile neutropenia (FN) due to one of the following:

1.1 Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer (see Table 1 in Background section) [16-19, 34, D, E]

OR

1.2 Patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown [E]

OR

1.3 One of the following:

1.3.1 Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN (see Table 2 in Background section) [16, 17, 34, I]

OR

1.3.2 Both of the following:

1.3.2.1 Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN (see Table 3 in Background section) [16, J]

AND

1.3.2.2 Patient has one or more risk factors associated with chemotherapy induced infection, FN, or neutropenia [16, 17, 34, K]

OR

1.4 Both of the following:

1.4.1 Patient is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [L]

AND

1.4.2 Patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis) [16, 17, 34]

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Neupogen and Granix only):

- Nivestym
- Zarxio

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, and Udenyca only):

- Neulasta/Neulasta Onpro
- Ziextenzo

Product Name: Rolvedon	
Diagnosis	Febrile Neutropenia Prophylaxis
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient will be receiving prophylaxis for febrile neutropenia (FN) due to one of the following:

1.1 Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer (see Table 1 in Background section) [16-19, 34, D, E]

OR

1.2 Patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown [E]

OR

1.3 One of the following:

1.3.1 Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN (see Table 2 in Background section) [16, 17, 34, I]

OR

1.3.2 Both of the following:

1.3.2.1 Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN (see Table 3 in Background section) [16, J]

AND

1.3.2.2 Patient has one or more risk factors associated with chemotherapy induced infection, FN, or neutropenia [16, 17, 34, K]

OR

1.4 Both of the following:

1.4.1 Patient is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [L]

AND

1.4.2 Patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis) [16, 17, 34]

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Trial and failure or intolerance to ONE of the following:

- Neulasta/Neulasta Onpro
- Ziextenzo

Product Name: Rolvedon	
Diagnosis	Febrile Neutropenia Prophylaxis
Approval Length	3 months or duration of therapy
Guideline Type	Non Formulary

Approval Criteria

1 - Patient will be receiving prophylaxis for febrile neutropenia (FN) due to one of the following:

1.1 Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer (see Table 1 in Background section) [16-19, 34, D, E]

OR

1.2 Patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown [E]

OR

1.3 One of the following:

1.3.1 Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN (see Table 2 in Background section) [16, 17, 34, I]

OR

1.3.2 Both of the following:

1.3.2.1 Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN (see Table 3 in Background section) [16, J]

AND

1.3.2.2 Patient has one or more risk factors associated with chemotherapy induced infection, FN, or neutropenia [16, 17, 34, K]

OR

1.4 Both of the following:

1.4.1 Patient is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [L]

AND

1.4.2 Patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis) [16, 17, 34]

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to ONE of the following:

- Neulasta/Neulasta Onpro
- Ziextenzo

Product Name: Fulphila, Fylnetra, Granix, Leukine, Neulasta/Neulasta Onpro, Neupogen, Nivestym, Nyvepria, Releuko, Stimufend, Udenyca, Zarxio, or Ziextenzo	
Diagnosis	Treatment of High-Risk Febrile Neutropenia (Off-label) [34]
Approval Length	3 Months of duration of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [34, l]

AND

2 - Diagnosis of febrile neutropenia (FN)

AND

3 - Patient is at high risk for infection-associated complications [16, 17, 34]

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

AND

5 - One of the following:

5.1 Trial and failure or intolerance to both of the following (applies to Neupogen, Releuko, and Granix only):

- Nivestym
- Zarxio

OR

5.2 Trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, Stimufend, and Udenyca only):

- Neulasta/Neulasta Onpro
- Ziextenzo

Product Name: Fulphila, Fylnetra, Granix, Neupogen, Nyvepria, Udenyca	
Diagnosis	Treatment of High-Risk Febrile Neutropenia (Off-label) [34]
Approval Length	3 Months of duration of therapy
Guideline Type	Non Formulary

Approval Criteria

1 - Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [34, l]

AND

2 - Diagnosis of febrile neutropenia (FN)

AND

3 - Patient is at high risk for infection-associated complications [16, 17, 34]

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

AND

5 - One of the following:

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Neupogen and Granix only):

- Nivestym
- Zarxio

OR

5.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, and Udenyca only):

- Neulasta/Neulasta Onpro
- Ziextenzo

Product Name: Neupogen, Nivestym, Releuko, or Zarxio	
Diagnosis	Severe Chronic Neutropenia (SCN)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For patients with severe chronic neutropenia (SCN) (i.e., congenital, cyclic, and idiopathic neutropenias with chronic absolute neutrophil count [ANC] less than or equal to 500 cells/mm^3) [16]

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

Product Name: Neupogen	
Diagnosis	Severe Chronic Neutropenia (SCN)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - For patients with severe chronic neutropenia (SCN) (i.e., congenital, cyclic, and idiopathic neutropenias with chronic absolute neutrophil count [ANC] less than or equal to 500 cells/mm^3) [16]

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following:

- Nivestym

- Zarxio

Product Name: Fulphila (Off-Label), Fylnetra (Off-label), Granix (Off-Label), Leukine, Neulasta/Neulasta Onpro, Neupogen, Nivestym (Off-Label), Nyvepria (Off-Label), Releuko (Off-Label), Stimufend (Off-label), Udenyca, Zarxio (Off-Label), or Ziextenzo (Off-Label)	
Diagnosis	Acute Radiation Syndrome (ARS)
Approval Length	1 Months [N]
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient was/will be acutely exposed to myelosuppressive doses of radiation

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - One of the following:

3.1 Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

OR

3.2 Trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, and Stimufend, Udenyca only):

- Neulasta/Neulasta Onpro
- Ziextenzo

Product Name: Fulphila (Off-Label), Fylnetra (Off-Label), Granix (Off-Label), Neupogen, Nyvepria (Off-Label), Udenyca	
Diagnosis	Acute Radiation Syndrome (ARS)
Approval Length	1 Months [N]
Guideline Type	Non Formulary

Approval Criteria

1 - Patient was/will be acutely exposed to myelosuppressive doses of radiation

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Neupogen only):

- Nivestym
- Zarxio

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Fulphila, Nyvepria, and Udenyca only):

- Neulasta/Neulasta Onpro
- Ziextenzo

Product Name: Leukine, Neupogen, Nivestym, Releuko, or Zarxio	
Diagnosis	Human Immunodeficiency Virus (HIV)-Related Neutropenia (Off-Label)

Approval Length	6 months [11, 15, H]
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is infected with HIV virus [11- 13]

AND

2 - ANC less than or equal to 1,000 (cells/mm3) [12, 13]

AND

3 - Prescribed by or in consultation with one of the following:

- Hematologist/oncologist
- Infectious disease specialist

AND

4 - Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

Product Name: Neupogen	
Diagnosis	Human Immunodeficiency Virus (HIV)-Related Neutropenia (Off-Label)
Approval Length	6 months [11, 15, H]
Guideline Type	Non Formulary

Approval Criteria

1 - Patient is infected with HIV virus [11- 13]

AND

2 - ANC less than or equal to 1,000 (cells/mm3) [12, 13]

AND

3 - Prescribed by or in consultation with one of the following:

- Hematologist/oncologist
- Infectious disease specialist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following:

- Nivestym
- Zarxio

Product Name: Neupogen, Nivestym, Releuko, Zarxio	
Diagnosis	Hepatitis-C Treatment Related Neutropenia (Off-Label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Patient is infected with Hepatitis C virus

AND

1.1.2 Patient is undergoing treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)

AND

1.1.3 Patient has neutropenia (absolute neutrophil count [ANC] less than or equal to 500 cells/mm3) after dose reduction of Peg-Intron or Pegasys [F]

OR

1.2 Both of the following:

1.2.1 Patient is experiencing interferon-induced neutropenia (ANC less than or equal to 500 cells/mm3) due to treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)

AND

1.2.2 One of the following: [G]

1.2.2.1 Patient with Human Immunodeficiency Virus (HIV) co-infection

OR

1.2.2.2 Status post liver transplant

OR

1.2.2.3 Patient with established cirrhosis

AND

2 - Prescribed by or in consultation with one of the following:

- Hematologist/oncologist
- Infectious disease specialist
- Hepatologist
- Gastroenterologist

AND

3 - Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

Product Name: Neupogen	
Diagnosis	Hepatitis-C Treatment Related Neutropenia (Off-Label)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Patient is infected with Hepatitis C virus

AND

1.1.2 Patient is undergoing treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)

AND

1.1.3 Patient has neutropenia (absolute neutrophil count [ANC] less than or equal to 500 cells/mm3) after dose reduction of Peg-Intron or Pegasys [F]

OR

1.2 Both of the following:

1.2.1 Patient is experiencing interferon-induced neutropenia (ANC less than or equal to 500 cells/mm3) due to treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)

AND

1.2.2 One of the following: [G]

1.2.2.1 Patient with Human Immunodeficiency Virus (HIV) co-infection

OR

1.2.2.2 Status post liver transplant

OR

1.2.2.3 Patient with established cirrhosis

AND

2 - Prescribed by or in consultation with one of the following:

- Hematologist/oncologist
- Infectious disease specialist
- Hepatologist
- Gastroenterologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following:

- Nivestym
- Zarxio

3 . Background

Benefit/Coverage/Program Information

Table 1. Intergroup C9741 Protocol [19]

Regimen	Drugs	G-CSF
Sequential	Doxorubicin q2 weeks x4 cycles, then paclitaxel q2 weeks x4 cycles, then cyclophosphamide q2 weeks x 4cycles	Days 3 to 10 of each cycle
Concurrent	Doxorubicin + cyclophosphamide q2 weeks x4 cycles, then paclitaxel q2 weeks x4 cycles	Days 3 to 10 of each cycle

Table 2. Examples of chemotherapy regimens with a high risk of FN (> 20%) [16]

Cancer	Regimen
Bladder Cancer	• Dose-dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
Bone Cancer	• VAI (vincristine, doxorubicin or dactinomycin, ifosfamide) • VDC-IE (vincristine, doxorubicin or dactinomycin, and cyclophosphamide alternating with ifosfamide and etoposide) • Cisplatin/doxorubicin • VDC (cyclophosphamide, vincristine, doxorubicin or dactinomycin) • VIDE (vincristine, ifosfamide, doxorubicin or dactinomycin, etoposide)
Breast Cancer[18]	• Dose-dense AC followed by dose-dense paclitaxel (doxorubicin, cyclophosphamide, paclitaxel) • TAX (docetaxel, doxorubicin, cyclophosphamide) • TC (docetaxel, cyclophosphamide) • TCH (docetaxel, carboplatin, trastuzumab)
Colorectal Cancer	• FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, irinotecan)
Head and Neck Squamous Cell Carcinoma	• TPF (docetaxel, cisplatin, 5-fluorouracil)
Hodgkin Lymphoma	• Brentuximab vedotin + AVD (doxorubicin, vinblastine, dacarbazine) • Escalated BEACOPP (bleomycin, etoposide, doxorubivin, cyclophosphamide, vincristine, procarbazine, prednisone)
Kidney Cancer	• Doxorubicin/gemcitabine
Non-Hodgkin's Lymphomas	• Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) • ICE (ifosfamide, carboplatin, etoposide) • Dose-dense CHOP-14 (cyclophosphamide, doxorubicin, vincristine, prednisone) • MINE (mesna, ifosfamide, mitoxantrone, etoposide) • DHAP (dexamethasone, cisplatin, cytarabine) • ESHAP (etoposide, methylprednisolone, cisplatin, cytarabine) • HyperCVAD (cyclophosphamide, vincristine, doxorubicin, dexamethasone)
Melanoma	• Dacarbazine-based combination with IL-2, interferon alfa (dacarbazine, cisplatin, vinblastine, IL-2, interferon alfa)
Multiple Myeloma	• DT-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide) +/- bortezomib (VTD-PACE)

Ovarian Cancer	• Topotecan • Docetaxel
Pancreatic Cancer	• FOLFIRINOX (fluorouracil, leucovorin, irinotecan, oxaliplatin)
Soft Tissue Sarcoma	• MAID (mesna, doxorubicin, ifosfamide, dacarbazine) • Doxorubicin • Ifosfamide/doxorubicin
Small Cell Lung Cancer	• Topotecan
Testicular Cancer	• VIP (etoposide, ifosfamide, cisplatin) • VeIP (vinblastine, ifosfamide, cisplatin) • TIP (paclitaxel, ifosfamide, cisplatin)

Table 3. Examples of chemotherapy regimens with an intermediate risk of FN (10-20%) [16]

Cancer	**Regimen**
Occult Primary-Adenocarcinoma	• Gemcitabine/docetaxel
Breast Cancer	• Docetaxel • AC (doxorubicin, cyclophosphamide) + sequential docetaxel (adjuvant) (taxane portion only) • Paclitaxel every 21 days•
Cervical Cancer	• Cisplatin/topotecan • Paclitaxel/cisplatin • Topotecan • Irinotecan
Colorectal Cancer	• FOLFOX (fluorouracil, leucovorin, oxaliplatin)
Non-Hodgkin's Lymphomas (NHL)[26]	• GDP (gemcitabine, dexamethasone, cisplatin/carboplatin) • CHOP (cyclophosphamide, doxorubivin, vincristine, prednisone) including regimens with pegylated liposomal doxorubicin • CHP (cyclophosphamide, doxorubicin, prednisone) + brentuximab vedotin • Bendamustine
Non-Small Cell Lung Cancer	• Cisplatin/paclitaxel • Cisplatin/vinorelbine • Cisplatin/docetaxel

	• Cisplatin/etoposide • Carboplatin/paclitaxel • Docetaxel
Ovarian Cancer	• Carboplatin/docetaxel
Prostate Cancer	• Cabazitaxel
Testicular Cancer	• Etoposide/cisplatin • BEP (bleomycin, etoposide, cisplatin)
Esophageal and Gastric Cancer	• Irinotecan/cisplatin • Epirubicin/cisplatin/5-flurouracil • Epirubicin/cisplatin/capecitabine
Small Cell Lung Cancer	• Etoposide/carboplatin
Uterine Cancer	• Docetaxel

Table 4. Examples of FDA-approved chemotherapeutic agents with dose-limiting myelosuppression

Generic Name	Brand Name
Busulfan	Busulfex®, Myleran®
Carboplatin	Paraplatin®
Carmustine (BCNU)	BiCNU®, Gliadel®
Chlorambucil	Leukeran®
Cladribine	Luestatin®
Cyclophosphamide	Cytoxan®
Cytarabine	N/A
Dacarbazine (DTIC)	DTIC-Dome®
Dactinomycin	Actinomycin D®, Cosmegen®
Daunorubicin	Cerubidine®
Daunorubicin Liposomal	DaunoXome®
Doxorubicin	Adriamycin PFS®, Adriamycin RDF®, Adriamycin®
Doxorubicin Liposomal	Doxil®
Etoposide	Etopophos®, Toposar®, VePesid®
Fluorouracil (5-FU)	Adrucil®, Efudex®, Fluoroplex®
Floxuridine	FUDR®
Fludarabine	Fludara®
Hydroxyurea	Droxia®, Hydrea®
Ifosfamide/Mesna	Ifex®, Mesnex®
Lomustine (CCNU)	CeeNU®
Mechlorethamine (Nitrogen Mustard)	Mustargen®
Melphalan	Alkeran®
Mercaptopurine (6-MP)	Purinethol®
Methotrexate	Rheumatrex®, Trexall®

Mitomycin	N/A
Mitoxantrone	Novantrone®
Paclitaxel	Onxol™, Taxol®
Procarbazine	Matulane®
Teniposide	Vumon®
Thioguanine (6-TG)	Tabloid®
Thiotepa	Thiotepa®
Vinblastine	N/A
Vincristine	Vincasar® PFS
Vinorelbine	Navelbine®

4 . Endnotes

A. Currently there is no information available about the effect of longer acting pegylated G-CSF in patients with myeloid leukemias, therefore pegylated G-CSF should not be used in such patients outside of clinical trials. [17]
B. The safety and efficacy of Leukine in AML induction or consolidation in adults younger than 55 years old have not been established in clinical trials. [3]
C. Per hematology/oncology consultant and member of P&T, most cycles of induction or consolidation chemotherapy last ~ 1 month, but patients who complete therapy typically receive 1 induction and 2-3 consolidations, so re-approval would need to occur every month.
D. The safety and efficacy of pegylated G-CSF has not been fully established in the setting of dose-dense chemotherapy. [17]
E. Per hematology/oncology consultant and member of P&T, in general, dose-dense regimens require growth factor support for chemotherapy administration. [16] Also, Neulasta is commonly used to support dose dense regimens in current community practice. It would be reasonable to allow Neulasta use [in the INT C9741 Protocol] and to broaden its use for other forms of dose dense chemotherapy.
F. The product information for both PEG-Intron and Pegasys recommends dose reduction in patients with neutropenia with an ANC level < 750 cells/mm^3. [21, 22]
G. Per GI consultant and member of P&T, his medical group of practicing hepatologists recommends Neupogen for a special subpopulation of patients with HIV infection, status post liver transplant, or established cirrhosis who experience interferon-induced neutropenia (ANC less than or equal to 500 cells/mm^3) due to treatment with Peg-Intron or Pegasys.
H. Guidelines issued by the U.S. Public Health Service (USPHS) and the Infectious Diseases Society of America (IDSA) recommend for HIV-related neutropenia, the length of therapy with G-CSF and GM-CSF is 2-4 weeks. The clinical benefit of G-CSF therapy was evaluated in a randomized, double-blind, placebo controlled trial of 30 patients evaluating G-CSF 03 mg/mL subcutaneously 3 times a week or placebo for 12 weeks. The 6 month approval duration mirrors the 6 month approval duration for the erythropoietic agents, as G-CSF has been effective when used alone or in conjunction with epoetin alfa in adults with acquired immunodeficiency syndrome (AIDS) to ameliorate the hematologic toxicity (severe anemia and/or granulocytopenia) associated with zidovudine therapy. [11, 15, 37]

I. Note: This list is NOT inclusive of all chemotherapy regimens with a high risk of FN: See Table 2 in Background section
J. Note: This list is NOT inclusive of all chemotherapy regimens with an intermediate risk of FN: See Table 3 in Background section
K. Risk factors are based on provider information, not the list in the table below. Examples of risk factors may include (but are NOT limited to): Risk factors associated with chemotherapy-induced infection, FN, or neutropenia • Age > 65 years [16, 17] • History of extensive prior chemotherapy or radiation therapy including large radiation ports [16, 17] • Previous episodes of FN [16, 17] • Administration of combined chemoradiotherapy [17] • Pre-existing neutropenia or bone marrow involvement with tumor [16, 17] • Pre-existing conditions [16] • Neutropenia • Active infection/open wounds • Recent surgery • Poor performance status [16, 17] • Poor renal function [16] • Liver dysfunction [16] • Poor nutritional status [17] • More advanced cancer [17] • Hypotension and multiorgan dysfunction (Sepsis syndrome) [16, 17] • Pneumonia [16] • Invasive fungal infection [16, 17] • Other clinically documented infections [16] • Hospitalization at the time of fever [16] • Anticipated prolonged (> 10 days) and profound neutropenia (< 100/mm^3) [17] • Uncontrolled primary disease [17] • Other serious comorbidities [17]
L. Note: This list is NOT all inclusive: See Table 4 in Background section
M. The FDA defines biosimilar as a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. [33] The American Society of Clinical Oncology states that pegfilgrastim, filgrastim, tbo-filgrastim, and filgrastim-sndz (and other biosimilars as they become available) can be used for the prevention of treatment-related febrile neutropenia. The choice of agent depends on convenience, cost, and clinical situation. [34] NCCN lists FDA-approved biosimilars as appropriate substitutes for filgrastim and pegfilgrastim. Limited data suggest that patients can alternate between the biosimilar and the originator biologic without any clinically meaningful differences regarding efficacy or safety. [16]
N. The efficacy of G-CSFs or GM-CSF for the acute radiation syndrome setting was studied in non-human primate models of radiation injury measuring 60-day survival. An expert panel convened by the World Health Organization recommends that patients receive G-CSF or GM-CSF treatment until their absolute neutrophil count reaches and maintains a level greater than 1.0 x 10^9 cells per liter in the absence of active infection. Patients with severe hematopoietic injury may recover, either spontaneously or after G-CSF treatment alone. In most cases, a duration of two to three weeks would be expected. [1-3, 36]

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6 . Revision History

Date	Notes
4/10/2023	2023 Annual Review

Prior Authorization Guideline

Guideline Name	Cometriq (cabozantinib)

Guideline Note:

Effective Date:	12/1/2022
P&T Approval Date:	2/19/2013
P&T Revision Date:	08/16/2018 ; 10/21/2020 ; 10/20/2021 ; 10/19/2022

1 . Indications

Drug Name: Cometriq (cabozantinib)
Medullary thyroid cancer Indicated for the treatment of patients with progressive, metastatic medullary thyroid cancer (MTC). **Off Label Uses: Non-small cell lung cancer** Has activity against RET gene rearrangements in non-small cell lung cancer (NSCLC). [3]

2 . Criteria

Product Name: Cometriq	
Diagnosis	Medullary Thyroid Cancer (MTC)
Approval Length	11 months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following: [1,2]

- Metastatic medullary thyroid cancer (MTC)
- Unresectable locally advanced MTC

AND

2 - One of the following: [2]

- Patient has symptomatic disease
- Patient has progressive disease

AND

3 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hematologist
- Endocrinologist

Product Name: Cometriq	
Diagnosis	Medullary Thyroid Cancer (MTC)
Approval Length	11 months [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Cometriq

Diagnosis	Non-Small Cell Lung Cancer (NSCLC) (off-label)
Approval Length	11 months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC) [3]

AND

2 - Positive for RET gene rearrangements [3]

AND

3 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Cometriq	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC) (off-label)
Approval Length	11 months [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. In a phase 3 clinical trial of 330 patients, a statistically significant prolongation in progression free survival (PFS) was demonstrated among Cometriq-treated patients compared to those receiving placebo, with a median PFS time of 11.2 months and 4 months in the Cometriq and placebo arms, respectively. [1]

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5 . Revision History

Date	Notes
10/3/2022	Annual review: No criteria changes, updated references.

Prior Authorization Guideline

Guideline Name	Commercial MEDLIMIT CDUR Criteria

Guideline Note:

Effective Date:	12/1/2022
P&T Approval Date:	2/16/2017
P&T Revision Date:	10/16/2019 ; 04/15/2020 ; 10/21/2020 ; 10/20/2021 ; 10/19/2022

1 . Criteria

Product Name: Requested opioid pain medication	
Diagnosis	Level of Care Change
Approval Length	1 Time(s)
Guideline Type	Administrative

Approval Criteria

1 - Provider confirms replacement prescription(s) of opioid medication(s) is needed because the patient is physically changing locations and cannot take their prescription with them [such as admission to a long term care (LTC) facility]

Product Name: Requested opioid pain medication

Diagnosis	Pain Due to Cancer or Sickle Cell Anemia
Approval Length	12 Months to override MME edit
Guideline Type	Administrative

Approval Criteria

1 - Confirmation opioids are being used for the management of cancer pain or sickle cell anemia

Product Name: Requested opioid pain medication	
Diagnosis	Hospice, Long Term Care, or End-of-Life Care Enrollment
Approval Length	12 Months to override MME edit
Guideline Type	Administrative

Approval Criteria

1 - Patient is currently enrolled in hospice, end-of-life care, or resides in a long term care facility

Product Name: Requested opioid pain medication	
Diagnosis	Other Pain
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - A written or verbal supporting statement is received from the requesting prescriber attesting that in his/her clinical judgment, the requested dose exceeding the current cumulative morphine milligram equivalent (MME) threshold* is medically required

Notes	*MME is calculated using all of the member's current opioid prescripti ons *Note: Ask provider, "Will there be a dose escalation in the patient 's opioid utilization in the next 90 days?" If yes, approve MME level 90 daily MME above the rejected level.

2 . Endnotes

A. All opioid medication edits are subject to review and modification (either to increase or decrease existing MME Limits) based on an Exception request received from the member or the member's provider. The decision to remove, modify, or retain an existing restriction on opioid pain medications will be based on evidence of new clinical information which is documented in the form of a written supporting statement received from the prescriber and which contains all of the required elements as outlined in the criteria above.

3 . References

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4 . Revision History

Date	Notes
10/5/2022	Annual review: Background updates.

Prior Authorization Guideline

Guideline Name	Compounded Drugs

Guideline Note:

Effective Date:	9/1/2022
P&T Approval Date:	8/17/2020
P&T Revision Date:	08/15/2019 ; 04/15/2020 ; 07/15/2020 ; 07/21/2021 ; 7/20/2022

1 . Criteria

Product Name: Compounded drugs**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Administrative

Approval Criteria

1 - Each active ingredient in the compounded drug is FDA-approved or national compendia* supported for the condition being treated

AND

2 - The therapeutic amounts are supported by national compendia* or two peer-reviewed literature for the condition being treated in the requested route of delivery

AND

3 - If any prescription ingredients require prior authorization and/or step therapy, all drug-specific criteria must be also met

AND

4 - The compounded drug must not include any ingredient that has been withdrawn or removed from the market due to safety reasons (refer to Table 1)

AND

5 - The patient has tried and failed therapy or had an intolerance to two FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless one of the following criteria are met:

5.1 Patient has a contraindication to commercially available products

OR

5.2 One or no other therapeutic alternatives are commercially available

OR

5.3 Prepared in a strength not commercially available or currently in short supply

OR

5.4 Prepared in a different dosage form for a patient who is unable to take the commercially available formulation (mixing or reconstituting commercially available products based on the manufacturer's instructions or the product's approved labeling does NOT meet this criteria).

OR

5.5 Patient has an allergy or sensitivity to inactive ingredients (e.g. dyes, preservatives, sugars, etc.) that are found in commercially available products.

AND

6 - The compounded drug must not be used for a cosmetic purpose.

AND

7 - If the compound is subject to the drug-specific/targeted compound program, the member meets all the applicable drug-specific criteria below for all the targeted ingredient(s) used in the requested compound product.

Notes	Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section. *Approved national compendia are referenced in the "Coverage of Off-Label or Non-FDA Approved Indications" Guideline **Administrative guideline may not apply to all compound reviews, depending on the ingredients being used and client elections.

Product Name: Diclofenac compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - Compounded drugs that include diclofenac will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 18 years of age or older

AND

1.2 Diagnosis of one of the following:

- Osteoarthritis
- Rheumatoid arthritis
- Mild to moderate pain
- Pain due to minor strains, sprains or contusions
- Migraine
- Primary dysmenorrhea
- Actinic keratosis
- Ankylosing spondylitis
- Inflammatory disorder of the eye
- Photophobia
- Pain in the eye

AND

1.3 The final dosage form will be for oral, topical, or ophthalmic use

AND

1.4 The final dosage form and strength of the diclofenac ingredient is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

Notes	Compounded drugs are considered experimental/investigational for re asons not listed in this coverage policy section. **Administrative guidel ine and other drug-specific guidelines may apply. This drug-specific cr iteria only applies to clients who enrolled in the diclofenac targeted co mpound program.

Product Name: Flurbiprofen compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - Compounded drugs that include flurbiprofen will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 18 years of age or older

AND

1.2 Diagnosis of one of the following:

- Osteoarthritis
- Rheumatoid arthritis
- Intraoperative miosis inhibition

AND

1.3 The final dosage form will be for oral or ophthalmic use

AND

1.4 The final dose is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

Notes	Compounded drugs are considered experimental/investigational for re asons not listed in this coverage policy section. **Administrative guidel ine and other drug-specific guidelines may apply. This drug-specific cr iteria only applies to clients who enrolled in the flurbiprofen targeted c ompound program.

Product Name: Fluticasone compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - Compounded drugs that include fluticasone will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 3 months of age or older

AND

1.2 Diagnosis of Inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, including but not limited to atopic dermatitis, contact dermatitis, eczema, psoriasis

AND

1.3 The final dose is not commercially available

AND

1.4 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

AND

1.5 The compounded product is not being used for cosmetic purposes (i.e., scar treatment, anti-aging, skin lightening, etc.)

Notes	Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section. **Administrative guideline and other drug-specific guidelines may apply. This drug-specific criteria only applies to clients who enrolled in the fluticasone targeted compound program.

Product Name: Gabapentin compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy

Guideline Type	Prior Authorization

Approval Criteria

1 - Compounded drugs that include gabapentin will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 3 years of age or older

AND

1.2 Patient must have one of the following diagnoses:

- Partial seizures
- Postherpetic neuralgia
- Restless leg syndrome (RLS)

AND

1.3 The final dosage form will be for oral use

AND

1.4 The requested dose is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

Notes	Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section. **Administrative guideline and other drug-specific guidelines may apply. This drug-specific criteria only applies to clients who enrolled in the gabapentin targeted compound program.

Product Name: Ketamine compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - Compounded drugs that include ketamine will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 16 years of age or older

AND

1.2 One of the following:

1.2.1 Patient is requiring ketamine for conscious sedation prior to a diagnostic or surgical procedure that do not require skeletal muscle relaxation

OR

1.2.2 Patient is requiring ketamine for the induction of anesthesia prior to the administration of other general anesthetic agents

OR

1.2.3 Patient is requiring ketamine as a supplement to low-potency anesthetic agents, such as nitrous oxide

AND

1.3 The final dosage form will be for injection

AND

1.4 The requested dose is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

AND

1.6 The requested dose does not exceed the concentration limit of 100mg/mL*

Notes	Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section. *According to the prescribing information, 100mg/ml product must be diluted prior to administration. **Administrative guideline and other drug-specific guidelines may apply. This drug-specific criteria only applies to clients who enrolled in the ketamine targeted compound program.

Product Name: Ketoprofen compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - Compounded drugs that include ketoprofen will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 18 years of age or older

AND

1.2 Diagnosis of one of the following:

- Osteoarthritis
- Rheumatoid arthritis
- Acute pain
- Primary dysmenorrhea

AND

1.3 The final dosage form will be for oral use

AND

1.4 The final dose is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

Notes	Compounded drugs are considered experimental/investigational for re asons not listed in this coverage policy section. **Administrative guidel ine and other drug-specific guidelines may apply. This drug-specific cr iteria only applies to clients who enrolled in the ketoprofen targeted co mpound program.

Product Name: Levocetirizine compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - Compounded drugs that include levocetirizine will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 6 months of age or older

AND

1.2 Diagnosis of one of the following:

- Seasonal or perennial allergic rhinitis

- Uncomplicated skin manifestations of chronic idiopathic urticaria

AND

1.3 The final dosage form will be for oral use

AND

1.4 The final dose is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

Notes	Compounded drugs are considered experimental/investigational for re asons not listed in this coverage policy section. **Administrative guidel ine and other drug-specific guidelines may apply. This drug-specific cr iteria only applies to clients who enrolled in the levocetirizine targeted compound program.

Product Name: Mometasone compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - Compounded drugs that include mometasone will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 2 years of age or older

AND

1.2 Diagnosis of Inflammatory and pruritic manifestations of corticosteroid-responsive

dermatoses, including but not limited to atopic dermatitis, contact dermatitis, eczema, psoriasis

AND

1.3 The final dose is not commercially available

AND

1.4 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

AND

1.5 The compounded product is not being used for cosmetic purposes (i.e., scar treatment, anti-aging, skin lightening, etc.)

Notes	Compounded drugs are considered experimental/investigational for re asons not listed in this coverage policy section. **Administrative guidel ine and other drug-specific guidelines may apply. This drug-specific cr iteria only applies to clients who enrolled in the mometasone targeted compound program.

Product Name: Acyclovir ointment 5% compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - Compounded drugs that include Acyclovir ointment 5% will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 18 years of age or older

AND

1.2 Diagnosis for one of the following:

- Management of initial genital herpes
- Limited non-life-threatening mucutaneous herpes simplex virus infection in immunocompromised patients

AND

1.3 The final dose is not commercially available

AND

1.4 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

Notes	Compounded drugs are considered experimental/investigational for re asons not listed in this coverage policy section. **Administrative guidel ine and other drug-specific guidelines may apply. This drug-specific cr iteria only applies to clients who enrolled in the Acyclovir ointment 5% targeted compound program.

Product Name: Doxepin cream 5% compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - Compounded drugs that include Doxepin cream 5% will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 18 years of age or older

AND

1.2 Treatment of moderate pruritus with atopic dermatitis or lichen simplex chronicus

AND

1.3 The final dose is not commercially available

AND

1.4 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

Notes	Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section. **Administrative guideline and other drug-specific guidelines may apply. This drug-specific criteria only applies to clients who enrolled in the Doxepin cream 5% targeted compound program.

2 . Background

Benefit/Coverage/Program Information

Table 1: Drugs that were withdrawn from the market due to safety or effectiveness

3,3',4',5-tetrachlorosalicylanilide	Methopholine Methoxylflurane
Adenosine phosphate	Methoxyflurane
Adrenal cortex	Mibefradil dihydrochloride
Alatrofloxacin mesylate	Nitrofurazone
Aminopyrine	Nomifensine maleate
Astemizole	Novobiocin
Azaribine	Ondansetron hydrochloride
Benoxaprofen	Oxyphenisatin

Bithionol	Oxyphenisatin acetate
Bromfenac sodium	Pemoline
Bromocriptine mesylate	Pergolide mesylate
Butamben	Phenacetin
Camphorated oil	Phenformin hydrochloride
Carbetapentane citrate	Phenylpropanolamine
Casein, iodinated	Pipamazine
Cerivastatin sodium	Polyethylene glycol 3350, sodium chloride, sodium bicarbonate, potassium chloride, and bisacodyl
Chloramphenicol	
Chlorhexidine gluconate	Potassium arsenite
Chlormadinone acetate	Potassium chloride
Chloroform	Povidone
Cisapride	Propoxyphene
Cobalt	Rapacuronium bromide
Dexfenfluramine hydrochloride	Reserpine
Diamthazole dihydrochloride	Rofecoxib
Dibromsalan	Sibutramine hydrochloride
Diethylstilbestrol	Sparteine sulfate
Dihydrostreptomycin sulfate	Sulfadimethoxine
Dipyrone	Sulfathiazole
Encainide hydrochloride	Suprofen
Esmolol hydrochloride	Sweet spirits of nitre
Etretinate	Tegaserod maleate

Fenfluramine hydrochloride	Temafloxacin hydrochloride
Flosequinan	Terfenadine
Gatifloxacin	Tetracycline
Gelatin	Ticrynafen
Glycerol, iodinated	Tribromsalan
Gonadotropin, chorionic	Trichloroethane
Grepafloxacin	Troglitazone
Mepazine	Trovafloxacin mesylate
Metabromsalan	Urethane
Methamphetamine hydrochloride	Valdexocib
Methapyrilene	Vinyl chloride
	Zirconium
	Zomepirac sodium

Diclofenac Compounds

There is little to no evidence-based literature support for the use of diclofenac for indications and in dosage forms not currently approved by the FDA. Use of compounds containing diclofenac should be limited to the following FDA-approved indications.

1. Diclofenac is indicated for a number of conditions including:
• Management of mild to moderate acute pain or osteoarthritis pain,
• Relief of signs and symptoms of ankylosing spondylitis and rheumatoid arthritis
• Relieve acute pain associated with minor sprains, strains, and contusions
• Treatment of primary dysmenorrhea
• Treatment of acute migraine attacks with or without aura in adults
• Treatment of actinic keratosis
• Treatment of postoperative inflammation in patients who have undergone cataract surgery and temporary relief of pain and photophobia associated with corneal refractive surgery.

2. Safety and efficacy in pediatric populations has not been established.

3. Diclofenac is commercially available in the several dosage forms: oral capsules, oral tablets, oral solution, topical patch, topical gel, topical solution, topical ointment and ophthalmic solution.

Flurbiprofen Compounds

There is little to no evidence-based literature support for the use of flurbiprofen for indications and in dosage forms not currently approved by the FDA. Use of compounds containing flurbiprofen should be limited to the following FDA-approved indications.

- Flurbiprofen tablets are indicated for relief of the signs and symptoms of rheumatoid arthritis and osteoarthritis.
- Flurbiprofen ophthalmic solution is indication for preventing intraoperative miosis.
- Flurbiprofen as a topically compounded formulation has not been shown to be more effective than currently commercially available topical NSAID products.
- Flurbiprofen is commercially available as a 50 and 100 mg oral tablet and also as 0.03% sterile ophthalmic solution.

Fluticasone Compounds

There is little to no evidence-based literature support for the use of fluticasone for indications and in dosage forms not currently approved by the FDA. Use of compounds containing fluticasone should be limited to the following FDA-approved indications.

- Fluticasone cream indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients 3 months of age or older.

Fluticasone is commercially available in the several dosage forms: topical cream, topical lotion, topical ointment, nasal spray and various aerosols and powders for inhalation

Gabapentin Compounds

There is little to no evidence-based literature support for the use of gabapentin for indications or in dosage forms not currently approved by the FDA. Use of compounds containing gabapentin should be limited to the following FDA-approved indications.

- Gabapentin is indicated for treatment postherpetic neuralgia in adults (Gralise prescribing information, 2012; Horizant prescribing information, 2013; Neurontin prescribing information, 2015).
- Gabapentin is indicated as adjunctive therapy in the treatment of partial onset seizures, with and without secondary generalization, in adults and pediatric patients 3 years and older with epilepsy (Neurontin prescribing information, 2015).

- Gabapentin is indicated for the treatment of moderate to severe primary restless leg syndrome (Horizant prescribing information, 2013).

Ketamine Compounds

There is little to no evidence-based literature support for the use of ketamine for indications or in dosage forms not currently approved by the FDA. Use of compounds containing ketamine should be limited to the following FDA-approved indications.

- Ketamine is indicated as the sole anesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation (Ketalar prescribing information, 2016)
- Ketamine is indicated for the induction of anesthesia prior to the administration of other general anesthetic agents (Ketalar prescribing information, 2016)
- Ketamine is indicated to supplement low-potency agents, such as nitrous oxide (Ketalar prescribing information, 2016)
- Esketamine (the S-enantiomer of racemic ketamine) is indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults (Spravato prescribing information, 2019). Coverage of compounds with racemic ketamine will continue to be limited to the FDA approved indications listed above.

Ketoprofen Compounds

There is little to no evidence-based literature support for the use of ketoprofen for indications and in dosage forms not currently approved by the FDA. Use of compounds containing ketoprofen should be limited to the following FDA-approved indications.

- Ketoprofen immediate-release capsules and ketoprofen extended-release capsules are indicated for the management of the signs and symptoms of rheumatoid arthritis and osteoarthritis.
- Ketoprofen immediate-release capsules are indicated for the management of pain and for treatment of primary dysmenorrhea.
- Ketoprofen extended-release capsules are not recommended for treatment of acute pain because of its extended-release characteristics.
- Ketoprofen as a topically compounded formulation has not been shown to be more effective than currently commercially available topical NSAID products.
- Ketoprofen is commercially available as a 50 and 75 mg oral capsule and 200 mg extended release oral capsule.

Levocetirizine Compounds

There is little to no evidence-based literature support for the use of levocetirizine for indications and in dosage forms not currently approved by the FDA. Use of compounds containing levocetirizine should be limited to the following FDA-approved indications.

- Levocetirizine dihydrochloride, a histamine (H1) receptor antagonist, is indicated for:
    - Treatment of perennial allergic rhinitis in adults and children 6 months of age or older.
    - Treatment of seasonal allergic rhinitis in adults and children 2 years of age and older
    - Uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 months of age and older

- Levocetirizine is commercially available as a 5 mg oral tablet and 2.5 mg/mL oral solution.

Mometasone Compounds

There is little to no evidence-based literature support for the use of mometasone for indications and in dosage forms not currently approved by the FDA. Use of compounds containing mometasone should be limited to the following FDA-approved indications.

- Mometasone cream & ointment are indicated for the treatment of relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patient's ≥ 2 years of age.
- Mometasone lotion is indicated for the treatment of relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patient's ≥12 years of age.
- Mometasone is commercially available inseveral dosage forms: topical cream, topical lotion, topical ointment, nasal spray,powder for inhalation and sinus implant.

Acyclovir ointment 5% Compounds

There is little to no evidence-based literature support for the use of Acyclovir ointment 5% for indications and in dosage forms not currently approved by the FDA. Use of compounds containing Acyclovir ointment 5% should be limited to the following FDA-approved indications.

- Acyclovir ointment 5% is indicated for the management of initial genital herpes and in limited non-life-threatening mucocutaneous Herpes simplex virus infection in immunocompromised patients.
- Acyclovir is commercially available in several dosage forms: topical ointment, topical cream, buccal tablet, tablet, capsule, oral suspension, and intravenous solution.

Doxepin cream 5% Compounds

There is little to no evidence-based literature support for the use of Doxepin cream 5% for indications and in dosage forms not currently approved by the FDA. Use of compounds containing Doxepin cream 5% should be limited to the following FDA-approved indications.

- Doxepin cream 5% is indicated for short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus.
- Doxepin cream 5% is commercially available in several dosage forms: topical cream, capsule, tablet, and oral concentrate

3 . Endnotes

A. Compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. [1]
B. Compound drugs are customized in the following ways to meet patients need: (1) Removal of a nonessential ingredient for patients' allergies; and (2) Change in medication formulation (e.g., pill to solution in a patient with swallowing difficulties). [1]
C. Benefit design recommendations provided in the Implementation Guide: (1) $200 Rx High Dollar Limit at Retail; (2) The processing of compound drugs will be subject to the same benefit plan edits: day supply, copay and drug coverage; (3) Multiple ingredient processing is recommended; (4) Bulk chemicals and compound kit recommended as standard exclusions.
D. Compounding does not generally include mixing or reconstituting commercially available products in accordance with the manufacturer’s instructions or the product’s approved labeling.

4 . References

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13. Xyzal Prescribing Information. UCB Pharma. Smyrna, GA. June 2016.
14. Elocon Cream, 0.1%. Merck & Co., Inc. Whitehouse Station, NJ. April 2013.
15. Elocon Lotion, 0.1%. Merck & Co., Inc. Whitehouse Station, NJ. September 2015.
16. Elocon Ointment, 0.1%. Merck & Co., Inc. Whitehouse Station, NJ. September 2015.
17. Spravato Prescribing Information. Janssen Pharmaceuticals. Titusville, NJ. May 2019.
18. Sinuva Prescribing Information. Intersect ENT, Inc. Menlo Park, CA. December 2017.
19. Zovirax Prescribing Information. Valeant Pharmaceuticals. Bridgewater, NJ. April 2018.
20. Zonalon Prescribing Information. Mylan Pharmaceuticals Inc. Morgantown, WV. June 2017.

5 . Revision History

Date	Notes
7/6/2022	Annual review: updated references, no criteria changes

Prior Authorization Guideline

Guideline Name	Constipation Agents

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	8/18/2008
P&T Revision Date:	04/15/2020 ; 03/17/2021 ; 04/21/2021 ; 04/20/2022 ; 02/16/2023 ; 4/19/2023

1 . Indications

Drug Name: Amitiza (lubiprostone)
Chronic Idiopathic Constipation (CIC) Indicated for the treatment of CIC in adults. **Opioid-Induced Constipation in Adult Patients with Chronic Non-Cancer Pain** Indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. Limitations of Use: Effectiveness of Amitiza in the treatment of opioid-induced constipation in patients taking diphenylheptane opioids (e.g., methadone) has not been established. **Irritable Bowel Syndrome with Constipation** Indicated for the treatment of irritable bowel syndrome with constipation in women at least 18 years old.
Drug Name: Linzess (linaclotide)
Irritable Bowel Syndrome with Constipation (IBS-C) Indicated in adults for the treatment of irritable bowel syndrome with constipation (IBS-C). **CIC** Indicated in adults for the treatment of CIC.

Drug Name: Movantik (naloxegol)
Opioid-Induced Constipation (chronic non-cancer pain, chronic pain related to prior cancer or its treatment) Indicated for the treatment of OIC in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.
Drug Name: Motegrity (prucalopride)
CIC Indicated for the treatment of CIC in adults.
Drug Name: Relistor (methylnaltrexone bromide) injection
Opioid-Induced Constipation (advanced illness or pain caused by active cancer) [1, 2] Indicated for the treatment of OIC in adult patients with advanced illness or pain caused by active cancer who require opioid dosage escalation for palliative care. **Opioid-Induced Constipation (chronic non-cancer pain, chronic pain related to prior cancer or its treatment)** Indicated for the treatment of OIC in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.
Drug Name: Relistor (methylnaltrexone bromide) tablet
Opioid-Induced Constipation (chronic non-cancer pain, chronic pain related to prior cancer or its treatment) Indicated for the treatment of OIC in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.
Drug Name: Symproic (naldemedine)
Opioid-Induced Constipation (chronic non-cancer pain, chronic pain related to prior cancer or its treatment) Indicated for the treatment of OIC in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.
Drug Name: Trulance (plecanatide)
CIC Indicated in adults for the treatment of CIC. **IBS-C** Indicated in adults for the treatment of IBS-C.

2 . Criteria

Product Name: Brand Amitiza, generic lubiprostone

Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to one of the following generics: [A]

- Lactulose
- Polyethylene glycol

AND

3 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to one of the following preferred brands: [B]

- Linzess
- Movantik
- Symproic

Product Name: Linzess, Movantik, Symproic	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to one of the following generics: [A]

- Lactulose
- Polyethylene glycol

Product Name: Motegrity, Trulance	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to one of the following generics: [A]

- Lactulose
- Polyethylene glycol

AND

3 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to Linzess

Product Name: Relistor injection, Relistor tablet	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to one of the following generics: [A]

- Lactulose
- Polyethylene glycol

AND

3 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to one of the following preferred brands: [B]

- Movantik
- Symproic

3 . Endnotes

A. Stimulant and osmotic laxatives should be tried/failed first before patients are placed on OIC agents (ie, Relistor and Movantik). [2, 3]
B. The 2019 American Gastroenterological Association (AGA) Guideline for Opioid-Induced Constipation (OIC) recommends traditional laxative therapy as first-line agents given their established efficacy, safety, and lower cost. If an adequate trial of laxatives does not optimally control symptoms, the AGA recommends treatment with peripherally acting mu-opioid receptor antagonist (PAMORA) drugs with higher quality evidence of efficacy, namely naldemedine and naloxegol. [2]

4 . References

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2. Per clinical consult with gastroenterologist, February 19, 2019.

3. Crockett SD, Greer KB, Heidelbaugh JJ, et al. American Gastroenterological Association Institute Guideline on the Medical Management of Opioid-Induced Constipation. Gastroenterology. Gastroenterology. 2019;156:218-226.
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5 . Revision History

Date	Notes
3/23/2023	2023 UM Annual Review. No criteria changes. Added minimum 30 d ay trial duration to trial and failure requirements. Updated references.

Prior Authorization Guideline

Guideline Name	Contraceptives for Non-Contraceptive Use

Guideline Note:

Effective Date:	10/1/2022
P&T Approval Date:	12/6/2004
P&T Revision Date:	07/15/2020 ; 07/15/2020 ; 07/15/2020 ; 02/18/2021 ; 07/21/2021 ; 8/18/2022

Note:

This guideline applies to grandfathered plans (i.e., plans with a separate contraceptive account or CSO) when the contraceptive is not being used for contraception purposes. This guideline is also used for members without HCR Contraceptive or Family Planning Benefits.

1 . Criteria

Product Name: Formulary and Non Formulary Contraceptives	
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria **1** - Patient is using the medication for non-contraception purposes*	

Notes	*Examples of non-contraception uses: (1) Abnormal or excessive bleeding disorders (eg, amenorrhea, oligomenorrhea, menorrhagia, dysfunctional uterine bleeding); (2) Acne; (3) Decrease in bone mineral density; (4) Dysmennorrhea; (5) Endometriosis; (6) Hirsutism; (7) Irregular menses / cycles; (8) Ovarian cysts; (9) Perimenopausal symptoms; (10) History of Pelvic Inflammatory Disease (PID); (11) Polycystic Ovarian Syndrome (PCO or PCOS); (12) Premenstrual Syndrome (PMS); (13) Premenstrual Dysphoric Disorder (PMDD); (14) Prevention of endometrial and/or ovarian cancer; (15) Prevention of menstrual migraines; (16) Turner's syndrome; (17) Uterine fibroids or adenomyosis. [1-7, 9-11]

2 . Background

Clinical Practice Guidelines

Table 1. Contraceptives [3, 8]

This information should not be considered comprehensive. Please refer to individual prescribing information for more details.

MONOPHASIC		
Product	**Estrogen (MCG)**	**Progestin (MG)**
Necon 1/50	50 mestranol	1 norethindrone
Norinyl 1/50		
Zovia 1/50E	50 ethinyl estradiol	1 ethynodiol diacetate
Ogestrel 0.5/50		0.5 norgestrel
Norgestimate/Ethinyl estradiol	35 ethinyl estradiol	0.25 norgestimate
Estarylla		
MonoNessa		
Ortho Cyclen-28		
Previfem		
Sprintec		

Alyacen 1/35	35 ethinyl estradiol	1 norethindrone
Cyclafem 1/35		
Dasetta 1/35		
Necon 1/35		
Norinyl 1/35		
Nortrel 1/35		
Ortho-Novum 1/35		
Pirmella 1/35		
Brevicon	35 ethinyl estradiol	0.5 norethindrone
Modicon		
Necon 0.5/35		
Nortrel 0.5/35		
Wera		
Balziva	35 ethinyl estradiol	0.4 norethindrone
Briellyn		
Femcon FE		
Gildagia		
Ovcon-35		
Philith		
Vyfemia		
Wymzya FE		
Zenchent		
Zenchent FE		
Kelnor 1/35	35 ethinyl estradiol	1 ethynodiol diacetate
Zovia 1/35E		
Ortho Evra	35 ethinyl estradiol	0.2 norelgestromin
Drospirenone/Ethinyl estradiol	30 ethinyl estradiol	3 drospirenone
Ocella		

Safyral		
Syeda		
Yasmin		
Zarah		
Desogestrel/Ethinyl estradiol	30 ethinyl estradiol	0.15 desogestrel
Apri		
Desogen		
Emoquette		
Ortho-Cept		
Reclipsen		
Solia		
Levonorgestrel/Ethinyl estradiol	30 ethinyl estradiol	0.15 levonorgestrel
Altavera		
Chateal		
Kurvelo		
Levora		
Marlissa		
Portia		
Cryselle	30 ethinyl estradiol	0.3 norgestrel
Elinest		
Low-Ogestrel		
Gildess 1.5/30	30 ethinyl estradiol	1.5 norethindrone
Gildess Fe 1.5/30		

Junel 21 Day 1.5/30		
Junel Fe 1.5/30		
Larin Fe 1.5/30		
Loestrin 1.5/30-21		
Loestrin Fe 1.5/30		
Lomedia 24 fe		
Microgestin 1.5/30		
Microgestin Fe 1.5/30		
Generess Fe	25 ethinyl estradiol	0.8 norethindrone
Gildess 1/20	20 ethinyl estradiol	1 norethindrone
Gildess Fe 1/20		
Junel 21 Day 1/20		
Junel Fe 1/20		
Loestrin 1/20-21		
Loestrin Fe 1/20		
Microgestin 1/20		
Microgestin Fe 1/20		
Levonorgestrel/Ethinyl estradiol		
Aviane	20 ethinyl estradiol	0.1 levonorgestrel
Falmina		
Lessina		
Lutera		
Orsythia		
Sronyx		
NuvaRing	15 ethinyl estradiol	0.12 etonogestrel
BIPHASIC		
Product	**Estrogen (MCG)**	**Progestin (MG)**

Azurette	20 ethinyl estradiol x 21d, placebo x 2d, 10 x 5d	0.15 desogestrel x 21d
Kariva		
Mircette		
Viorele		
Necon 10/11	35 ethinyl estradiol	0.5 norethindrone x 10d, 1 x 11d
TRIPHASIC		
Product	**Estrogen (MCG)**	**Progestin (MG)**
Estrostep Fe	20 ethinyl estradiol x 5d, 30 x 7d, 35 x 9d	1 norethindrone x 21d
Tilia Fe		
Tri-Legest Fe		
Ortho Tri-Cyclen Lo	25 ethinyl estradiol x 21d	0.18 norgestimate x 7d, 0.215 x 7d, 0.25 x 7d
Caziant	25 ethinyl estradiol x 21d	0.1 desogestrel x 7d, 0.125 x 7d, 0.15 x 7d
Cesia		
Cyclessa		
Velivet		
Enpresse	30 ethinyl estradiol x 6d, 40 x 5d, 30 x 10d	0.05 levonorgestrel x 6d, 0.075 x 5d, 0.125 x 10d
Levonest		
Myzilra		
Trivora		
Norgestimate/Ethinyl estradiol	35 ethinyl estradiol x 21d	0.18 norgestimate x 7d, 0.215 x 7d, 0.25 x 7d
Ortho Tri-Cyclen		

Tri-Estarylla		
Tri-Linyah		
Trinessa		
Tri-Previfem		
Tri-Sprintec		
Aranelle	35 ethinyl estradiol x 21d	0.5 norethindrone x 7d, 1 x 9d, 0.5 x 5d
Leena		
Tri-Norinyl		
Alyacen 7/7/7	35 ethinyl estradiol x 21d	0.5 norethindrone x 7d, 0.75 x 7d, 1 x 7d
Cyclafem 7/7/7		
Dasetta 7/7/7		
Necon 7/7/7		
Nortrel 7/7/7		
Ortho-Novum 7/7/7		
Pirmella 7/7/7		
FOUR-PHASIC		
Product	**Estrogen (MG)**	**Progestin (MG)**
Natazia	3 estradiol valerate x 2d, 2 x 22d, 1 x 2d, 0 x 2d	0 dienogest x 2d, 2 x 5d, 3 x 17d, 0 x 4d
EXTENDED-/CONTINUOUS-CYCLE		
Product	**Estrogen (MCG)**	**Progestin (MG)**
Lo Loestrin Fe	10 ethinyl estradiol x 26d	1 norethindrone x 24d
Lo Minastrin Fe		
Loestrin-24 FE	20 ethinyl estradiol x 24d	1 norethindrone x 24d
Minastrin 24 Fe		
Levonorgestrel/Ethinyl estradiol	20 ethinyl estradiol x 84d, 10 x 7d	0.1 levonorgestrel x 84d
Amethia Lo		
Camrese Lo		

LoSeasonique		
Levonorgestrel/Ethinyl estradiol	30 ethinyl estradiol x 84d	0.15 levonorgestrel x 84d
Introvale		
Jolessa		
Quasense		
Amethia	30 ethinyl estradiol x 84d, 10 x 7d	0.15 levonorgestrel x 84d
Camrese		
Daysee		
Seasonique		
Quartette	20 ethinyl estradiol x 42d, 25 x 21d, 30 x 21d, 10 x 7d	0.15 levonorgestrel x 84d
Beyaz	20 ethinyl estradiol x 24d	3 drospirenone x 24d
Gianvi		
Loryna		
Vestura		
Yaz		
Amethyst	20 ethinyl estradiol	0.09 levonorgestrel
PROGESTIN-ONLY		
Product	**Estrogen (MCG)**	**Progestin (MG)**
Camila	N/A	0.35 norethindrone
Errin		
Heather		
Jencycla		
Jolivette		
Lyza		
Nora-BE		
Norethindrone		

Norlyroc		
Nor-QD		
Ortho-Micronor		

3 . References

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4 . Revision History

Date	Notes
8/2/2022	2022 Annual Review- no criteria changes

Prior Authorization Guideline

Guideline Name	Copper Chelating Agents [Syprine (trientine), Cuprimine (penicillamine)] - PA, NF

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	8/20/2014
P&T Revision Date:	10/16/2019 ; 12/18/2019 ; 04/15/2020 ; 09/16/2020 ; 04/21/2021 ; 01/19/2022 ; 04/20/2022 ; 4/15/2023

1 . Indications

Drug Name: Cuprimine (penicillamine)
Wilson's Disease Indicated in the treatment of Wilson's disease. **Cystinuria** Indicated in the treatment of cystinuria. **Rheumatoid Arthritis** Indicated in the treatment of severe, active rheumatoid arthritis who have failed to respond to an adequate trial of conventional therapy.
Drug Name: Syprine (trientine)
Wilson's Disease Indicated in the treatment of patients with Wilson's disease who are intolerant of penicillamine.

2 . Criteria

Product Name: Brand Cuprimine, generic penicillamine	
Diagnosis	Wilson's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)

AND

2 - Documentation of one of the following: [5]

- Presence of Kayser-Fleisher rings
- Serum ceruloplasmin (CPN) less than 20 mg/dL
- 24-hour urinary copper excretion greater than 100 mcg
- Liver biopsy with copper dry weight greater than 250 mcg/g
- ATP7B mutation via genetic testing

AND

3 - Trial and failure, or intolerance to Depen (penicillamine) tablets

AND

4 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- Hepatologist

Product Name: Brand Cuprimine, generic penicillamine	
Diagnosis	Cystinuria
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystinuria

AND

2 - Trial and failure, contraindication, or intolerance to both of the following:

- Urinary alkalinization therapy [4]
- Thiola (tiopronin) [A]

AND

3 - Trial and failure, or intolerance to Depen (penicillamine) tablets

AND

4 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Urologist

Product Name: Brand Cuprimine, generic penicillamine	
Diagnosis	Rheumatoid Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe, active rheumatoid arthritis

AND

2 - Patient's condition is unresponsive to conventional therapy [e.g., traditional DMARDs (e.g., methotrexate, sulfasalazine), TNF inhibitor (e.g., Humira (adalimumab), Enbrel (etanercept)), Non-TNF biologic (e.g., Rinvoq (upadacitinb), Xeljanz (tofacitinib)]

AND

3 - Trial and failure, or intolerance to Depen (penicillamine) tablets

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name: Brand Cuprimine, generic penicillamine	
Diagnosis	Wilson's disease, Cystinuria, Rheumatoid Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy

Product Name: Brand Cuprimine, generic penicillamine	
Diagnosis	Wilson's Disease
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)

AND

2 - Documentation of one of the following: [5]

- Presence of Kayser-Fleisher rings
- Serum ceruloplasmin (CPN) less than 20 mg/dL
- 24-hour urinary copper excretion greater than 100 mcg
- Liver biopsy with copper dry weight greater than 250 mcg/g
- ATP7B mutation via genetic testing

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Depen (penicillamine) tablets

AND

4 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- Hepatologist

Product Name: Brand Cuprimine, generic penicillamine	
Diagnosis	Cystinuria
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of cystinuria

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to both of the following:

- Urinary alkalinization therapy [4]
- Thiola (tiopronin) [A]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Depen (penicillamine) tablets

AND

4 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Urologist

Product Name: Brand Cuprimine, generic penicillamine	
Diagnosis	Rheumatoid Arthritis
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of severe, active rheumatoid arthritis

AND

2 - Patient's condition is unresponsive to conventional therapy [e.g., traditional DMARDs (e.g.,

methotrexate, sulfasalazine), TNF inhibitor (e.g., Humira (adalimumab), Enbrel (etanercept)), Non-TNF biologic (e.g., Rinvoq (upadacitinb), Xeljanz (tofacitinib)]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Depen (penicillamine) tablets

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name: Brand Syprine, generic trientine	
Diagnosis	Wilson's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)

AND

2 - Documentation of one of the following: [5]

- Presence of Kayser-Fleisher rings
- Serum ceruloplasmin (CPN) less than 20 mg/dL
- 24-hour urinary copper excretion greater than 100 mcg
- Liver biopsy with copper dry weight greater than 250 mcg/g
- ATP7B mutation via genetic testing

AND

3 - Trial and failure, contraindication, or intolerance to Depen (penicillamine) tablets

AND

4 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- Hepatologist

Product Name: Brand Syprine, generic trientine	
Diagnosis	Wilson's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy

3 . Endnotes

A. Cystine-binding thiol drugs should be offered to patients with cysteine stones who are unresponsive to dietary modification and urinary alkalinization [3]. Tiopronin should be considered first as it is possibly more effective and associated with fewer adverse events than d-penicillamine.

4 . References

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5 . Revision History

Date	Notes
4/6/2023	Annual Review

Prior Authorization Guideline

Guideline Name	Corlanor (ivabradine)

Guideline Note:

Effective Date:	10/1/2022
P&T Approval Date:	7/14/2015
P&T Revision Date:	08/15/2019 ; 01/15/2020 ; 08/13/2020 ; 08/19/2021 ; 8/18/2022

1 . Indications

Drug Name: Corlanor (ivabradine)
Chronic Heart Failure Indicated to reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic, chronic heart failure with left ventricular ejection fraction less than or equal to 35%, who are in sinus rhythm with a resting heart rate greater than or equal to 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use. **Heart Failure due to Dilated Cardiomyopathy (DCM)** Indicated for the treatment of stable symptomatic heart failure due to dilated cardiomyopathy (DCM) in pediatric patients aged 6 months and older, who are in sinus rhythm with an elevated heart rate. **Off Label Uses: Inappropriate Sinus Tachycardia (IST)** Has been used for the treatment of inappropriate sinus tachycardia (IST). [7]

2 . Criteria

Product Name: Corlanor	
Diagnosis	Chronic Heart Failure
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic heart failure [3, 5]

AND

2 - Patient has New York Heart Association (NYHA) Class II, III, or IV symptoms [3, 5, A]

AND

3 - Patient has a left ventricular ejection fraction of less than or equal to 35% [3, 5]

AND

4 - Patient is in sinus rhythm [3, 5]

AND

5 - Patient has a resting heart rate that is greater than or equal to 70 beats per minute [3, 5, E]

AND

6 - Trial and failure, contraindication, or intolerance to all of the following at a maximally tolerated dose: [10]

6.1 One of the following:

- Angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)

- Angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)
- Angiotensin receptor-neprilysin inhibitor (ARNI) [e.g., Entresto (sacubitril and valsartan)]

AND

6.2 One of the following: [3, 5, 10, B-F]

- bisoprolol
- carvedilol
- metoprolol succinate extended-release

AND

6.3 Sodium-glucose co-transporter 2 (SGLT2) inhibitor [e.g., Jardiance (empagliflozin), Farxiga (dapagliflozin), Xigduo XR (dapagliflozin and metformn)]

AND

6.4 Mineralocorticoid receptor antagonist (MRA) [e.g., eplerenone, spironolactone]

AND

7 - Patient has been hospitalized for worsening heart failure in the previous 12 months [3]

AND

8 - Prescribed by or in consultation with a cardiologist

Product Name: Corlanor	
Diagnosis	Heart Failure due to Dilated Cardiomyopathy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of heart failure due to dilated cardiomyopathy

AND

2 - Patient has New York Heart Association (NYHA) Class II, III, or IV symptoms [6]

AND

3 - Patient is in sinus rhythm

AND

4 - Patient has an elevated heart rate

AND

5 - Trial and failure, contraindication, or intolerance to one of the following: [1, 4, 6]

- Beta blocker (e.g., bisoprolol, metoprolol succinate extended release)
- Angiotensin-converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Diuretic Agent (e.g., spironolactone, furosemide)

AND

6 - Prescribed by or in consultation with a cardiologist

Product Name: Corlanor	
Diagnosis	Inappropriate Sinus Tachycardia (IST) [off-label]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of inappropriate sinus tachycardia (IST) confirmed by both of the following: [7]

- Sinus heart rate greater than 100 beats per minute at rest
- A mean 24 hour heart rate greater than 90 beats per minute

AND

2 - Documentation that other causes of sinus tachycardia have been ruled out (e.g., hyperthyroidism, anemia, illicit stimulant drug use, caffeine, etc.) [7]

AND

3 - Documentation that symptoms of IST are causing significant functional impairment or distress (e.g., palpitations, light-headedness, syncope, chest pain, dyspnea, etc.) [8, 9]

AND

4 - Prescribed by or in consultation with a cardiologist

Product Name: Corlanor	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

3 . Endnotes

A. In the pivotal trial evaluating the efficacy of Corlanor in patients with heart failure, patients' heart failure was defined as New York Heart Association class II, III or IV [1, 3]
B. In the pivotal trial evaluating the efficacy of Corlanor in patients with heart failure, the main reasons for not achieving guideline-recommended doses of beta-blocker therapy were hypotension, fatigue, dyspnea, dizziness, history of cardiac decompensation, and bradycardia [1, 3]
C. In the pivotal trial evaluating the efficacy of Corlanor in patients with heart failure, the main reasons that patients were unable to receive beta-blocker therapy were due to a diagnosis of chronic obstructive pulmonary disease, hypotension or asthma [1, 3]
D. The following are examples of contraindications to beta-blocker therapy but is not a comprehensive list: severe bradycardia, decompensated cardiac failure, cardiogenic shock, second-or-third degree heart block, sick sinus syndrome (without a functional permanent pacemaker) [4]
E. Corlanor slows the heart rate by inhibiting the cardiac pacemaker If current and therefore heart rate should be at or above 70 beats per minute prior to initiation of therapy to ensure bradycardia does not ensue following initiation of therapy with Corlanor [2]
F. Per 2022 AHA/ACC/HFSA guideline for the management of Heart Failure, three beta blockers have been shown to be effective in reducing the risk of death in patients with HFrEF: bisoprolol, metoprolol succinate, and carvedilol. [10]

4 . References

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10. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure. Journal of Cardiac Failure. Published online April 2022.

5 . Revision History

Date	Notes
8/1/2022	2022 Annual Review - Addition of SGLT2 and MRA as step requirem ents to chronic heart failure indication.

Prior Authorization Guideline

Guideline Name	Cosentyx (secukinumab) - PA, NF

Guideline Note:

Effective Date:	2/1/2023
P&T Approval Date:	2/18/2015
P&T Revision Date:	11/14/2019 ; 07/15/2020 ; 08/13/2020 ; 09/16/2020 ; 07/21/2021 ; 08/19/2021 ; 10/20/2021 ; 01/19/2022 ; 03/16/2022 ; 06/15/2022 ; 08/18/2022 ; 10/19/2022 ; 12/14/2022

1 . Indications

Drug Name: Cosentyx (secukinumab)
Plaque Psoriasis (PsO) Indicated for the treatment of moderate to severe plaque psoriasis in patients 6 years and older who are candidates for systemic therapy or phototherapy. **Psoriatic Arthritis (PsA)** Indicated for the treatment of active psoriatic arthritis in patients 2 years of age and older. **Ankylosing Spondylitis (AS)** Indicated for the treatment of adult patients with active ankylosing spondylitis. **Non-radiographic Axial Spondyloarthritis (nr-axSpA)** Indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation. **Enthesitis-Related Arthritis (ERA)** Indicated for the treatment of active enthesitis-related arthritis in patients 4 years of age and older.

2 . Criteria

Product Name: Cosentyx	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Patient is 6 years of age or older

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)

- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

6 - Both of the following:

6.1 One of the following:

6.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to THREE of the following:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab) or Amjevita (adalimumab-atto)
- Skyrizi (risankizumab)
- Stelara (ustekinumab)
- Tremfya (guselkumab)

OR

6.1.2 Both of the following:

6.1.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy

AND

6.1.2.2 Documentation of positive clinical response to therapy as evidenced by ONE of the following [2]:

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

AND

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Taltz (ixekizumab)

Product Name: Cosentyx	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1-3]:

- Reduction the BSA involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Taltz (ixekizumab)

Product Name: Cosentyx	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis

- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Patient is 6 years of age or older

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

6 - Both of the following:

6.1 One of the following:

6.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to THREE of the following:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab) or Amjevita (adalimumab-atto)
- Skyrizi (risankizumab)
- Stelara (ustekinumab)
- Tremfya (guselkumab)

OR

6.1.2 Both of the following:

6.1.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy

AND

6.1.2.2 Documentation of positive clinical response to therapy as evidenced by ONE of the following [1-3]:

- Reduction the BSA involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

AND

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Taltz (ixekizumab)

Product Name: Cosentyx	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [4]:

- Actively inflamed joints

- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Patient is 2 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

AND

5 - One of the following:

5.1 Both of the following:

5.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab) or Amjevita (adalimumab-atto)
- Simponi (golimumab)
- Stelara (ustekinumab)
- Tremfya (guselkumab)
- Skyrizi (risankizumab-rzaa)
- Rinvoq (upadacitinib)
- Xeljanz/XR (tofacitinib/ER)

AND

5.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to BOTH of the following:

- Orencia (abatacept)

- Taltz (ixekizumab)

OR

5.2 Both of the following:

5.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy

AND

5.2.2 Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name: Cosentyx	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the BSA involvement from baseline

Product Name: Cosentyx	
Diagnosis	Psoriatic Arthritis (PsA)

Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [4]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Patient is 2 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

AND

5 - One of the following:

5.1 Both of the following:

5.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following:

- Cimzia (certolizumab pegol)

- Enbrel (etanercept)
- Humira (adalimumab) or Amjevita (adalimumab-atto)
- Simponi (golimumab)
- Stelara (ustekinumab)
- Tremfya (guselkumab)
- Skyrizi (risankizumab-rzaa)
- Rinvoq (upadacitinib)
- Xeljanz/XR (tofacitinib/ER)

AND

5.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to BOTH of the following:

- Orencia (abatacept)
- Taltz (ixekizumab)

OR

5.2 Both of the following:

5.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy

AND

5.2.2 Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the BSA involvement from baseline

Product Name: Cosentyx	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of one month trial and failure, contraindication, or intolerance to two different nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab) or Amjevita (adalimumab-atto)
- Simponi (golimumab)
- Rinvoq (upadacitinib)
- Xeljanz/XR (tofacitinib/ER)

AND

4.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Taltz (ixekizumab)

OR

4.2 Both of the following:

4.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy

AND

4.2.2 Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Notes	*Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Cosentyx	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)

- Total active (swollen and tender) joint count

Product Name: Cosentyx	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab) or Amjevita (adalimumab-atto)
- Simponi (golimumab)
- Rinvoq (upadacitinib)

- Xeljanz/XR (tofacitinib/ER)

AND

4.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Taltz (ixekizumab)

OR

4.2 Both of the following:

4.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy

AND

4.2.2 Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Notes	*Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Cosentyx	
Diagnosis	Non-radiographic Axial Spondyloarthritis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active non-radiographic axial spondyloarthritis

AND

2 - Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) [1, 3]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

AND

5 - One of the following:

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to ALL of the following:

- Cimzia (certolizumab pegol)
- Taltz (ixekizumab)
- Rinvoq (upadacitinib)

OR

5.2 Both of the following:

5.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy

AND

5.2.2 Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Product Name: Cosentyx	
Diagnosis	Non-radiographic Axial Spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Product Name: Cosentyx	
Diagnosis	Non-radiographic Axial Spondyloarthritis
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of active non-radiographic axial spondyloarthritis

AND

2 - Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) [1, 3]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

AND

5 - One of the following:

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to ALL of the following:

- Cimzia (certolizumab pegol)
- Taltz (ixekizumab)
- Rinvoq (upadacitinib)

OR

5.2 Both of the following:

5.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy

AND

5.2.2 Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Product Name: Cosentyx	
Diagnosis	Enthesitis-Related Arthritis (ERA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active enthesitis-related arthritis

AND

2 - Patient is 4 years of age or older

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum

duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [6]

Product Name: Cosentyx	
Diagnosis	Enthesitis-Related Arthritis (ERA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy as evidenced by at least one of the following [1, 6]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Cosentyx	
Diagnosis	Enthesitis-Related Arthritis (ERA)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of active enthesitis-related arthritis

AND

2 - Patient is 4 years of age or older

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [6]

3 . References

1. Cosentyx prescribing information. Novartis Pharmaceuticals Corp. East Hanover, NJ. December 2021.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
3. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
5. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613.
6. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Care Res. 2019;71(6):717-734.

4 . Revision History

Date	Notes
2/1/2023	Addition of Amjevita as another preferred step option for PsO, PsA, a nd AS; addition of Rinvoq as another step requirement for nr-axSpA

Prior Authorization Guideline

Guideline Name	Cotellic (cobimetinib)

Guideline Note:

Effective Date:	2/1/2023
P&T Approval Date:	1/27/2016
P&T Revision Date:	07/17/2019 ; 07/15/2020 ; 07/21/2021 ; 07/20/2022 ; 12/14/2022

1 . Indications

Drug Name: Cotellic (cobimetinib)
Melanoma Indicated for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib. **Histiocytic Neoplasms** Indicated as a single agent for the treatment of adult patients with histiocytic neoplasms.

2 . Criteria

Product Name: Cotellic	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of unresectable or metastatic melanoma

AND

2 - One of the following: [A]

2.1 Patient has a BRAF V600E mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., cobas 4800 BRAF V600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

OR

2.2 Patient has a BRAF V600K mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., cobas 4800 BRAF V600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Used in combination with Zelboraf (vemurafenib)*

AND

4 - Prescribed by or in consultation with an oncologist

Notes	*This product may require prior authorization.

Product Name: Cotellic	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of histiocytic neoplasm

AND

2 - Used as monotherapy

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Cotellic	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has not experienced disease progression while on therapy

3 . Endnotes

A. The cobas 4800 BRAF V600 Mutation Test is an FDA approved option and was used in the pivotal trial. [2, 3] The cobas 4800 BRAF V600 Mutation Test is also listed as the FDA approved companion diagnostic device for Zelboraf (vemurafenib). [3]

4 . References

1. Cotellic Prescribing Information. Genentech, Inc. South San Francisco, CA. October 2022.

2. Larkin J, Ascierto PA, Dréno B, et al. Combined vemurafenib and cobimetinib in BRAF-mutated melanoma. N Engl J Med. 2014;371(20):1867-76.
3. U.S. Food and Drug Administration. List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Available at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm301431.htm. Accessed June 1, 2022.

5 . Revision History

Date	Notes
11/30/2022	Addition of new indication

Prior Authorization Guideline

Guideline Name	Coverage of Off-Label Non-FDA Approved Indications

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	10/2/2007
P&T Revision Date:	10/16/2019 ; 10/21/2020 ; 11/18/2021 ; 11/17/2022

1 . Criteria

Product Name: A drug (non-anti-cancer chemotherapeutic regimen) used for an off-label indication or non-FDA approved indication	
Diagnosis	Off-label non-cancer indication
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 Diagnosis is supported as a use in American Hospital Formulary Service Drug Information (AHFS DI) [1]

OR

1.2 Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of IIb or better (see DRUGDEX Strength of Recommendation table in Background section) [1]

OR

1.3 The use is supported by clinical research in two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal

Notes	Off-label use may be reviewed for medical necessity and denied as su ch if the off-label criteria are not met. Please refer to drug specific PA guideline for off-label criteria if available.

Product Name: A drug or biological in an anti-cancer chemotherapeutic regimen	
Diagnosis	Off-label cancer indication
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 Diagnosis is supported as a use in AHFS DI [2]

OR

1.2 Diagnosis is supported as a use in the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B (see NCCN Categories of Evidence and Consensus table in Background section) [2, A]

OR

1.3 Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of Class I, Class IIa, or Class IIb (see DRUGDEX Strength of Recommendation table in Background section) [2]

OR

1.4 Diagnosis is supported as an indication in Clinical Pharmacology [2]

OR

1.5 Off-label use is supported in one of the published, peer-reviewed medical literature listed below: [2, B]

- American Journal of Medicine
- Annals of Internal Medicine
- Annals of Oncology
- Annals of Surgical Oncology
- Biology of Blood and Marrow Transplantation
- Blood
- Bone Marrow Transplantation
- British Journal of Cancer
- British Journal of Hematology
- British Medical Journal
- Cancer
- Clinical Cancer Research
- Drugs
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology)
- Gynecologic Oncology
- International Journal of Radiation, Oncology, Biology, and Physics
- The Journal of the American Medical Association
- Journal of Clinical Oncology
- Journal of the National Cancer Institute
- Journal of the National Comprehensive Cancer Network (NCCN)
- Journal of Urology
- Lancet
- Lancet Oncology
- Leukemia
- The New England Journal of Medicine

- Radiation Oncology

OR

1.6 Diagnosis is supported as a use in Wolters Kluwer Lexi-Drugs rated as "Evidence Level A" with a "Strong" recommendation. (see Lexi-Drugs Strength of Recommendation table in Background section) [2, 4, 5]

Notes	Off-label use may be reviewed for medical necessity and denied as su ch if the off-label criteria are not met. Please refer to drug specific PA guideline for off-label criteria if available.

2 . Background

Clinical Practice Guidelines

DRUGDEX Strength of Recommendation [6]

Class	Recommendation	Description
Class I	Recommended	The given test or treatment has been proven useful, and should be performed or administered.
Class IIa	Recommended, In Most Cases	The given test or treatment is generally considered to be useful, and is indicated in most cases.
Class IIb	Recommended, in Some Cases	The given test or treatment may be useful, and is indicated in some, but not most, cases.
Class III	Not Recommended	The given test or treatment is not useful, and should be avoided

Class Indeterminate	Evidence Inconclusive	

NCCN Categories of Evidence and Consensus [A]

Category	Level of Consensus
1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2B	Based upon lower-level evidence, there is NCCN consens the intervention is appropriate.
3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

Lexi-Drugs: Strength of Recommendation for Inclusion in Lexi-Drugs for Oncology Off-Label Use and Level of Evidence Scale for Oncology Off-Label Use [5]

Strength of Recommendation for Inclusion

Strong (for proposed off-label use)	The evidence persuasively supports the off-label use (ie, Level of Evidence A).
Equivocal (for proposed off-label use)	The evidence to support the off-label use is of uncertain clinical significance (ie, Level of Evidence B, C). Additional studies may

	be necessary to further define the role of this medication for the off-label use.
Against proposed off-label use	The evidence either advocates against the off-label use or suggests a lack of support for the off-label use (independent of Level of Evidence). Additional studies are necessary to define the role of this medication for the off-label use.

Level of Evidence Scale for Oncology Off-Label Use

A	**Consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form (eg, results of the introduction of penicillin treatment) to support off-label use. Further research is unlikely to change confidence in the estimate of benefit.**

B	**Evidence from randomized, controlled trials with important limitations (eg, inconsistent results, methodologic flaws, indirect, imprecise); or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on confidence in the estimate of benefit and risk and may change the estimate.**
C	**Evidence from observational studies (eg, retrospective case series/reports providing significant impact on patient care); unsystematic clinical experience; or potentially flawed randomized, controlled trials (eg, when limited options exist for condition). Any estimate of effect is uncertain.**
G	**Use has been substantiated by inclusion in at least one evidence-based or consensus-based clinical practice guideline.**

3 . Endnotes

A. NCCN Categories of Evidence and Consensus. Category 1: The recommendation is based on high-level evidence (i.e., high-powered randomized clinical trials or meta-analyses), and the NCCN Guideline Panel has reached uniform consensus that the recommendation is indicated. In this context, uniform means near unanimous positive support with some possible neutral positions. Category 2A: The recommendation is based on lower level evidence, but despite the absence of higher level studies, there is uniform consensus that the recommendation is appropriate. Lower level evidence is interpreted broadly, and runs the gamut from phase II to large cohort studies to case series to individual practitioner experience. Importantly, in many instances, the retrospective studies are derived from clinical experience of treating large numbers of patients at a member institution, so NCCN Guideline Panel Members have first-hand knowledge of the data. Inevitably, some recommendations must address clinical situations for which limited or no data exist. In these instances the congruence of experience-based judgments provides an informed if not confirmed direction for optimizing patient care. These recommendations carry the implicit recognition that they may be superseded as higher level evidence becomes available or as outcomes-based information becomes more prevalent. Category 2B: The recommendation is based on lower level evidence, and there is nonuniform consensus that the recommendation should be made. In these instances, because the evidence is not conclusive, institutions take different approaches to the management of a particular clinical scenario. This nonuniform consensus does not represent a major disagreement, rather it recognizes that given imperfect information, institutions may adopt different approaches. A Category 2B designation should signal to the user that more than one approach can be inferred from the existing data. Category 3: Including the recommendation has engendered a

major disagreement among the NCCN Guideline Panel Members. The level of evidence is not pertinent in this category, because experts can disagree about the significance of high level trials. Several circumstances can cause major disagreements. For example, if substantial data exist about two interventions but they have never been directly compared in a randomized trial, adherents to one set of data may not accept the interpretation of the other side's results. Another situation resulting in a Category 3 designation is when experts disagree about how trial data can be generalized. An example of this is the recommendation for internal mammary node radiation in postmastectomy radiation therapy. One side believed that because the randomized studies included this modality, it must be included in the recommendation. The other side believed, based on the documented additional morbidity and the role of internal mammary radiation therapy in other studies, that this was not necessary. A Category 3 designation alerts users to a major interpretation issue in the data and directs them to the manuscript for an explanation of the controversy. [3]

B. Abstracts (including meeting abstracts) are excluded from consideration. When evaluating peer-reviewed medical literature, the following (among other things) should be considered: 1) Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence 2) Whether the administered chemotherapy regimen is adequately represented in the published evidence. 3) Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. 4) Whether the study is appropriate to address the clinical question. The following should be considered: a) Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover.); b) That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and c) That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs. [2]

4 . References

1. Center for Medicaid & Medicare Services. Medicare Prescription Drug Benefit Manual. Chapter 6 – Part D Drugs and Formulary Requirements. Section 10.6. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. Accessed October 27, 2022.
2. Center for Medicaid & Medicare Services. Medicare Benefit Policy Manual. Chapter 15 - Covered Medical and Other Health Services. Section 50.4.5. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf. Accessed October 27, 2022.
3. National Comprehensive Cancer Network Categories of Evidence and Consensus. Available at: https://www.nccn.org/professionals/physician_gls/categories_of_consensus.aspx. Accessed September 9, 2020.
4. Center for Medicaid & Medicare Services. Medicare Benefit Policy Manual. Wolters Kluwer Clinical Drug Information Lexi-Drugs Compendium Revision Request - CAG-00443O. Available at: https://www.cms.gov/medicare-coverage-

database/details/medicare-coverage-document-details.aspx?MCDId=31#decision. Accessed October 27, 2022.
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5 . Revision History

Date	Notes
10/28/2022	2022 UM Annual Review.

Prior Authorization Guideline

Guideline Name	Crinone Gel 8% Quantity Limit

Guideline Note:

Effective Date:	10/1/2022
P&T Approval Date:	4/18/2018
P&T Revision Date:	12/18/2019 ; 08/13/2020 ; 08/19/2021 ; 8/18/2022

Note:

This quantity limit program is for the 8% strength of Crinone only. Requests for Crinone 4% should be reviewed using the General Quantity Limit Guideline.

1 . Indications

Drug Name: Crinone Gel 8%
Assisted Reproductive Technology Indicated for progesterone supplementation or replacement as part of an Assisted Reproductive Technology (“ART”) treatment for infertile women with progesterone deficiency. **Secondary Amenorrhea** Indicated for the treatment of secondary amenorrhea. Crinone 8% is indicated for use in women who have failed to respond to treatment with Crinone 4%.

2 . Criteria

Product Name: Crinone 8%	
Diagnosis	Assisted Reproductive Technology (ART)
Approval Length	12 Week(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Quantity requested is intended for use as part of an Assisted Reproductive Technology (ART) treatment for infertile women

AND

2 - One of the following:

2.1 Dose or quantity requested is supported in the dosage and administration section of the manufacturer's prescribing information

OR

2.2 Dose or quantity is supported by one of the following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System

AND

3 - One of the following:

3.1 Patient is 35 years of age or older [2]

OR

3.2 Trial and failure, intolerance, or contraindication to Endometrin

AND

4 - Prescribed by or in consultation with a reproductive endocrinologist

3 . References

1. Crinone Prescribing Information. Allergan USA, Inc. Irvine, CA. June 2017.
2. Endometrin Prescribing Information. Ferring Pharmaceuticals, Inc. Parsippany, NJ. January 2018.

4 . Revision History

Date	Notes
8/22/2022	Annual review: no criteria changes.

Prior Authorization Guideline

Guideline Name	Dacogen (decitabine)/Inqovi (decitabine and cedazuridine) tablets - PA, NF

Guideline Note:

Effective Date:	10/1/2022
P&T Approval Date:	12/2/2006
P&T Revision Date:	09/18/2019 ; 08/13/2020 ; 10/21/2020 ; 08/19/2021 ; 01/19/2022 ; 8/18/2022

1 . Indications

Drug Name: Dacogen (decitabine)
Myelodysplastic Syndromes (MDS) Indicated for treatment of adult patients with myelodysplastic syndromes (MDS) including previously treated and untreated, de novo and secondary MDS of all French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia) and Intermediate-1, Intermediate-2, and high-risk International Prognostic Scoring System groups.
Drug Name: Inqovi (decitabine and cedazuridine) tablets
Myelodysplastic Syndromes (MDS) Indicated for treatment of adult patients with myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.

2 . Criteria

Product Name: Brand Dacogen, Generic decitabine	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myelodysplastic syndrome

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Inqovi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myelodysplastic syndrome

AND

2 - Patient is intermediate-1, intermediate-2, or high-risk per the International Prognostic Scoring System (IPSS)

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Brand Dacogen, Generic decitabine, Inqovi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Inqovi	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of myelodysplastic syndrome

AND

2 - Patient is intermediate-1, intermediate-2, or high-risk per the International Prognostic Scoring System (IPSS)

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

3 . References

1. Dacogen prescribing information. Astex Pharmaceuticals, Inc. Dublin, CA. November 2021.
2. National Comprehensive Cancer (NCCN) Drugs & Biologics Compendium [internet database]. National Comprehensive Cancer Network, Inc. 2022. Updated periodically. Accessed July 1, 2022.
3. Inqovi prescribing information. Taiho Oncology, Inc. Princeton, NY. March 2022.

4 . Revision History

Date	Notes
7/5/2022	Annual Review

Prior Authorization Guideline

Guideline Name	Daliresp (roflumilast)

Guideline Note:

Effective Date:	2/1/2023
P&T Approval Date:	8/16/2011
P&T Revision Date:	08/15/2019 ; 09/16/2020 ; 09/16/2020 ; 09/15/2021 ; 09/21/2022 ; 12/14/2022 ; 1/18/2023

1 . Indications

Drug Name: Daliresp (roflumilast)
Chronic obstructive pulmonary disorder (COPD) Indicated as a treatment to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations. Limitations of Use: Roflumilast is not a bronchodilator and is not indicated for the relief of acute bronchospasm. Daliresp 250 mcg is a starting dose, for the first 4 weeks of treatment only and is not the effective (therapeutic) dose.

2 . Criteria

Product Name: Brand Daliresp, generic roflumilast	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic obstructive pulmonary disease (COPD) [A, B]

AND

2 - History of COPD exacerbations which require the use of systemic corticosteroids, antibiotics, or hospital admission [C]

AND

3 - Trial and failure, intolerance, or contraindication to two prior therapies for COPD (e.g. Combivent, Spiriva)

AND

4 - Trial and failure or intolerance to generic roflumilast (Applies to brand Daliresp only)

Notes	Daliresp 250 mcg is a starting dose, for the first 4 weeks of treatment only and is not the effective (therapeutic) dose.

Product Name: Brand Daliresp, generic roflumilast	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Trial and failure or intolerance to generic roflumilast (Applies to brand Daliresp only)

Notes	Daliresp 250 mcg is a starting dose, for the first 4 weeks of treatment only and is not the effective (therapeutic) dose.

3 . Endnotes

A. Patients enrolled in the pivotal trials had a forced expiratory volume in 1 second [FEV1] less than or equal to 50% of predicted and FEV1/forced vital capacity [FVC] less than 0.7). [1-3]
B. According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) treatment guidelines, moderate COPD is defined as FEV1 less than 80% but greater than or equal to 50%; severe COPD is defined as FEV1 less than 50% but greater than or equal to 30%; and very severe COPD is defined as FEV1 less than 30%. [4]
C. In the pivotal studies the rate of moderate exacerbations was defined as requiring intervention with systemic glucocorticosteroids. Severe exacerbations were defined as leading to hospitalization and/or to death. [1]

4 . References

1. Daliresp Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. March 2020.
2. Micromedex Healthcare Series [database on the Internet]. Greenwood Village (CO): IBM Corporation.; Updated periodically. Available by subscription at: https://www.micromedexsolutions.com/. Accessed August 24, 2021.
3. FDA Summary Review. Accessed at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/022522Orig1s000SumR.pdf. Accessed August 24, 2021.
4. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2022 report). Accessed at: https://goldcopd.org/wp-content/uploads/2021/12/GOLD-REPORT-2022-v1.1-22Nov2021_WMV.pdf.Accessed August 4, 2022.

5 . Revision History

Date	Notes
12/19/2022	Formulary strategy for brand Daliresp to require a trial of its generic.

Prior Authorization Guideline

Guideline Name	Daraprim (pyrimethamine)

Guideline Note:

Effective Date:	8/1/2022
P&T Approval Date:	10/13/2015
P&T Revision Date:	05/14/2020 ; 06/17/2020 ; 06/16/2021 ; 6/15/2022

1 . Indications

Drug Name: Daraprim (pyrimethamine)
Treatment of toxoplasmosis Indicated for the treatment of toxoplasmosis when used conjointly with a sulfonamide, since synergism exists with this combination.

2 . Criteria

Product Name: Brand Daraprim, generic pyrimethamine	
Diagnosis	Toxoplasmosis
Approval Length	12 Months [A, B]
Guideline Type	Prior Authorization
Approval Criteria	

1 - Both of the following:

1.1 One of the following:

1.1.1 Patient is using pyrimethamine for one of the following: [2, 3]

- Active treatment of toxoplasmosis (e.g., toxoplasmic encephalitis, ocular toxoplasmosis)
- Secondary prophylaxis of toxoplasmosis
- Treatment of congenital toxoplasmosis

OR

1.1.2 All of the following: [2]

1.1.2.1 Patient is using pyrimethamine for primary prophylaxis of toxoplasmosis

AND

1.1.2.2 Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX)

AND

1.1.2.3 One of the following:

1.1.2.3.1 Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate

OR

1.1.2.3.2 Evidence of life-threatening reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past (e.g., toxic epidermal necrolysis [TEN], Stevens-Johnson syndrome)

AND

1.2 Prescribed by or in consultation with an infectious disease specialist

Product Name: Brand Daraprim, generic pyrimethamine	
Diagnosis	Malaria (off-label)
Guideline Type	Prior Authorization

Approval Criteria

1 - Requests for coverage of any pyrimethamine products for the treatment and/or prophylaxis of malaria are not authorized and will not be approved. The use of pyrimethamine for the treatment and/or prophylaxis of malaria is not recommended by the Centers for Disease Control and Prevention (CDC) [5]

3 . Endnotes

A. Prescriber should consider discontinuation of primary prophylaxis if CD4 is greater than 200 cells/mm3 for more than 3 months after institution of combination antiretroviral therapy. [2]
B. Prescriber should consider discontinuation of secondary prophylaxis if CD4 is greater than 200 cells/mm3 for more than 6 months after institution of combination antiretroviral therapy. [2]

4 . References

1. Daraprim Prescribing Information. Vyera Pharmaceuticals. New York, NY. August 2017.
2. Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV. https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-opportunistic-infection/whats-new-guidelines. Accessed May 5, 2022.
3. Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Exposed and HIV-Infected Children. https://clinicalinfo.hiv.gov/sites/default/files/guidelines/archive/OI_Guidelines_Pediatrics_2022_01_04.pdf. Accessed May 5, 2022.
4. Parasites - Toxoplasmosis (Toxoplasma infection). https://www.cdc.gov/parasites/toxoplasmosis/health_professionals/index.html#tx. Accessed May 5, 2022
5. Centers for Disease Control and Prevention. CDC Yellow Book 2020: Health Information for International Travel. New York: Oxford University Press; 2020. https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/malaria. Accessed May 5, 2022.

5 . Revision History

Date	Notes
6/8/2022	Annual Review

Prior Authorization Guideline

Guideline Name	Darzalex (daratumumab), Darzalex Faspro (daratumumab and hyaluronidase-fihj) - PA, NF

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	1/27/2016
P&T Revision Date:	09/18/2019 ; 12/18/2019 ; 03/18/2020 ; 05/14/2020 ; 07/15/2020 ; 10/21/2020 ; 03/17/2021 ; 09/15/2021 ; 12/15/2021 ; 02/17/2022 ; 3/15/2023

1 . Indications

Drug Name: Darzalex (daratumumab)
Multiple Myeloma - Monotherapy Indicated as monotherapy, for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent. **Multiple Myeloma - Combination therapy** Indicated in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy. **Multiple Myeloma - Combination therapy** Indicated in combination with carfilzomib and dexamethasone in patients who have received one to three prior lines of therapy. **Multiple Myeloma - Combination therapy** Indicated in combination pomalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor. **Newly Diagnosed Multiple Myeloma** Indicated in combination with bortezomib, melphalan,

and prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.

Newly Diagnosed Multiple Myeloma Indicated in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant

Newly Diagnosed Multiple Myeloma Indicated in combination with bortezomib, thalidomide, and dexamethasone for the treatment of patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant.

Drug Name: Darzalex Faspro (daratumumab and hyaluronidase-fihj)

Multiple Myeloma - Monotherapy Indicated as monotherapy, for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent.

Multiple Myeloma - Combination Indicated in combination with lenalidomide and dexamethasone or bortezomib and dexamethasone in patients who have received at least one prior therapy.

Multiple Myeloma - Combination Indicated in combination with pomalidomide and dexamethasone in patients who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor.

Multiple Myeloma - Combination Multiple Myeloma - Combination therapy Indicated in combination with carfilzomib and dexamethasone in patients who have received one to three prior lines of therapy.

Newly Diagnosed Multiple Myeloma Indicated in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant

Newly Diagnosed Multiple Myeloma Indicated in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant

Newly Diagnosed Multiple Myeloma Indicated in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant

Light Chain (AL) Amyloidosis Indicated in combination with bortezomib, cyclophosphamide and dexamethasone in newly diagnosed patients. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

2 . Criteria

Product Name: Darzalex	
Diagnosis	Relapsed/Refractory Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Used as monotherapy

AND

2.1.2 One of the following:

2.1.2.1 Patient has received at least three prior treatment regimens which included both of the following:

- Proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])
- Immunomodulatory agent (e.g., lenalidomide [Revlimid], thalidomide [Thalomid])

OR

2.1.2.2 Patient is double-refractory to a proteasome inhibitor and an immunomodulatory agent

OR

2.2 Both of the following:

2.2.1 Used in combination with one of the following treatment regimens:

- lenalidomide and dexamethasone
- bortezomib and dexamethasone
- carfilzomib and dexamethasone

AND

2.2.2 Patient has received at least one prior therapy (e.g., bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro]), lenalidomide [Revlimid], thalidomide [Thalomid]) [2]

OR

2.3 Both of the following:

2.3.1 Used in combination with both of the following:

- pomalidomide
- dexamethasone

AND

2.3.2 Patient has received at least two prior therapies including lenalidomide and a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])

AND

3 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Darzalex	
Diagnosis	Newly Diagnosed Multiple Myeloma

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Newly diagnosed multiple myeloma

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient is ineligible for autologous stem cell transplant

AND

2.1.2 One of the following:

2.1.2.1 Used in the combination with all of the following:

- bortezomib
- melphalan
- prednisone

OR

2.1.2.2 Both of the following:

- lenalidomide
- dexamethasone

OR

2.2 Both of the following:

2.2.1 Patient is eligible for autologous stem cell transplant

AND

2.2.2 Used in combination with all of the following:

- bortezomib
- thalidomide
- dexamethasone

AND

3 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Darzalex Faspro	
Diagnosis	Relapsed/Refractory Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Used as monotherapy

AND

2.1.2 One of the following:

2.1.2.1 Patient has received at least three prior treatment regimens which included both of the following:

- Proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])
- Immunomodulatory agent (e.g., lenalidomide [Revlimid], thalidomide [Thalomid])

OR

2.1.2.2 Patient is double-refractory to a proteasome inhibitor and an immunomodulatory agent

OR

2.2 Both of the following:

2.2.1 Used in combination with one of the following treatment regimens:

- lenalidomide and dexamethasone
- bortezomib and dexamethasone
- carfilzomib and dexamethasone

AND

2.2.2 Patient has received at least one prior therapy (e.g., bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro]), lenalidomide [Revlimid], thalidomide [Thalomid]) [2]

OR

2.3 Both of the following:

2.3.1 Used in combination with both of the following:

- pomalidomide
- dexamethasone

AND

2.3.2 Patient has received at least one prior line of therapy including lenalidomide and a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])

AND

3 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Darzalex Faspro	
Diagnosis	Relapsed/Refractory Multiple Myeloma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

2.1 Both of the following:

2.1.1 Used as monotherapy

AND

2.1.2 One of the following:

2.1.2.1 Patient has received at least three prior treatment regimens which included both of the following:

- Proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])
- Immunomodulatory agent (e.g., lenalidomide [Revlimid], thalidomide [Thalomid])

OR

2.1.2.2 Patient is double-refractory to a proteasome inhibitor and an immunomodulatory agent

OR

2.2 Both of the following:

2.2.1 Used in combination with one of the following treatment regimens:

- lenalidomide and dexamethasone
- bortezomib and dexamethasone
- carfilzomib and dexamethasone

AND

2.2.2 Patient has received at least one prior therapy (e.g., bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro]), lenalidomide [Revlimid], thalidomide [Thalomid]) [2]

OR

2.3 Both of the following:

2.3.1 Used in combination with both of the following:

- pomalidomide
- dexamethasone

AND

2.3.2 Patient has received at least one prior line of therapy including lenalidomide and a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])

AND

3 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Darzalex Faspro	
Diagnosis	Newly Diagnosed Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Newly diagnosed multiple myeloma

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient is ineligible for autologous stem cell transplant

AND

2.1.2 One of the following:

2.1.2.1 Used in the combination with all of the following:

- bortezomib
- melphalan
- prednisone

OR

2.1.2.2 Both of the following:

- lenalidomide
- dexamethasone

OR

2.2 Both of the following:

2.2.1 Patient is eligible for autologous stem cell transplant

AND

2.2.2 Used in combination with all of the following:

- bortezomib
- thalidomide
- dexamethasone

AND

3 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Darzalex Faspro	
Diagnosis	Newly Diagnosed Multiple Myeloma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Newly diagnosed multiple myeloma

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

2.1 Both of the following:

2.1.1 Patient is ineligible for autologous stem cell transplant

AND

2.1.2 One of the following:

2.1.2.1 Used in the combination with all of the following:

- bortezomib
- melphalan
- prednisone

OR

2.1.2.2 Both of the following:

- lenalidomide
- dexamethasone

OR

2.2 Both of the following:

2.2.1 Patient is eligible for autologous stem cell transplant

AND

2.2.2 Used in combination with all of the following:

- bortezomib
- thalidomide
- dexamethasone

AND

3 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Darzalex Faspro

Diagnosis	Light Chain Amyloidosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Newly diagnosed light chain (AL) amyloidosis

AND

2 - Used in combination with ALL of the following:

- Bortezomib
- Cyclophosphamide
- Dexamethasone

AND

3 - All of the following

- Patient does not have New York Heart Association (NYHA) Class IIIB disease
- Patient does not have New York Heart Association (NYHA) Class IV disease
- Patient does not have Mayo Stage IIIB disease

AND

4 - Prescribed by or in consultation with a hematologist

Product Name: Darzalex Faspro	
Diagnosis	Light Chain Amyloidosis
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Newly diagnosed light chain (AL) amyloidosis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming medication is being used in combination with ALL of the following:

- Bortezomib
- Cyclophosphamide
- Dexamethasone

AND

3 - All of the following

- Patient does not have New York Heart Association (NYHA) Class IIIB disease
- Patient does not have New York Heart Association (NYHA) Class IV disease
- Patient does not have Mayo Stage IIIB disease

AND

4 - Prescribed by or in consultation with a hematologist

Product Name: Darzalex, Darzalex Faspro	
Diagnosis	All Indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Darzalex Prescribing Information. Janssen Biotech, Inc. Horsham, PA. January 2023.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Multiple Myeloma v4.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma_blocks.pdf. Accessed December 2021.
3. Darzalex Faspro Prescribing Information. Janssen Biotech, Inc. Horsham, PA. December 2022

4 . Revision History

Date	Notes
2/28/2023	2023 UM Annual Review. Updated NF criteria to require submission of medical records or paid claims. Updated references.

Prior Authorization Guideline

Guideline Name	DAW Override

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	12/19/2015
P&T Revision Date:	10/16/2019 ; 10/21/2020 ; 11/18/2021 ; 11/17/2022

Note:

The intent of this policy is to serve as guidance for clients who would like to implement a dispense as written (DAW) override program. The standard DAW (brand name) override criteria are for clients who opt for such a program to help manage prescription costs. The criteria is applied when a provider/patient requests for coverage of a brand medication when a generic is available.

1 . Criteria

Product Name: Brand drugs with two or more generic equivalents available	
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria	

1 - Patient has tried two generic equivalents of the requested drug from different manufacturers

AND

2 - One of the following:

2.1 Patient has had an allergic reaction or intolerance to an inactive ingredient

OR

2.2 Patient has experienced an inadequate response to the generic equivalent of the requested drug

AND

3 - One of the following:

3.1 Requested drug is FDA-approved for the condition being treated

OR

3.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

Product Name: Brand drugs with only one generic equivalent available	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - Patient has tried one generic equivalent of the requested drug from a different manufacturer

AND

2 - One of the following:

2.1 Patient has had an allergic reaction or intolerance to an inactive ingredient

OR

2.2 Patient has experienced an inadequate response to the generic equivalent of the requested drug

AND

3 - One of the following:

3.1 Requested drug is FDA-approved for the condition being treated

OR

3.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

2 . Endnotes

A. The standard DAW (brand name) override criteria are for clients who opt for such a program to help manage prescription costs. The criteria is applied when a provider/patient requests for coverage of a brand medication when a generic is available. There must be a clinical reason why the patient cannot take the generic version of the medication. Acceptable clinical reasons include having an inadequate response, an allergic reaction, or intolerance to two generic manufacturers of the branded product (or one if only one generic equivalent is available). Intolerance of the generic version may occur due to excipients in the generic version of the product. In order to receive approval for the prescribed drug, the prescriber will document the clinical reason as to why the patient cannot use a generic version of the product.

3 . Revision History

Date	Notes
10/27/2022	2022 Annual Review.

Prior Authorization Guideline

Guideline Name	Deferasirox products

Guideline Note:

Effective Date:	7/1/2022
P&T Approval Date:	5/20/2015
P&T Revision Date:	01/15/2020 ; 05/14/2020 ; 07/15/2020 ; 09/16/2020 ; 05/20/2021 ; 5/19/2022

1 . Indications

Drug Name: Exjade (deferasirox), deferasirox tablet, Jadenu (deferasirox), Jadenu Sprinkle (deferasirox)
Chronic Iron Overload Due to Blood Transfusions (Transfusional Iron Overload) Indicated for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in patients 2 years of age and older. Limitations of Use: The safety and efficacy of deferasirox when administered with other iron chelation therapy have not been established. **Treatment of Chronic Iron Overload in Non-Transfusion-Dependent Thalassemia Syndromes** Indicated for the treatment of chronic iron overload in patients 10 years of age and older with non-transfusion-dependent thalassemia (NTDT) syndromes and with a liver iron concentration (LIC) of at least 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) and a serum ferritin greater than 300 mcg/L. Limitations of Use: The safety and efficacy of deferasirox when administered with other iron chelation therapy have not been established. **Off Label Uses: Myelodysplastic syndrome (MDS)** Low to intermediate risk myelodysplastic syndrome (MDS) for management of iron overload and in potential transplant patients who have received more than 20 red blood cell transfusions [11]

2 . Criteria

Product Name: Brand Jadenu, Brand Jadenu Sprinkle, Brand Exjade	
Diagnosis	Chronic iron overload due to blood transfusions (transfusional hemosiderosis)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis)

AND

2 - Patient is 2 years of age or older

AND

3 - Patient has a baseline ferritin level more than 1,000 mcg/L

AND

4 - Patient has required the transfusion of at least 100 mL/kg packed red blood cells

AND

5 - Trial and failure of generic deferasirox

Product Name: Generic deferasirox

Diagnosis	Chronic iron overload due to blood transfusions (transfusional hemosiderosis)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis)

AND

2 - Patient is 2 years of age or older

AND

3 - Patient has a baseline ferritin level more than 1,000 mcg/L

AND

4 - Patient has required the transfusion of at least 100 mL/kg packed red blood cells

Product Name: Brand Jadenu, Brand Jadenu Sprinkle, Brand Exjade	
Diagnosis	Myelodysplastic syndrome (MDS) [off-label]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myelodysplastic syndrome

AND

2 - Patient has Low or Intermediate-1 disease or is a potential transplant patient

AND

3 - Patient has received more than 20 red blood cell transfusions

AND

4 - Trial and failure of generic deferasirox

Product Name: Generic deferasirox	
Diagnosis	Myelodysplastic syndrome (MDS) [off-label]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myelodysplastic syndrome

AND

2 - Patient has Low or Intermediate-1 disease or is a potential transplant patient

AND

3 - Patient has received more than 20 red blood cell transfusions

Product Name: Brand Jadenu, Brand Jadenu Sprinkle, Brand Exjade

Diagnosis	Chronic iron overload due to blood transfusions (transfusional hemosiderosis) & Myelodysplastic syndrome (MDS) [off-label]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient experienced a reduction, from baseline, in serum ferritin level or liver iron concentration (LIC)

AND

2 - Trial and failure of generic deferasirox

Product Name: Generic deferasirox	
Diagnosis	Chronic iron overload due to blood transfusions (transfusional hemosiderosis) & Myelodysplastic syndrome (MDS) [off-label]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient experienced a reduction, from baseline, in serum ferritin level or liver iron concentration (LIC)

Product Name: Brand Jadenu, Brand Jadenu Sprinkle, Brand Exjade	
Diagnosis	Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)

AND

2 - Patient is 10 years of age or older

AND

3 - Liver iron concentration (LIC) 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) or higher

AND

4 - Serum ferritin level greater than 300 mcg/L

AND

5 - Trial and failure of generic deferasirox

Product Name: Generic deferasirox	
Diagnosis	Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)

AND

2 - Patient is 10 years of age or older

AND

3 - Liver iron concentration (LIC) 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) or higher

AND

4 - Serum ferritin level greater than 300 mcg/L

Product Name: Brand Jadenu, Brand Jadenu Sprinkle, Brand Exjade	
Diagnosis	Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has liver iron concentration (LIC) 3 mg Fe/g dw or higher

AND

2 - Patient experienced a reduction, from baseline, in serum ferritin level or liver iron concentration (LIC)

AND

3 - Trial and failure of generic deferasirox

Product Name: Generic deferasirox	
Diagnosis	Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has liver iron concentration (LIC) 3 mg Fe/g dw or higher

AND

2 - Patient experienced a reduction, from baseline, in serum ferritin level or liver iron concentration (LIC)

3 . References

1. Exjade Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. July 2020.
2. Cappellini MD, Cohen A, Piga A, et al. A Phase III study of deferasirox (ICL670), a once-daily oral iron chelator, in patients with [beta]-thalassemia. Blood. 2006;107(9):3455-62.
3. Cappellini MD. Iron-chelating therapy with the new oral agent ICL670 (Exjade). Best Pract Res Clin Haematol. 2005;18(2):289-98.
4. Galanello R, Piga A, Alberti D, Rouan MC, Bigler H, Sechaud R. Safety, tolerability, and pharmacokinetics of ICL670, a new orally active iron-chelating agent in patients with transfusion-dependent iron overload due to beta-thalassemia. J Clin Pharmacol. 2003;43(6):565-72.
5. Nisbet-Brown E, Olivieri NF, Giardina PJ, et al. Effectiveness and safety of ICL670 in iron-loaded patients with thalassaemia: a randomized, double-blind, placebo-controlled, dose-escalation trial. Lancet. 2003;361(9369):1597-602.
6. International Association of Sickle Cell Nurses and Physician Assistants. Nursing Practice Guidelines: Care of the Patient with Sickle Cell Disease and Iron Overload. 2008. http://www.iascnapa.org/guidelines/Guidelines_IronOverload.pdf. Accessed on April 8, 2021.
7. Ho PJ, Tay L, Linderman R, Catley L, Bowden DK. Australian guidelines for the assessment of iron overload and iron chelation in transfusion-dependent thalassaemia major, sickle cell disease and other congenital anaemias. Intern Med J. 2011;41(7):516-24.

8. Angelucci E, Barosi G, Camaschella C, et al. Italian Society of Hematology practice guidelines for the management of iron overload in thalassemia major and related disorders. Haematologica. 2008;93(5):741-52.
9. Porter JB and Shah FT. Iron overload in thalassemia and related conditions: therapeutic goals and assessment of response to chelation therapies. 2010 Dec;24(6):1109-30.
10. Jadenu, Jadenu Sprinkle Prescribing Information. Novartis Pharmaceuticals. East Hanover, NJ. July 2020.
11. AHFS Drug Information (Adult and Pediatric) [Internet database]. Bethesda, Maryland. Lexicomp, Inc. Updated periodically. Available by subscription at: http://online.lexi.com/. Accessed on April 8, 2021.
12. Deferasirox tablet Prescribing Information. Cipla USA, Inc. Warren, NJ. August 2020.

4 . Revision History

Date	Notes
4/28/2022	Annual review: No changes to criteria

Prior Authorization Guideline

Guideline Name	Demser (metyrosine)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	3/16/2022
P&T Revision Date:	3/15/2023

1 . Indications

Drug Name: Demser (metyrosine)
Pheochromocytoma Indicated for the treatment of patients with pheochromocytoma for preoperative preparation of patients for surgery, management of patients when surgery is contraindicated, and chronic treatment of patients with malignant pheochromocytoma. Metyrosine capsules are not recommended for the control of essential hypertension.

2 . Criteria

Product Name: Brand Demser, generic metyrosine	
Diagnosis	Preoperative preparation
Approval Length	1 Time(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pheochromocytoma confirmed by one of the following biochemical testing:

- plasma free metanephrines
- urinary fractioned metanephrines

AND

2 - Medication is being used for preoperative preparation

AND

3 - Trial and failure, contraindication, or intolerance to both of the following:

- alpha-adrenergic blocker (e.g., phenoxybenzamine, doxazosin, terazosin)
- beta-adrenergic blocker (e.g., propranolol, metoprolol)

AND

4 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Endocrine surgeon

Product Name: Brand Demser, generic metyrosine	
Diagnosis	Treatment of pheochromocytoma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pheochromocytoma confirmed by one of the following biochemical testing:

- plasma free metanephrines
- urinary fractioned metanephrines

AND

2 - Patient with hormonally active (catecholamine excess) pheochromocytoma

AND

3 - One of the following:

3.1 Patient is not a candidate for surgery

OR

3.2 Chronic treatment due to malignant pheochromocytoma

AND

4 - Patient has not reached normotension after treatment with a selective alpha-1-adrenergic blocker (e.g., doxazosin, terazosin) and beta-adrenergic blocker (e.g., propranolol, metoprolol)

AND

5 - Medication will not be used to control essential hypertension

AND

6 - Prescribed by or in consultation with one of the following:

- Endocrinologist

- Provider who specializes in the management of pheochromocytoma

Product Name: Brand Demser, generic metyrosine	
Diagnosis	Treatment of pheochromocytoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., decreased frequency and severity of hypertensive attacks)

3 . References

1. Metyrosine Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. November 2020.
2. Naruse M, Satoh F, Tanabe A, et al. Efficacy and safety of metyrosine in pheochromocytoma/paraganglioma: a multi-center trial in Japan. Endocrine Journal. 2018;65(3):359-371.
3. Lenders JWM, Duh Q-Y, Eisenhofer G, et al. Pheochromocytoma and Paraganglioma: An Endocrine Society Clinical Practice Guideline. The Journal of Clinical Endocrinology & Metabolism. 2014;99(6):1915-1942.

4 . Revision History

Date	Notes
3/1/2023	2023 Annual Review - no changes

Prior Authorization Guideline

Guideline Name	Descovy (emtricitabine/tenofovir alafenamide)

Guideline Note:

Effective Date:	12/1/2022
P&T Approval Date:	10/16/2019
P&T Revision Date:	10/21/2020 ; 10/20/2021 ; 03/16/2022 ; 10/19/2022

1 . Indications

Drug Name: Descovy (emtricitabine/tenofovir alafenamide)
Treatment of HIV-1 Infection Indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35kg. Indicated in combination with other antiretroviral agents other than protease inhibitors that require a CYP3A inhibitor for the treatment of HIV-1 infection in pediatric patients weighing at least 14 kg and less than 35 kg. **HIV-1 Pre-exposure Prophylaxis (PrEP)** Indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of human immunodeficiency virus-1 (HIV-1) infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex. Individuals must have a negative HIV-1 test immediately prior to initiating Descovy for HIV-1 PrEP. Limitations of Use: The indication does not include use of Descovy in individuals at risk of HIV-1 from receptive vaginal sex because effectiveness in this population has not been evaluated.

2 . Criteria

Product Name: Descovy	
Diagnosis	Treatment of HIV Infection
Approval Length	24 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Descovy is being used for the treatment of HIV infection

Product Name: Descovy	
Diagnosis	HIV Pre-exposure Prophylaxis (PrEP)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Descovy is being used for HIV Pre-exposure Prophylaxis (PrEP)

AND

2 - Patient has a history of intolerance or contraindication to generic Truvada 200/300mg (emtricitabine/tenofovir disoproxil fumarate)

3 . References

1. Descovy Prescribing Information. Gilead Sciences, Inc. Foster City, CA. January 2022.

4 . Revision History

Date	Notes
10/19/2022	Annual review - no changes.

Prior Authorization Guideline

Guideline Name	Diacomit (stiripentol)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 05/19/2022 ; 09/21/2022 ; 5/18/2023

1 . Indications

Drug Name: Diacomit (stiripentol)
Dravet syndrome (DS) Indicated for the treatment of seizures associated with Dravet syndrome in patients taking clobazam who are 6 months of age or older and weighing 7 kg or more.There are no clinical data to support the use of DIACOMIT as monotherapy in Dravet syndrome.

2 . Criteria

Product Name: Diacomit	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of seizures associated with Dravet syndrome (DS)

AND

2 - Used in combination with clobazam

AND

3 - BOTH of the following:

- Patient is 6 months of age or older
- Patient weighs 7kg or more

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Diacomit	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Used in combination with clobazam

3 . References

1. Diacomit Prescribing Information. Biocodex. Gentilly, France. July 2022.

4 . Revision History

Date	Notes
4/10/2023	Annual review - no changes to criteria

Prior Authorization Guideline

Guideline Name	Dibenzyline (phenoxybenzamine)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	3/16/2022
P&T Revision Date:	3/15/2023

1 . Indications

Drug Name: Dibenzyline (phenoxybenzamine)
Pheochromocytoma Indicated in the treatment of pheochromocytoma to control episodes of hypertension and swelling.

2 . Criteria

Product Name: Brand Dibenzyline, generic phenoxybenzamine	
Diagnosis	Pheochromocytoma
Approval Length	1 Time(s) [A]
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of pheochromocytoma confirmed by one of the following biochemical testing: [2]

- plasma free metanephrines
- urinary fractioned metanephrines

AND

2 - Medication is being used for preoperative preparation [A,1]

AND

3 - Trial and failure, contraindication, or intolerance to one of the following:

- doxazosin
- terazosin
- prazosin

AND

4 - Treatment will also include a high-sodium diet and fluid intake [B]

AND

5 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Endocrine surgeon

3 . Endnotes

A. Phenoxybenzamine is most commonly used for preoperative control of blood pressure. Its only current clinical use is in preparing patients with pheochromocytoma for surgery. [1]
B. Retrospective studies report that initiation of high-sodium diet a few days after the start of alpha-adrenergic receptor blockade reverses blood volume contraction, prevents

orthostatic hypotension before surgery, and reduces the risk of significant hypotension after surgery. [2]

4 . References

1. Farrugia F, Martikos G, Tzanetis P, et al. Pheochromocytoma, diagnosis and treatment: Review of the literature. Endocrine Regulations. 2017;51(3):168-181.
2. Lenders JWM, Duh Q-Y, Eisenhofer G, et al. Pheochromocytoma and Paraganglioma: An Endocrine Society Clinical Practice Guideline. The Journal of Clinical Endocrinology & Metabolism. 2014;99(6):1915-1942.
3. Phenoxybenzamine Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. December 2020.

5 . Revision History

Date	Notes
3/1/2023	2023 Annual Review - no changes

Prior Authorization Guideline

Guideline Name	DPP-4 Inhibitors

Guideline Note:

Effective Date:	8/1/2022
P&T Approval Date:	2/20/2007
P&T Revision Date:	05/14/2020 ; 06/16/2021 ; 6/15/2022

1 . Indications

Drug Name: Janumet (sitagliptin/metformin), Janumet XR (sitagliptin/metformin extended-release)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: 1) Not for the treatment of type 1 diabetes, 2) Has not been studied in patients with a history of pancreatitis.
Drug Name: Januvia (sitagliptin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: 1) Januvia should not be used in patients with type 1 diabetes, 2) Januvia has not been studied in patients with a history of pancreatitis.
Drug Name: Tradjenta (linagliptin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: 1) Should not be used in patients with type 1 diabetes, 2) Has not been studied in patients with a history of pancreatitis.

Drug Name: Jentadueto (linagliptin/metformin), Jentadueto XR (linagliptin/metformin extended-release)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: 1) Not for treatment of type 1 diabetes, 2) Has not been studied in patients with a history of pancreatitis.

2 . Criteria

Product Name: Janumet, Janumet XR, Januvia, Jentadueto, Jentadueto XR, Tradjenta	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure, contraindication, or intolerance to one of the following generics:

- metformin
- metformin ER
- glipizide-metformin
- glyburide-metformin
- pioglitazone-metformin

3 . References

1. Janumet Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. December 2021.
2. Janumet XR Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. December 2021.
3. Januvia Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. December 2021.

4. Jentadueto Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. April 2022.
5. Jentadueto XR Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. October 2021.
6. Tradjenta Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. April 2022.

4 . Revision History

Date	Notes
6/17/2022	Added criterion "Requested drug is being used for a Food and Drug Administration (FDA)-approved indication." Cosmetic update to guide line name.

Prior Authorization Guideline

Guideline Name	Duexis (ibuprofen and famotidine) - PA, NF

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	5/17/2018
P&T Revision Date:	02/14/2020 ; 02/14/2020 ; 02/18/2021 ; 09/15/2021 ; 02/17/2022 ; 06/15/2022 ; 2/16/2023

1 . Indications

Drug Name: Duexis (ibuprofen/famotidine)
Osteoarthritis, rheumatoid arthritis, and gastrointestinal ulcers Indicated for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers, which in the clinical trials was defined as a gastric and /or duodenal ulcer, in patients who are taking ibuprofen for those indications. The clinical trials primarily enrolled patients less than 65 years of age without a prior history of gastrointestinal ulcer. Controlled trials do not extend beyond 6 months.

2 . Criteria

Product Name: Brand Duexis, generic ibuprofen-famotidine F	
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Osteoarthritis
- Rheumatoid Arthritis

AND

2 - One of the following [2]:

- History of peptic ulcer disease
- History of gastrointestinal (GI) bleeding, obstruction, or perforation
- Erosive esophagitis
- Used in combination with aspirin

AND

3 - History of a minimum 30 day trial and failure, contraindication or intolerance to two of the following generics:

- etodolac
- fenoprofen
- flurbiprofen
- ibuprofen
- indomethacin
- ketoprofen
- ketorolac
- meloxicam
- nabumetone
- naproxen
- oxaprozin
- piroxicam
- sulindac
- tolmetin
- diclofenac

AND

4 - History of a minimum 30 day trial and failure, or intolerance to two of the following generic H2-receptor antagonists:

- cimetidine
- famotidine
- nizatidine
- ranitidine

AND

5 - Physician has provided rationale for needing to use fixed-dose combination therapy with brand Duexis or generic ibuprofen-famotidine instead of taking individual products in combination

Product Name: Brand Duexis, generic ibuprofen-famotidine NF	
Approval Length	3 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting one of the following diagnoses:

- Osteoarthritis
- Rheumatoid Arthritis

AND

2 - Submission of medical records (e.g., chart notes) documenting one of the following [2]:

- History of peptic ulcer disease
- History of gastrointestinal (GI) bleeding, obstruction, or perforation
- Erosive esophagitis
- Used in combination with aspirin

AND

3 - Paid claims or submission of medical records (e.g., chart notes) documenting history of a minimum 30 day trial and failure, contraindication or intolerance to two of the following generics:

- etodolac
- fenoprofen
- flurbiprofen
- ibuprofen
- indomethacin
- ketoprofen
- ketorolac
- meloxicam
- nabumetone
- naproxen
- oxaprozin
- piroxicam
- sulindac
- tolmetin
- diclofenac

AND

4 - Paid claims or submission of medical records (e.g., chart notes) documenting history of a minimum 30 day trial and failure, contraindication or intolerance to two of the following generic H2-receptor antagonists:

- cimetidine
- famotidine
- nizatidine
- ranitidine

AND

5 - Physician has provided rationale for needing to use fixed-dose combination therapy with brand Duexis or generic ibuprofen-famotidine instead of taking individual products in combination

3 . References

1. Duexis [prescribing information]. Deerfield, IL: Horizon Medicines, LLC; April 2021.
2. Solomon C. Upper Gastrointestinal Bleeding Due to a Peptic Ulcer. N Engl J Med. 2016;374:2367-2376.

4 . Revision History

Date	Notes
1/31/2023	2023 Annual Review

Prior Authorization Guideline

Guideline Name	Dupixent (dupilumab)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	11/17/2016
P&T Revision Date:	09/18/2019 ; 12/18/2019 ; 02/13/2020 ; 07/15/2020 ; 03/17/2021 ; 08/19/2021 ; 11/18/2021 ; 12/15/2021 ; 03/16/2022 ; 04/20/2022 ; 05/19/2022 ; 07/20/2022 ; 11/17/2022 ; 5/18/2023

1 . Indications

Drug Name: Dupixent (dupilumab)
Atopic Dermatitis (AD) Indicated for the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids. **Asthma** Indicated as an add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma. Limitations of use: Dupixent is not indicated for the relief of acute bronchospasm or status asthmaticus. **Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)** Indicated as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP). **Eosinophilic Esophagitis (EoE)** Indicated for the treatment of adult and pediatric patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE).

Prurigo Nodularis (PN) Indicated for the treatment of adult patients with prurigo nodularis (PN).

2 . Criteria

Product Name: Dupixent	
Diagnosis	Atopic Dermatitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe atopic dermatitis

AND

2 - One of the following:

- Involvement of at least 10% body surface area (BSA)
- SCORing Atopic Dermatitis (SCORAD) index value of at least 25 [A]

AND

3 - Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to at least ONE of the following [2]:

- Medium or higher potency topical corticosteroid
- Pimecrolimus cream
- Tacrolimus ointment
- Eucrisa (crisaborole) ointment

AND

4 - Patient is 6 months of age or older

AND

5 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist/Immunologist

Notes	*Product may require step therapy

Product Name: Dupixent	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy as evidenced by at least ONE of the following:

- Reduction in BSA involvement from baseline
- Reduction in SCORAD index value from baseline [A]

Product Name: Dupixent	
Diagnosis	Eosinophilic Asthma
Approval Length	6 Months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe asthma

AND

2 - Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter [C, D]

AND

3 - Patient is 6 years of age or older

AND

4 - One of the following:

4.1 Patient has had at least two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months [4, 5, 7]

OR

4.2 Prior asthma-related hospitalization within the past 12 months [4, 5, E]

AND

5 - Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

5.1 Both of the following [4, 5, 7]:

- High-dose inhaled corticosteroid (ICS) (i.e., greater than 500 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium)

OR

5.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Symbicort [budesonide/formoterol], Breo Ellipta [fluticasone/vilanterol])

AND

6 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name: Dupixent	
Diagnosis	Eosinophilic Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy (e.g., reduction in exacerbations, improvement in FEV1, decreased use of rescue medications)

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications

AND

3 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name: Dupixent	
Diagnosis	Oral Corticosteroid Dependent Asthma
Approval Length	6 Months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe asthma

AND

2 - Patient is 6 years of age or older

AND

3 - Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

4 - Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

4.1 Both of the following [6]:

- High-dose inhaled corticosteroid (ICS) (i.e., greater than 500 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium)

OR

4.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Symbicort [budesonide/formoterol], Breo Ellipta [fluticasone/vilanterol])

AND

5 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name: Dupixent	
Diagnosis	Oral Corticosteroid Dependent Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy (e.g., reduction in exacerbations, improvement in FEV1, reduction in oral corticosteroid dose)

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications

AND

3 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name: Dupixent

Diagnosis	Chronic rhinosinusitis with nasal polyposis (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP)

AND

2 - Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone) [8, 9]

AND

3 - Used in combination with another agent for CRSwNP [F]

AND

4 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Otolaryngologist
- Pulmonologist

Product Name: Dupixent	
Diagnosis	Chronic rhinosinusitis with nasal polyposis (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS; 0-8 scale], improvement in nasal congestion/obstruction score [NC; 0-3 scale])

AND

2 - Used in combination with another agent for CRSwNP [F]

AND

3 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Otolaryngologist
- Pulmonologist

Product Name: Dupixent	
Diagnosis	Eosinophilic Esophagitis (EoE)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of eosinophilic esophagitis (EoE)

AND

2 - Patient has symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, gastroesophageal reflux disease [GERD]/heartburn symptoms, chest pain, abdominal pain) [13-15]

AND

3 - Patient has at least 15 intraepithelial eosinophils per high power field (HPF) [1, 13-15]

AND

4 - Other causes of esophageal eosinophilia have been excluded [13-15]

AND

5 - Both of the following:

- Patient is at least 12 years of age
- Patient weighs at least 40 kg

AND

6 - Trial and failure, contraindication, or intolerance to at least an 8-week trial of one of the following:

- Proton pump inhibitors (e.g., pantoprazole, omeprazole)
- Topical (esophageal) corticosteroids (e.g., budesonide, fluticasone)

AND

7 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- Allergist/Immunologist

Product Name: Dupixent	
Diagnosis	Eosinophilic Esophagitis (EoE)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy as evidenced by improvement of at least one of the following from baseline [1, 13-15]:

- Symptoms (e.g., dysphagia, food impaction, heartburn, chest pain)
- Histologic measures (e.g., esophageal intraepithelial eosinophil count)
- Endoscopic measures (e.g., edema, furrows, exudates, rings, strictures)

Product Name: Dupixent	
Diagnosis	Prurigo Nodularis (PN)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of prurigo nodularis (PN)

AND

2 - Patient has at least 20 nodular lesions

AND

3 - Trial and failure, contraindication, or intolerance to one previous PN treatment (e.g., topical corticosteroids, topical calcineurin inhibitors [pimecrolimus, tacrolimus], topical capsaicin) [16, 17]

AND

4 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Dermatologist

Product Name: Dupixent	
Diagnosis	Prurigo Nodularis (PN)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy as evidenced by at least ONE of the following:

- Reduction in the number of nodular lesions from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

3 . Background

Clinical Practice Guidelines

Table 1. Relative potencies of topical corticosteroids [2]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05

	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 2. Low, medium and high daily doses of inhaled corticosteroids in adolescents and adults 12 years and older [7]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	> 500-1000	> 1000
Beclometasone dipropionate (DPI or pMDI, extrafine particle*, HFA)	100-200	> 200-400	> 400

Budesonide (DPI, or pMDI, standard particle, HFA)	200-400	> 400-800	> 800
Ciclesonide (pMDI, extrafine particle*, HFA)	80-160	> 160-320	> 320
Fluticasone furoate (DPI)	100		200
Fluticasone propionate (DPI)	100-250	> 250-500	> 500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	> 250-500	> 500
Mometasone furoate (DPI)	Depends on DPI device – see product information		
Mometasone furoate (pMDI, standard particle, HFA)	200-400		> 400

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.

***This is not a table of equivalence**,* but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply potency equivalence. Doses may be country - specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

4 . Endnotes

A. The Scoring Atopic Dermatitis (SCORAD) index is a clinical tool for assessing the severity of atopic dermatitis lesions based on affected body area and intensity of plaque characteristics. [10, 11] The extent and severity of AD over the body area (A) and the severity of 6 specific symptoms (erythema, edema/papulation, excoriations, lichenification, oozing/crusts, and dryness) (B) are assessed and scored by the

Investigator. Subjective assessment of itch and sleeplessness is scored by the patient (C). The SCORAD score is a combined score (A/5 + 7B/2 + C) with a maximum of 103. Higher scores indicate greater severity/worsened state. A score of 25 to 50 indicates moderate disease severity and greater than 50 indicates severe disease. [12]

B. The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention update recommends that patients with asthma should be reviewed regularly to monitor their symptom control, risk factors and occurrence of exacerbations, as well as to document the response to any treatment changes. Ideally, response to Type 2-targeted therapy should be re-evaluated every 3-6 months, including re-evaluation of the need for ongoing biologic therapy for patients with good response to Type 2 targeted therapy.
C. In AS Trial 2, reductions in exacerbations were significant in the subgroup of subjects with baseline blood eosinophils greater than or equal to 150 cells/mcL. In subjects with baseline blood eosinophil count less than 150 cells/mcL, similar severe exacerbation rates were observed between Dupixent and placebo. [1]
D. The Institute for Clinical and Economic Review (ICER) defines eosinophilic inflammation as a blood eosinophil level greater than or equal to 150 cells per microliter at initiation of therapy. This is the lowest measured threshold for eosinophilic asthma in pivotal trials. [3]
E. Recommendation inferred from the national P&T committee meeting, December 2015, regarding similar agent first-in-class IL-5 antagonist Nucala (mepolizumab) in the use of severe eosinophilic asthma.
F. Other agents used for CRSwNP include intranasal corticosteroids and nasal saline.

5 . References

1. Dupixent Prescribing Information. Sanofi-aventis U.S. LLC. Bridgewater, NJ. October 2022.
2. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014; 71(1):116-32.
3. Institute for Clinical and Economic Review (ICER). Biologic therapies for treatment of asthma associated with type 2 inflammation: effectiveness, value, and value-based price benchmarks. https://icer.org/wp-content/uploads/2020/10/ICER_Asthma-Final-Report_Unredacted_08122020.pdf. Published December 20, 2018. Accessed March 2, 2021.
4. Wenzel S, Castro M, Corren J, et al. Dupilumab efficacy and safety in adults with uncontrolled persistent asthma despite use of medium-to-high dose inhaled corticosteroids plus a long-acting B2 agonist: a randomized double-blind placebo-controlled pivotal phase 2b dose-ranging trial. Lancet. 2016;388:31-44.
5. Castro M, Corren J, Pavord ID, et al. Dupilumab efficacy and safety in moderate-to-severe uncontrolled asthma. N Engl J Med. 2018; 378(26):2486-96.
6. Rabe KF, Nair P, Brusselle G, et al. Efficacy and safety of dupilumab in glucocorticoid-dependent severe asthma. N Engl J Med. 2018; 378(26):2475-85.
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13. Gonsalves NP, Aceves SS. Diagnosis and treatment of eosinophilic esophagitis. J Allergy Clin Immunol. 2020;145(1):1-7.
14. Hirano I, Chan ES, Rank MA, et al. AGA Institute and the Joint Task Force on allergy-immunology practice parameters clinical guidelines for the management of eosinophilic esophagitis. Gastroenterology. 2020;158:1776-86.
15. Dellon ES, Khoury P, Muir AB, et al. A clinical severity index for eosinophilic esophagitis: development, consensus, and future directions. Gastroenterology. 2022;1-18 [Epub ahead of print].
16. Williams KA, Huang AH, Belzberg M, et al. Prurigo nodularis: pathogenesis and management. J Am Acad Dermatol. 2020;83(6):1567-75.
17. Leis M, Fleming P, Lynde CW. Prurigo nodularis: review and emerging treatments. Skin Therapy Lett. 2021;26(3):5-8.

6 . Revision History

Date	Notes
4/26/2023	2023 UM Annual Review. No criteria changes. Background updates

Prior Authorization Guideline

Guideline ID	GL-109068
Guideline Name	Elaprase (idursulfase)

Guideline Note:

Effective Date:	9/1/2022
P&T Approval Date:	7/30/2004
P&T Revision Date:	07/08/2020 ; 07/21/2021 ; 7/20/2022

1 . Indications

Drug Name: Elaprase (idursulfase) [1]
Hunter Syndrome Is indicated for patients with Hunter syndrome (Mucopolysaccharidosis II, MPS II). Elaprase has been shown to improve walking capacity in patients 5 years and older. In patients 16 months to 5 years of age, no data are available to demonstrate improvement in disease-related symptoms or long term clinical outcome; however, treatment with Elaprase has reduced spleen volume similarly to that of adults and children 5 years of age and older. The safety and efficacy of Elaprase have not been established in pediatric patients less than 16 months of age.

2 . Criteria

Product Name: Elaprase (idursulfase)	
Approval Length	60 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Hunter syndrome (Mucopolysaccharidosis II, MPS II)

3 . References

1. Elaprase Prescribing Information. Takeda Pharmaceuticals U.S.A., Inc. Lexington, MA. October 2021.

4 . Revision History

Date	Notes
7/6/2022	Annual Review, no criteria changes.

Prior Authorization Guideline

Guideline Name	Elmiron (pentosan polysulfate sodium)

Guideline Note:

Effective Date:	1/1/2022
P&T Approval Date:	4/21/2021
P&T Revision Date:	

1 . Indications

Drug Name: Elmiron (pentosan polysulfate sodium)
Interstitial Cystitis Indicated for the relief of bladder pain or discomfort associated with interstitial cystitis.

2 . Criteria

Product Name: Elmiron	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of interstitial cystitis

AND

2 - Patient has bladder pain or discomfort

AND

3 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to two of the following: [2]

- Amitriptyline
- Cimetidine
- Hydroxyzine

Product Name: Elmiron	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

3 . References

1. Elmiron Prescribing Information. Janssen Pharmaceuticals, Inc. Titusville, NJ. June 2020.
2. Hanno PM, Erickson D, Moldwin R, et al. Diagnosis and treatment of interstitial cystitis/bladder pain syndrome: AUA guideline amendment. J Urol . 2015 May;193(5):1545-53. doi: 10.1016/j.juro.2015.01.086.

4 . Revision History

Date	Notes
9/15/2021	Addition of EHB Formulary to guideline

Prior Authorization Guideline

Guideline Name	Emflaza (deflazacort) - PA, NF

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	4/26/2017
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 08/19/2021 ; 05/19/2022 ; 5/18/2023

1 . Indications

Drug Name: Emflaza (deflazacort)
Duchenne muscular dystrophy (DMD) Indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older.

2 . Criteria

Product Name: Emflaza	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of Duchenne muscular dystrophy (DMD)

AND

2 - Patient has received genetic testing for a mutation of the dystrophin gene [A, 2]

AND

3 - One of the following [A, 2]:

3.1 Documentation of a confirmed mutation of the dystrophin gene

OR

3.2 Muscle biopsy confirmed an absence of dystrophin protein

AND

4 - Patient is 2 years of age or older

AND

5 - Prescribed by or in consultation with a neurologist who has experience treating children

AND

6 - Patient has had a trial and failure or intolerance to prednisone or prednisolone given at a dose of 0.75 mg/kg/day or 10 mg/kg/weekend [B, 3-5]

AND

7 - Dose will not exceed 0.9 milligrams per kilogram of body weight once daily

Product Name: Emflaza	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a benefit from therapy (e.g., improvement or preservation of muscle strength)

AND

2 - Dose will not exceed 0.9 milligrams per kilogram of body weight once daily

Product Name: Emflaza	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of Duchenne muscular dystrophy (DMD)

AND

2 - Patient has received genetic testing for a mutation of the dystrophin gene [A, 2]

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting one of the following [A, 2]:

3.1 Documentation of a confirmed mutation of the dystrophin gene

OR

3.2 Muscle biopsy confirmed an absence of dystrophin protein

AND

4 - Patient is 2 years of age or older

AND

5 - Prescribed by or in consultation with a neurologist who has experience treating children

AND

6 - Patient has had a trial and failure or intolerance to prednisone or prednisolone given at a dose of 0.75 mg/kg/day or 10 mg/kg/weekend [B, 3-5]

AND

7 - Dose will not exceed 0.9 milligrams per kilogram of body weight once daily

3 . Endnotes

A. Genetic testing after a positive biopsy diagnosis of Duchenne muscular dystrophy (DMD) is mandatory [2]. However a muscle biopsy is not necessary if a positive genetic diagnosis is confirmed first. In rare cases, when a genetic test has been done but no mutation has been found, a muscle biopsy is the next necessary step for patients who have increased creatine kinase concentrations and symptoms consistent with DMD.
B. Prednisone 0.75 mg/kg/d should be considered the optimal prednisone dose in DMD. Over 12 months, prednisone 10 mg/kg/weekend is equally effective, although long term outcomes of this alternative regimens are unknown [3].

4 . References

1. Emflaza Prescribing Information. PTC Therapeutics, Inc. South Plainfield, NJ. June 2021.
2. Bushby K, Finkel R, Birnkrant DJ, et al; DMD Care Considerations Working Group. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and pharmacological and psychosocial management. Lancet Neurol. 2010;9(1):77-93.
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5. FDA Center for Drug Evaluation and Research. Medical Review [Application Number 208684Orig1s000, 208685Orig1s000]. FDA Web site. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/208684,208685Orig1s000MedR.pdf. Accessed March 30, 2023.

5 . Revision History

Date	Notes
5/4/2023	Annual review: Updated Non Formulary criteria and background.

Prior Authorization Guideline

Guideline Name	Empliciti (elotuzumab)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	1/27/2016
P&T Revision Date:	01/15/2020 ; 05/14/2020 ; 02/18/2021 ; 02/17/2022 ; 3/15/2023

1 . Indications

Drug Name: Empliciti (elotuzumab)
Multiple myeloma Indicated in combination with lenalidomide and dexamethasone for the treatment of adult patient with multiple myeloma who have received one to three prior therapies. **Multiple myeloma** Indicated in combination with pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.

2 . Criteria

Product Name: Empliciti	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient has received at least one prior therapy for multiple myeloma [e.g., Revlimid (lenalidomide), Thalomid (thalidomide), Velcade (bortezomib)]

AND

2.1.2 Used in combination with both of the following: [2]

- Revlimid (lenalidomide)*
- Dexamethasone

OR

2.2 Both of the following:

2.2.1 Patient has received at least two prior therapies including Revlimid (lenalidomide) and a proteasome inhibitor

AND

2.2.2 Used in combination with both of the following: [2]

- Pomalyst (pomalidomide)**
- dexamethasone

AND

3 - Prescribed by or in consultation with a hematologist/oncologist	
Notes	*This product may require prior authorization.

Product Name: Empliciti	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on therapy	

3 . References

1. Empliciti Prescribing Information. Bristol-Myers Squibb Company. Princeton, NJ. March 2022.
2. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Multiple Myeloma v. 2.2020. Available by subscription at: http://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed February 27, 2023.

4 . Revision History

Date	Notes
2/27/2023	2023 Annual Review

Prior Authorization Guideline

Guideline Name	Emsam (selegiline transdermal system)

Guideline Note:

Effective Date:	9/1/2022
P&T Approval Date:	7/21/2021
P&T Revision Date:	7/20/2022

1 . Indications

Drug Name: Emsam (selegiline transdermal system)
Major Depressive Disorder Indicated for the treatment of adults with major depressive disorder (MDD).

2 . Criteria

Product Name: Emsam	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria	

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to two of the following generics:

- bupropion
- citalopram
- desvenlafaxine ER
- duloxetine
- escitalopram
- fluoxetine
- mirtazapine
- paroxetine
- paroxetine ER
- sertraline
- venlafaxine
- venlafaxine ER

OR

2.2 For continuation of prior therapy

3 . References

1. Emsam Prescribing Information. Mylan Specialty L.P. Morgantown, WV. May 2020.

4 . Revision History

Date	Notes
7/7/2022	Annual review: Updated criteria.

Prior Authorization Guideline

Guideline Name	Enbrel (etanercept)

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	5/15/2005
P&T Revision Date:	08/15/2019 ; 09/18/2019 ; 10/16/2019 ; 11/14/2019 ; 04/15/2020 ; 09/16/2020 ; 12/16/2020 ; 04/21/2021 ; 03/16/2022 ; 04/20/2022 ; 06/15/2022 ; 10/19/2022 ; 4/19/2023

1 . Indications

Drug Name: Enbrel
Rheumatoid Arthritis (RA) Indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis. Enbrel can be initiated in combination with methotrexate (MTX) or used alone. **Polyarticular Juvenile Idiopathic Arthritis (PJIA)** Indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients ages 2 and older. **Psoriatic Arthritis (PsA)** Indicated for reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis. Enbrel can be used with or without MTX. **Plaque Psoriasis (PsO)** Indicated for the treatment of patients 4 years of age and older with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Ankylosing Spondylitis (AS) Indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.

2 . Criteria

Product Name: Enbrel	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide
- sulfasalazine

Product Name: Enbrel	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Enbrel	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4]:

- leflunomide
- methotrexate

Product Name: Enbrel

Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Enbrel	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [5]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Product Name: Enbrel	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 5]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name: Enbrel	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe chronic plaque psoriasis

AND

2 - One of the following [6]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [7]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name: Enbrel	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1, 6]:

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name: Enbrel	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [8]

Product Name: Enbrel	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following [1, 8]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)

- Total active (swollen and tender) joint count

3 . References

1. Enbrel Prescribing Information. Amgen. Thousand Oaks, CA. June 2022.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.
3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.
4. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Rheumatol. 2019;71(6):846-863.
5. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
6. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
7. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.
8. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613.

4 . Revision History

Date	Notes
4/5/2023	Annual review - no criteria changes; background updates

Prior Authorization Guideline

Guideline Name	Enhertu (fam-trastuzumab deruxtecan-nxki)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	2/13/2020
P&T Revision Date:	02/18/2021 ; 03/17/2021 ; 02/17/2022 ; 06/15/2022 ; 10/19/2022 ; 3/15/2023

1 . Indications

Drug Name: Enhertu (fam-trastuzumab deruxtecan-nxki)
Breast cancer Indicated for the treatment of adult patients with unresectable or metastatic human epidermal growth factor receptor 2 (HER2) - positive breast cancer who have received a prior anti-HER2-based regimen in either the metastatic setting or in the neoadjuvant or adjuvant setting and have developed disease recurrence during or within six months of completing therapy. **Breast cancer** Indicated for the treatment of adult patients with unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy. **Gastric Cancer** Indicated for the treatment of adult patients with locally advanced or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen. **Non-Small Cell Lung Cancer** Indicated for the treatment of adult patients with unresectable or metastatic non-small cell lung cancer (NSCLC) whose tumors have activating HER2 (ERBB2) mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy. This indication is approved under accelerated approval based on objective

response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

2 . Criteria

Product Name: Enhertu	
Diagnosis	Gastric Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastric or gastroesophageal junction (GEJ) adenocarcinoma

AND

2 - Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

3 - Disease is ONE of the following:

- Locally advanced
- Metastatic

AND

4 - Patient has received a prior trastuzumab-based regimen (e.g., Kanjinti, Trazimera)

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Enhertu	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Disease is ONE of the following:

- Unresectable
- Metastatic

AND

3 - One of the following:

3.1 Both of the following:

- Disease is human epidermal growth factor receptor 2 (HER2)-positive
- Patient has received one prior anti-HER2-based regimens (e.g. trastuzumab + pertuzumab + docetaxel, ado-trastuzumab emtansine) [2] [3]

OR

3.2 Both of the following:

- Disease is HER2-low
- Patient has received a prior chemotherapy

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Enhertu	
Diagnosis	Non-Small Cell Lung Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Non-Small Cell Lung Cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Unresectable
- Metastatic

AND

3 - Patient has known active human epidermal growth factor receptor 2 (HER2) ERBB2 mutations as detected by a U.S. Food and Drug Administration (FDA) -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - Patient has received a prior systemic therapy (e.g., chemotherapy)

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Enhertu	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on therapy	

3 . References

1. Enhertu Prescribing Information. Daiichi Sankyo, Inc., Basking Ridge, NJ. August 2022.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Breast Cancer. v.3.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed August 22, 2022.
3. Modi S, Saura C, Yamashita T, et al. Trastuzumab Deruxtecan in previously treated HER2-positive breast cancer. N Engl J Med, 2019 December.
4. Shitara K, Bang YJ, Iwasa S, et al. DESTINY-Gastric01 Investigators. Trastuzumab Deruxtecan in Previously Treated HER2-Positive Gastric Cancer. N Engl J Med. 2020 June.

4 . Revision History

Date	Notes
2/27/2023	2023 Annual Review

Prior Authorization Guideline

Guideline Name	Epclusa (sofosbuvir/velpatasvir) - PA, NF

Guideline Note:

Effective Date:	8/23/2022
P&T Approval Date:	6/22/2016
P&T Revision Date:	05/14/2020 ; 12/16/2020 ; 06/16/2021 ; 11/18/2021 ; 01/19/2022 ; 06/15/2022 ; 6/15/2022

1 . Indications

Drug Name: Epclusa (sofosbuvir and velpatasvir)
Chronic hepatitis C virus (HCV) Indicated for the treatment of adults and pediatric patients 3 years of age and older with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis, and with decompensated cirrhosis for use in combination with ribavirin.

2 . Criteria

Product Name: Epclusa*	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 1, 2, 3, 4, 5, or 6
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 1, 2, 3, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient does NOT have decompensated liver disease (Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

Notes	*Approve brand Epclusa at NDC level (i.e., closed NDC) if criteria are met.

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 1, 4, 5, or 6
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 1, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient does NOT have decompensated liver disease (Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - One of the following:

5.1 Both of the following:

5.1.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

5.1.2 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

5.2 For continuation of prior brand sofosbuvir/velpatasvir

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 1, 4, 5, or 6
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C virus genotype 1, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient does NOT have decompensated liver disease (Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - One of the following:

5.1 Both of the following:

5.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

5.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

5.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 2, 3
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 2 or 3

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient does NOT have decompensated liver disease (Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - One of the following:

5.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to BOTH of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Mavyret (glecaprevir/pibrentasvir)

OR

5.2 For continuation of prior brand sofosbuvir/velpatasvir

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 2, 3
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C virus genotype 2 or 3

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient does not have decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - One of the following:

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to BOTH of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Mavyret (glecaprevir/pibrentasvir)

OR

5.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Epclusa*	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6 - Patients with Decompensated Liver Disease - Epclusa plus ribavirin
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 1, 2, 3, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Both of the following:

- Patient has decompensated liver disease (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

Notes	*Approve brand Epclusa at NDC level (i.e., closed NDC) if criteria are met.

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 - Patients with Decompensated Liver Disease - Epclusa plus ribavirin
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 1, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Both of the following:

- Patient has decompensated liver disease (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - Trial and failure or intolerance to ONE of the following:

- Brand Epclusa
- Brand Harvoni (ledipasvir/sofosbuvir)

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 - Patients with Decompensated Liver Disease - Epclusa plus ribavirin
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C virus genotype 1, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Both of the following:

- Patient has decompensated liver disease (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to ONE of the following:

- Brand Epclusa
- Brand Harvoni (ledipasvir/sofosbuvir)

Product Name: Brand sofosbuvir/velpatasvir

Diagnosis	Chronic Hepatitis C - Genotype 2, 3 - Patients with Decompensated Liver Disease - Epclusa plus ribavirin
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 2 or 3

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Both of the following:

- Patient has decompensated liver disease (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - Trial and failure or intolerance to Brand Epclusa, unless already receiving sofosbuvir/velpatasvir therapy

Product Name: Brand sofosbuvir/velpatasvir

Diagnosis	Chronic Hepatitis C - Genotype 2, 3 - Patients with Decompensated Liver Disease - Epclusa plus ribavirin
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C virus genotype 2 or 3

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Both of the following:

- Patient has decompensated liver disease (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - One of the following:

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to Brand Epclusa

OR

5.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Epclusa*	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6 - Patients with Decompensated Liver Disease - Ribavirin Intolerance/Ineligible OR Prior Sofosbuvir or NS5A-based Treatment Failure
Approval Length	24 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 1, 2, 3, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient has decompensated liver disease (Child-Pugh Class B or C)

AND

4 - One of the following:

4.1 Patient is ribavirin intolerant or ineligible

OR

4.2 Both of the following:

4.2.1 Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based treatment

AND

4.2.2 Used in combination with ribavirin

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

Notes	*Approve brand Epclusa at NDC level (i.e., closed NDC) if criteria are met.

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 - Patients with Decompensated Liver Disease - Ribavirin Intolerance/Ineligible OR Prior Sofosbuvir or NS5A-based Treatment Failure
Approval Length	24 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 1, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient has decompensated liver disease (Child-Pugh Class B or C)

AND

4 - One of the following:

4.1 Patient is ribavirin intolerant or ineligible

OR

4.2 Both of the following:

4.2.1 Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based treatment

AND

4.2.2 Used in combination with ribavirin

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

6 - Trial and failure or intolerance to ONE of the following:

- Brand Epclusa

- Brand Harvoni (ledipasvir/sofosbuvir)

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 - Patients with Decompensated Liver Disease - Ribavirin Intolerance/Ineligible OR Prior Sofosbuvir or NS5A-based Treatment Failure
Approval Length	24 Week(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C virus genotype 1, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient has decompensated liver disease (Child-Pugh Class B or C)

AND

4 - One of the following:

4.1 Patient is ribavirin intolerant or ineligible

OR

4.2 Both of the following:

4.2.1 Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based treatment

AND

4.2.2 Used in combination with ribavirin

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to ONE of the following:

- Brand Epclusa
- Brand Harvoni (ledipasvir/sofosbuvir)

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 2, 3 - Patients with Decompensated Liver Disease - Ribavirin Intolerance/Ineligible OR Prior Sofosbuvir or NS5A-based Treatment Failure
Approval Length	24 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 2 or 3

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient has decompensated liver disease (Child-Pugh Class B or C)

AND

4 - One of the following:

4.1 Patient is ribavirin intolerant or ineligible

OR

4.2 Both of the following:

4.2.1 Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based treatment

AND

4.2.2 Used in combination with ribavirin

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

6 - Trial and failure or intolerance to Brand Epclusa, unless already receiving sofosbuvir/velpatasvir therapy

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 2, 3 - Patients with Decompensated Liver Disease - Ribavirin Intolerance/Ineligible OR Prior Sofosbuvir or NS5A-based Treatment Failure
Approval Length	24 Week(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C virus genotype 2 or 3

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient has decompensated liver disease (Child-Pugh Class B or C)

AND

4 - One of the following:

4.1 Patient is ribavirin intolerant or ineligible

OR

4.2 Both of the following:

4.2.1 Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based treatment

AND

4.2.2 Used in combination with ribavirin

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

6 - One of the following:

6.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to Brand Epclusa

OR

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

3 . References

1. Epclusa Prescribing Information. Gilead Science, Inc. Foster City, CA. April 2022.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. September 2021. http://www.hcvguidelines.org/full-report-view. Accessed May 16, 2022.

4 . Revision History

Date	Notes
8/23/2022	Background update

Prior Authorization Guideline

Guideline Name	Epidiolex (cannabidiol)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	8/16/2018
P&T Revision Date:	05/14/2020 ; 10/21/2020 ; 05/20/2021 ; 05/19/2022 ; 5/18/2023

1 . Indications

Drug Name: Epidiolex (cannabidiol oral solution)
Lennox-Gastaut syndrome (LGS) Indicated for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 1 year of age and older. **Dravet syndrome (DS)** Indicated for the treatment of seizures associated with Dravet syndrome (DS) in patients 1 year of age and older. **Tuberous sclerosis complex (TSC)** Indicated for the treatment of seizures associated with tuberous sclerosis complex (TSC) in patients 1 year of age and older.

2 . Criteria

Product Name: Epidiolex	
Diagnosis	Lennox-Gastaut syndrome (LGS)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS)

AND

2 - Trial of, contraindication, or intolerance to TWO formulary anticonvulsants (e.g., topiramate, lamotrigine, valproate) [2, A-B]

AND

3 - Patient is 1 year of age or older

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Epidiolex	
Diagnosis	Dravet syndrome (DS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of seizures associated with Dravet syndrome (DS)

AND

2 - Patient is 1 year of age or older

AND

3 - Prescribed by or in consultation with a neurologist

Product Name: Epidiolex	
Diagnosis	Tuberous sclerosis complex
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of seizures associated with tuberous sclerosis complex (TSC)

AND

2 - Patient is 1 year of age or older

AND

3 - Prescribed by or in consultation with a neurologist

Product Name: Epidiolex	
Diagnosis	Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), Tuberous sclerosis complex (TSC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

3 . Endnotes

A. The effectiveness of Epidiolex for the treatment of seizures associated with LGS was established in two randomized, double-blind, placebo-controlled trials in patients aged 2 to 55 years. In study 2, 225 patients underwent randomization, of whom 76 were assigned to the 20-mg cannabidiol group, 73 to the 10-mg cannabidiol group, and 76 to the placebo group; Patients in each group had previously received a median of 6 antiepileptic drugs (range, 0 to 22), but the drugs had failed to control the seizures; the patients were receiving a median of 3 antiepileptic drugs concomitantly at the time of trial entry. [3]
B. To improve patient care and facilitate clinical research, the International League Against Epilepsy (ILAE) appointed a Task Force to formulate a consensus definition of drug resistant epilepsy. The following definition was formulated: Drug resistant epilepsy may be defined as failure of adequate trials of two tolerated and appropriately chosen and used antiepileptic drug (AED) schedules (whether as monotherapies or in combination) to achieve sustained seizure freedom. [4]

4 . References

1. Epidiolex Prescribing Information. Greenwich Biosciences, Inc. Carlsbad, CA. April 2022.
2. Per clinical consult with neurologist, July 30, 2018.
3. Devinsky O, Patel AD, Cross JH, et al. Effect of cannabidiol on drop seizures in the Lennox-Gastaut syndrome. N Engl J Med. 2018 May 17;378(20):1888-1897.
4. Kwan P, Arzimanoglou A, Berg AT, et al. Definition of drug resistant epilepsy: consensus proposal by the ad hoc Task Force of the ILAE Commission on Therapeutic Strategies. Epilepsia. 2010 Jun;51(6):1069-77.

5 . Revision History

Date	Notes
4/6/2023	Annual review - No criteria changes

Prior Authorization Guideline

Guideline Name	Ergot Alkaloids

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	4/15/2020
P&T Revision Date:	12/16/2020 ; 04/21/2021 ; 06/16/2021 ; 11/18/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: D.H.E. 45 (dihydroergotamine mesylate) injection
Migraine Indicated for the acute treatment of migraine headaches with or without aura. **Cluster Headache** Indicated for the acute treatment of cluster headache episodes.
Drug Name: Migranal (dihydroergotamine mesylate) nasal spray
Migraine Indicated for the acute treatment of migraine headaches with or without aura. Not intended for the prophylactic therapy of migraine or for the management of hemiplegic or basilar migraine.
Drug Name: Cafergot (ergotamine tartrate and caffeine) tablet, Ergomar (ergotamine tartrate) sublingual tablet, Migergot (ergotamine tartrate and caffeine) suppository
Headache Indicated as therapy to abort or prevent vascular headache, e.g., migraine, migraine variants, or so-called “histaminic cephalalgia”.
Drug Name: Trudhesa (dihydroergotamine mesylate) nasal spray

Migraine Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: - Not indicated for the preventive treatment of migraine. - Not indicated for the management of hemiplegic or basilar migraine.

2 . Criteria

Product Name: Brand Cafergot tablet, Generic ergotamine tartrate/caffeine tablet, Brand D.H.E. 45 injection, Generic dihydroergotamine mesylate injection, Ergomar sublingual tablet, Migergot suppository, Brand Migranal nasal spray, Generic dihydroergotamine mesylate nasal spray, or Trudhesa nasal spray	
Diagnosis	Migraines
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine headaches with or without aura

AND

2 - Will be used for the acute treatment of migraine

AND

3 - Patient is 18 years of age or older [A]

AND

4 - One of the following: [3]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

5 - If patient has 4 or more headache days per month, patient must be currently treated with one of the following, unless there is a contraindication or intolerance to these medications: [B, 4]

- An antidepressant (i.e., Elavil [amitriptyline] or Effexor [venlafaxine])
- An anticonvulsant (i.e., Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate])
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol)
- Atacand (candesartan)

AND

6 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [C]

Product Name: Brand Cafergot tablet, Generic ergotamine tartrate/caffeine tablet, Brand D.H.E. 45 injection, Generic dihydroergotamine mesylate injection, Ergomar sublingual tablet, Migergot suppository, Brand Migranal nasal spray, Generic dihydroergotamine mesylate nasal spray, or Trudhesa nasal spray	
Diagnosis	Migraines
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)

AND

2 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [C]

Product Name: Brand Cafergot tablet, Generic ergotamine tartrate/caffeine tablet, Brand D.H.E. 45 injection, Generic dihydroergotamine mesylate injection, Ergomar sublingual tablet, or Migergot suppository	
Diagnosis	Cluster Headaches
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cluster headache

AND

2 - Patient is 18 years of age or older [A]

AND

3 - Trial and failure, contraindication, or intolerance to sumatriptan injection [5]

AND

4 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [C]

Product Name: Brand Cafergot tablet, Generic ergotamine tartrate/caffeine tablet, Brand D.H.E. 45 injection, Generic dihydroergotamine mesylate injection, Ergomar sublingual tablet, or Migergot suppository	
Diagnosis	Cluster Headaches
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [C]

3 . Endnotes

A. The safety and effectiveness in pediatric patients has not been established. [1, 2]
B. The American Academy of Neurology supports the use of the following medications for the prevention of episodic migraine in adult patients (with level A or B evidence): antidepressants [i.e., Elavil (amitriptyline), Effexor (venlafaxine)], antiepileptics [i.e., Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], beta-blockers [i.e., atenolol, propranolol, nadolol, timolol, metoprolol], and candesartan. [3, 4]
C. Headache specialists are physicians certified by the United Council for Neurologic Subspecialties (UCNS) [6]

4 . References

1. D.H.E. 45 Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. April 2022.
2. Migranal Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. April 2022.

3. AHS Consensus Statement. Update on integrating new migraine treatments into clinical practice. Headache. 2021 Jul;61(7):1021-1039.
4. Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016 May 10;86(19):1818-26.
5. Robbins MS, Starling AJ, Pringsheim TM, et al. Treatment of Cluster Headache: The American Headache Society Evidence-Based Guidelines. Headache. 2016 Jul;56(7):1093-106.
6. United Council for Neurologic Subspecialties website. www.ucns.org. Accessed March 9, 2023.
7. Cafergot Prescribing Information. Sandoz Inc. Princeton, NJ. May 2018
8. Ergomar Prescribing Information. TerSera Therapeutics LLC. Deerfield, IL. February 2020.
9. Migergot Prescribing Information. Cosette Pharmaceuticals, Inc.. South Plainfield, NJ. June 2020.
10. Trudhesa Prescribing Information. Impel NeuroPharma Inc. Seattle, WA. September 2021.

5 . Revision History

Date	Notes
4/5/2023	Annual review: Updated migraine criteria and background.

Prior Authorization Guideline

Guideline Name	Erivedge (vismodegib)

Guideline Note:

Effective Date:	11/1/2022
P&T Approval Date:	4/10/2012
P&T Revision Date:	09/18/2019 ; 09/16/2020 ; 09/15/2021 ; 9/21/2022

1 . Indications

Drug Name: Erivedge (vismodegib)
Basal cell carcinoma Indicated for the treatment of adults with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation.

2 . Criteria

Product Name: Erivedge	
Diagnosis	Basal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of metastatic basal cell carcinoma

OR

1.2 Both of the following:

1.2.1 Diagnosis of locally advanced basal cell carcinoma

AND

1.2.2 One of the following:

- Disease recurred following surgery
- Patient is not a candidate for both surgery and radiation

AND

2 - Prescribed by or in consultation with one of the following [3]:

- Dermatologist
- Oncologist

Product Name: Erivedge	
Diagnosis	Basal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Erivedge Prescribing Information. Genentech USA Inc. South San Francisco, CA. August 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed August 4, 2020..
3. Per clinical consult with oncologist, February 24, 2011.

4 . Revision History

Date	Notes
9/9/2022	Annual Review - reauth verbiage updated to include "while on therapy". Patient characteristics updated to require patient is not a candidate for both surgery AND radiation.

Prior Authorization Guideline

Guideline Name	Erythropoietic Agents - PA, NF

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	3/17/2000
P&T Revision Date:	11/14/2019 ; 04/15/2020 ; 11/12/2020 ; 01/20/2021 ; 11/18/2021 ; 12/15/2021 ; 02/17/2022 ; 11/17/2022

1 . Indications

Drug Name: Aranesp (darbepoetin alfa)
Anemia Due to Chronic Kidney Disease Indicated for the treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and patients not on dialysis. **Anemia Due to Chemotherapy in Patients with Cancer** Indicated for treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of 2 additional months of planned chemotherapy. Limitations of Use: Aranesp has not been shown to improve quality of life, fatigue, or patient well-being. Aranesp is not indicated for use: (1) In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy; (2) In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure; (3) In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion; and (4) As a substitute for red blood cell (RBC) transfusions in patients who require immediate correction of anemia. **Off Label Uses: Anemia in patients with Myelodysplastic Syndrome (MDS)** Has been used for the treatment of anemia in patients with MDS. [20]

Drug Name: Epogen (epoetin alfa), Procrit (epoetin alfa), and Retacrit (epoetin alfa-epbx)
Anemia Due to Chronic Kidney Disease Indicated for the treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and not on dialysis to decrease the need for red blood cell (RBC) transfusion. **Anemia Due to Zidovudine in Patients with HIV-infection** Indicated for the treatment of anemia due to zidovudine administered at less than or equal to 4200 mg/week in patients with HIV-infection with endogenous serum erythropoietin levels of less than or equal to 500 mUnits/mL. **Anemia Due to Chemotherapy in Patients with Cancer** Indicated for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy and upon initiation, there is a minimum of 2 additional months of planned chemotherapy. Limitations of Use: Epoetin alfa has not been shown to improve quality of life, fatigue, or patient well-being. Epoetin alfa is not indicated for use: (1) In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy; (2) In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure; (3) In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion; (4) As a substitute for red blood cell (RBC) transfusions in patients who require immediate correction of anemia. **Reduction of Allogeneic Red Blood Cell Transfusions in Patients Undergoing Elective, Noncardiac, Nonvascular Surgery** Indicated to reduce the need for allogeneic RBC transfusions among patients with perioperative hemoglobin greater than 10 to less than or equal to 13 g/dL who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery. Epoetin alfa is not indicated for patients who are willing to donate autologous blood preoperatively. Limitations of Use: Epoetin alfa has not been shown to improve quality of life, fatigue, or patient well-being. Epoetin alfa is not indicated for use: (1) In patients scheduled for surgery who are willing to donate autologous blood; (2) In patients undergoing cardiac or vascular surgery. **Off Label Uses: Anemia associated with HIV infection** Have been used for the treatment of anemia associated with HIV infection in patients not receiving zidovudine. [5] **Anemia in Hepatitis C virus (HCV) infected patients due to combination therapy of ribavirin and interferon or peg-interferon** Have been used for the treatment of anemia in patients with hepatitis C virus (HCV) infection who are being treated with the combination of ribavirin and interferon or peginterferon alfa. [20] **Anemia in patients with Myelodysplastic Syndrome (MDS)** Have been used for the treatment of anemia in patients with MDS. [5, 20]
Drug Name: Mircera (methoxy polyethylene glycol-epoetin beta)
Anemia Due to Chronic Kidney Disease Indicated for the treatment of anemia associated with chronic kidney disease (CKD) in: (1) adult patients on dialysis and adult patients not on dialysis; (2) pediatric patients 5 to 17 years of age on hemodialysis who are converting from

another ESA after their hemoglobin level was stabilized with an ESA. Limitations of use: Mircera is not indicated and is not recommended: (1) In the treatment of anemia due to cancer chemotherapy; or (2) As a substitute for RBC transfusions in patients who require immediate correction of anemia. Mircera has not been shown to improve symptoms, physical functioning, or health-related quality of life.

2 . Criteria

Product Name: Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia Due to Chronic Kidney Disease (CKD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - Verification of iron evaluation for adequate iron stores^ [A, J]

AND

3 - Verification of anemia as defined by one of the following laboratory values collected within 30 days of the request: [1-3, 9, 13-17, 29, 33, B]

- Hematocrit (Hct) less than 30%
- Hemoglobin (Hgb) less than 10 g/dL

AND

4 - One of the following: [1-3, 33, L]

4.1 Patient is on dialysis

OR

4.2 All of the following:

4.2.1 Patient is NOT on dialysis

AND

4.2.2 The rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion

AND

4.2.3 Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal

AND

5 - History of use or unavailability of both of the following (applies to Epogen only): [O]

- Aranesp
- Retacrit or Procrit

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

Product Name: Mircera	
Diagnosis	Anemia Due to Chronic Kidney Disease (CKD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - Verification of iron evaluation for adequate iron stores^ [A, J]

AND

3 - One of the following:

3.1 All of the following:

3.1.1 Patient is greater than or equal to 18 years of age

AND

3.1.2 Verification of anemia as defined by one of the following laboratory values collected within 30 days of the request: [9, 13-17, 29, 31, B]

- Hematocrit (Hct) less than 30%
- Hemoglobin (Hgb) less than 10 g/dL

AND

3.1.3 One of the following: [31]

3.1.3.1 Patient is on dialysis

OR

3.1.3.2 All of the following:

3.1.3.2.1 Patient is NOT on dialysis

AND

3.1.3.2.2 The rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion

AND

3.1.3.2.3 Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal

OR

3.2 All of the following:

3.2.1 Patient is between 5 and 17 years of age

AND

3.2.2 Patient is on hemodialysis

AND

3.2.3 Patient's hemoglobin level has been stabilized by treatment with another erythropoietin stimulating agent (ESA) (e.g., Aranesp, Retacrit)

AND

3.2.4 Patient is converting to Mircera from another ESA (e.g., Aranesp, Retacrit)

AND

4 - History of use or unavailability of both of the following: [O]

- Aranesp
- Retacrit or Procrit

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

Product Name: Aranesp, Epogen, Mircera, Procrit, or Retacrit	
Diagnosis	Anemia Due to Chronic Kidney Disease (CKD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - One of the following:

2.1 Both of the following:

- Patient is on dialysis
- Most recent or average Hct over 3 months is 33% or less (Hgb 11 g/dL or less)

OR

2.2 Both of the following:

- Patient is not on dialysis
- Most recent or average (avg) Hct over 3 mo is 30% or less (Hgb 10 g/dL or less)

OR

2.3 Both of the following:

- Request is for a pediatric patient
- Most recent or average Hct over 3 mo is 36% or less (Hgb 12 g/dL or less)

AND

3 - One of the following: [1-3, 31, 33]

3.1 Decrease in the need for blood transfusion

OR

3.2 Hemoglobin (Hgb) increased greater than or equal to 1g/dL from pre-treatment level

AND

4 - Verification of iron evaluation for adequate iron stores^ [A, J]

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

Product Name: Epogen, Procrit	
Diagnosis	Anemia Due to Chronic Kidney Disease (CKD)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - Verification of iron evaluation for adequate iron stores^ [A, J]

AND

3 - Verification of anemia as defined by one of the following laboratory values collected within 30 days of the request: [1-3, 9, 13-17, 29, 33, B]

- Hematocrit (Hct) less than 30%
- Hemoglobin (Hgb) less than 10 g/dL

AND

4 - One of the following: [1-3, 33, L]

4.1 Patient is on dialysis

OR

4.2 All of the following:

4.2.1 Patient is NOT on dialysis

AND

4.2.2 The rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion

AND

4.2.3 Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming history of use or unavailability of both of the following (applies to Epogen only): [O]

- Aranesp

• Retacrit or Procrit	
Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

Product Name: Epogen, Procrit, or Retacrit	
Diagnosis	Anemia in Patients with HIV-infection
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Verification of iron evaluation for adequate iron stores^ [2-3, 33]

AND

2 - Verification of anemia as defined by one of the following laboratory values collected within 30 days of the request:

- Hemoglobin (Hgb) less than 12 g/dL [11, 25-28, K]
- Hematocrit (Hct) less than 36%

AND

3 - Serum erythropoietin level less than or equal to 500 mU/mL [2-3, 24, 26, 33]

AND

4 - One of the following:

- Patient is receiving zidovudine therapy [2-3, 33]
- Diagnosis of HIV infection [off-label] [5, 11, 24-28]

AND

5 - History of use or unavailability of Retacrit or Procrit (applies to Epogen only) [O]

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

Product Name: Epogen, Procrit, or Retacrit	
Diagnosis	Anemia in Patients with HIV-infection
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Verification of anemia as defined by one of the following: [2, 3, 33]

- Most recent or average hematocrit (Hct) over a 3-month period was below 36%
- Most recent or average hemoglobin (Hgb) over a 3-month period was below 12 g/dL

AND

2 - One of the following: [2, 3, 33]

2.1 Decrease in the need for blood transfusion

OR

2.2 Hemoglobin (Hgb) increased greater than or equal to 1g/dL from pre-treatment level

Product Name: Epogen, Procrit	
Diagnosis	Anemia in Patients with HIV-infection
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Verification of iron evaluation for adequate iron stores^ [2-3, 33]

AND

2 - Verification of anemia as defined by one of the following laboratory values collected within 30 days of the request:

- Hemoglobin (Hgb) less than 12 g/dL [11, 25-28, K]
- Hematocrit (Hct) less than 36%

AND

3 - Serum erythropoietin level less than or equal to 500 mU/mL [2-3, 24, 26, 33]

AND

4 - One of the following:

- Patient is receiving zidovudine therapy [2-3, 33]
- Diagnosis of HIV infection [off-label] [5, 11, 24-28]

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming history of use or unavailability of Retacrit or Procrit (applies to Epogen only) [O]

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

Product Name: Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia Due to Chemotherapy in Patients with Cancer
Approval Length	3 Months [C]
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Verification that other causes of anemia have been ruled out [1-3, 33, M]

AND

2 - Verification of anemia as defined by one of the following laboratory values collected within the prior two weeks of the request: [1-3, 33]

- Hematocrit (Hct) less than 30%
- Hemoglobin (Hgb) less than 10 g/dL [N]

AND

3 - Verification of iron evaluation for adequate iron stores ^ [1-3, 8, 33, G]

AND

4 - Verification that the cancer is a non-myeloid malignancy [1-3, 33, F]

AND

5 - Patient is receiving chemotherapy [1-3, 33, D]

AND

6 - History of use or unavailability of both of the following (applies to Epogen only): [O]

- Aranesp
- Retacrit or Procrit

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

Product Name: Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia Due to Chemotherapy in Patients with Cancer
Approval Length	3 Months [C]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Verification of anemia as defined by one of the following laboratory values collected within the prior two weeks of the request: [1-3, 33]

- Hemoglobin (Hgb) less than 10 g/dL
- Hematocrit (Hct) less than 30% [10, 18-19]

AND

2 - One of the following: [1-3, 33]

2.1 Decrease in the need for blood transfusion

OR

2.2 Hemoglobin (Hgb) increased greater than or equal to 1 g/dL from pre-treatment level

AND

3 - Patient is receiving chemotherapy [D]

Product Name: Epogen, Procrit	
Diagnosis	Anemia Due to Chemotherapy in Patients with Cancer
Approval Length	3 Months [C]
Guideline Type	Non Formulary

Approval Criteria

1 - Verification that other causes of anemia have been ruled out [1-3, 33, M]

AND

2 - Verification of anemia as defined by one of the following laboratory values collected within the prior two weeks of the request: [1-3, 33]

- Hematocrit (Hct) less than 30%
- Hemoglobin (Hgb) less than 10 g/dL [N]

AND

3 - Verification of iron evaluation for adequate iron stores ^ [1-3, 8, 33, G]

AND

4 - Verification that the cancer is a non-myeloid malignancy [1-3, 33, F]

AND

5 - Patient is receiving chemotherapy [1-3, 33, D]

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming history of use or unavailability of both of the following (applies to Epogen only): [O]

- Aranesp
- Retacrit or Procrit

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

Product Name: Epogen, Procrit, or Retacrit

Diagnosis	Preoperative use for reduction of allogeneic blood transfusion in patients undergoing surgery
Approval Length	1 month [2]
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery

AND

2 - Hemoglobin (Hgb) is greater than 10 to less than or equal to 13 g/dL

AND

3 - Patient is at high risk for perioperative transfusions

AND

4 - Patient is unwilling or unable to donate autologous blood pre-operatively

AND

5 - Verification of iron evaluation for adequate iron stores^ [2-3, 33]

AND

6 - History of use or unavailability of Retacrit or Procrit (applies to Epogen only) [O]

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

Product Name: Epogen, Procrit

Diagnosis	Preoperative use for reduction of allogeneic blood transfusion in patients undergoing surgery
Approval Length	1 month [2]
Guideline Type	Non Formulary

Approval Criteria

1 - Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery

AND

2 - Hemoglobin (Hgb) is greater than 10 to less than or equal to 13 g/dL

AND

3 - Patient is at high risk for perioperative transfusions

AND

4 - Patient is unwilling or unable to donate autologous blood pre-operatively

AND

5 - Verification of iron evaluation for adequate iron stores^ [2-3, 33]

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming history of use or unavailability of Retacrit or Procrit (applies to Epogen only) [O]

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

Product Name: Aranesp, Epogen, Procrit, or Retacrit

Diagnosis	Anemia in Myelodysplastic Syndrome (MDS) patients [off-label] [4-6, 20]
Approval Length	3 months [I]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Myelodysplastic Syndrome (MDS) [4]

AND

2 - One of the following: [4]

- Serum erythropoietin level less than or equal to 500 mU/mL
- Diagnosis of transfusion-dependent MDS

AND

3 - Verification of iron evaluation for adequate iron stores ^ [4, A, H]

AND

4 - History of use or unavailability of both of the following (applies to Epogen only): [O]

- Aranesp
- Retacrit or Procrit

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

Product Name: Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia in Myelodysplastic Syndrome (MDS) patients [off-label]
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Verification of anemia as defined by one of the following: [4, E]

- Most recent or average hematocrit (Hct) over a 3-month period was less than or equal to 36%
- Most recent or average hemoglobin (Hgb)over a 3-month period was less than or equal to 12 g/dL

AND

2 - One of the following: [1-3, 33]

2.1 Decrease in the need for blood transfusion

OR

2.2 Hemoglobin (Hgb) increased greater than or equal to 1 g/dL from pre-treatment level

Product Name: Epogen, Procrit	
Diagnosis	Anemia in Myelodysplastic Syndrome (MDS) patients [off-label] [4-6, 20]
Approval Length	3 months [I]
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Myelodysplastic Syndrome (MDS) [4]

AND

2 - One of the following: [4]

- Serum erythropoietin level less than or equal to 500 mU/mL
- Diagnosis of transfusion-dependent MDS

AND

3 - Verification of iron evaluation for adequate iron stores ^ [4, A, H]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming history of use or unavailability of both of the following (applies to Epogen only): [O]

- Aranesp
- Retacrit or Procrit

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

Product Name: Epogen, Procrit, or Retacrit	
Diagnosis	Anemia in HCV-infected patients due to ribavirin in combination with interferon or peg-interferon [off-label] [6]
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hepatitis C viral (HCV) infection [12, 20]

AND

2 - Verification of iron evaluation for adequate iron stores^ [2-3, 33]

AND

3 - Verification of anemia as defined by one of the following laboratory values collected within 30 days of the request: [P]

- Hematocrit (Hct) less than 36%
- Hemoglobin (Hgb) less than 12 g/dL

AND

4 - Verification of both of the following:

4.1 Patient is receiving ribavirin

AND

4.2 Patient is receiving one of the following:

- interferon alfa-2b
- interferon alfacon-1
- peginterferon alfa-2b
- peginterferon alfa-2a

AND

5 - History of use or unavailability of Retacrit or Procrit (applies to Epogen only) [O]

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

Product Name: Epogen, Procrit, or Retacrit	
Diagnosis	Anemia in HCV-infected patients due to ribavirin in combination with interferon or peg-interferon [off-label]
Approval Length	3 Months or if patient has demonstrated response to therapy, authorization will be issued for the full course of ribavirin therapy.
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Verification of anemia as defined by one of the following: [35]

- Most recent or average hematocrit (Hct) over a 3-month period was 36% or less
- Most recent or average hemoglobin (Hgb) over a 3-month period was 12 g/dL or less

AND

2 - One of the following: [2, 3, 33]

2.1 Decrease in the need for blood transfusion

OR

2.2 Hemoglobin (Hgb) increased greater than or equal to 1 g/dL from pre-treatment level

Product Name: Epogen, Procrit	
Diagnosis	Anemia in HCV-infected patients due to ribavirin in combination with interferon or peg-interferon [off-label] [6]
Approval Length	3 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of hepatitis C viral (HCV) infection [12, 20]

AND

2 - Verification of iron evaluation for adequate iron stores^ [2-3, 33]

AND

3 - Verification of anemia as defined by one of the following laboratory values collected within 30 days of the request: [P]

- Hematocrit (Hct) less than 36%
- Hemoglobin (Hgb) less than 12 g/dL

AND

4 - Verification of both of the following:

4.1 Patient is receiving ribavirin

AND

4.2 Patient is receiving one of the following:

- interferon alfa-2b
- interferon alfacon-1
- peginterferon alfa-2b
- peginterferon alfa-2a

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming history of use or unavailability of Retacrit or Procrit (applies to Epogen only) [O]

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

Product Name: Aranesp, Epogen, Mircera, Procrit, or Retacrit	
Diagnosis	Other Off-Label Uses
Guideline Type	Prior Authorization

Approval Criteria

1 - Off-label guideline approval criteria have been met*

AND **2** - Off-label requests other than those listed above for coverage in patients with Hgb greater than 10 g/dL or Hct greater than 30% will not be approved [1-3, 31, 33]

Notes	*Off-label requests will be evaluated on a case-by-case basis by a clinical pharmacist

Product Name: Epogen, Procrit	
Diagnosis	Other Off-Label Uses
Guideline Type	Non Formulary

Approval Criteria

1 - Off-label guideline approval criteria have been met*

AND

2 - Off-label requests other than those listed above for coverage in patients with Hgb greater than 10 g/dL or Hct greater than 30% will not be approved [1-3, 31, 33]

Notes	*Off-label requests will be evaluated on a case-by-case basis by a clinical pharmacist

3 . Endnotes

A. Aranesp, Epogen, Mircera, Procrit, and Retacrit Prescribing Information recommend prior and during therapy, the patient's iron stores should be evaluated. Administer supplemental iron therapy when serum ferritin is less than 100 mcg/L or when serum transferrin saturation is less than 20%. The majority of patients with CKD will require supplemental iron during the course of ESA therapy. [1-3, 31, 33]
B. Aranesp, Epogen, Mircera, Procrit, or Retacrit Prescribing Information states that dialysis, and non-dialysis patients with symptomatic anemia considered for therapy should have a Hgb < 10 g/dL. [1-3, 31, 33]
C. ESA treatment duration for each course of chemotherapy includes the 8 weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regimen. [18]
D. ESAs are not indicated for patients receiving myelosuppressive therapy when the anticipated outcome is cure. [1-3, 33]

E. NCCN panel recommends MDS patients aim for a target hemoglobin level of less than or equal to 12 g/dL. [4]
F. The American Cancer Society definition of "non-myeloid malignancy" is any malignancy that is not a myeloid leukemia. Non-myeloid cancers include all types of carcinoma, all types of sarcoma, melanoma, lymphomas, lymphocytic leukemias (ALL and CLL), and multiple myeloma. [30]
G. Absolute iron deficiency is defined as ferritin <30 ng/mL and TSAT <20%. Functional iron deficiency in patients receiving ESAs is defined as ferritin 30-800 ng/mL and TSAT 20%-50%. No iron deficiency is defined as ferritin >800 ng/mL or TSAT greater or equal to 50%. [8]
H. Iron repletion needs to be verified before instituting Epo therapy. [4]
I. Detection of erythroid responses generally occurs within 6 to 8 weeks of treatment. If no response occurs in this time frame, this treatment should be considered a failure and discontinued. [4]
J. Iron stores evaluation is recommended to occur every month during initial erythropoietin treatment in adults with chronic kidney disease or at least every 3 months during stable ESA treatment or in patients with HD-CKD not treated with an erythropoietin. [7]
K. Anemia in HIV patients has been defined as hemoglobin less than 10 g/dL [11, 25-26], hemoglobin less than 11 g/dL [11, 27], or hemoglobin less than 12 g/dL. [17]
L. Although primarily used in patients with ESRD, ESAs such as erythropoietin and darbepoetin alfa also correct the anemia in those with CKD who do not yet require dialysis. [21, 32]
M. Examples of other anemias include: vitamin B12, folate or iron deficiency anemia, hemolysis, or gastrointestinal bleeding.
N. Data from a systematic review by the Agency for Healthcare Research and Quality (AHRQ) determined that delaying ESA treatment until hemoglobin is less than 10 g/dL resulted in fewer thromboembolic events and a reduced mortality. [8]
O. Per consult with hematologist/oncologist, if a patient does not respond to one short-acting ESA, switching to another short-acting agent would not provide any added benefit; instead, one would increase the dose or perhaps switch to a long-acting agent. [34]
P. Epoetin alfa was effective in maintaining the dose of rivabirin in anemic patients with chronic hepatitis C virus in patients with a baseline hemoglobin of 12 g/dL or less. [20]

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5 . Revision History

Date	Notes
11/22/2022	Annual review: no criteria changes.

Prior Authorization Guideline

Guideline Name	Evrysdi (risdiplam)

Guideline Note:

Effective Date:	12/1/2022
P&T Approval Date:	10/21/2020
P&T Revision Date:	12/16/2020 ; 10/20/2021 ; 06/15/2022 ; 07/20/2022 ; 10/19/2022

1 . Indications

Drug Name: Evrysdi (risdiplam)
Spinal Muscular Atrophy Indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.

2 . Criteria

Product Name: Evrysdi	
Diagnosis	Spinal Muscular Atrophy
Approval Length	12 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of spinal muscular atrophy (SMA) Type I, II, or III [1-3, A]

AND

2 - Both of the following: [1-7]

2.1 The mutation or deletion of genes in chromosome 5q resulting in one of the following: [B]

2.1.1 Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13)

OR

2.1.2 Compound heterozygous mutation (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2])

AND

2.2 Patient has at least 2 copies of SMN2 [C]

AND

3 - Patient is not dependent on invasive ventilation or tracheostomy [2-3, D]

AND

4 - Patient is not dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep [3, D]

AND

5 - At least one of the following exams (based on patient age and motor ability) has been conducted to establish baseline motor ability*: [2-7, E]

- Hammersmith Infant Neurological Exam Part 2 (HINE-2) (infant to early childhood)

- Hammersmith Functional Motor Scale Expanded (HFMSE)
- Revised Upper Limb Module (RULM) Test (Non ambulatory)
- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
- Motor Function Measure 32 (MFM-32) Scale
- Item 22 of the Bayley Scales of Infant and Toddler Development Third Edition (BSID-III)

AND

6 - Prescribed by or in consultation with a neurologist with expertise in the diagnosis and treatment of SMA

AND

7 - Patient is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Spinraza) [2-3, 10, F]

AND

8 - One of the following: [2-3, 10, F]

8.1 Patient has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma)

OR

8.2 Both of the following:

- Patient has previously received gene therapy for the treatment of SMA (e.g., Zolgensma)
- Documentation of inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months)

Notes	*Baseline assessments for patients less than 2 months of age requesting risdiplam are not necessary in order to not delay access to initial therapy in recently diagnosed infants. Initial assessments shortly post-therapy can serve as baseline with respect to efficacy reauthorization assessment.

Product Name: Evrysdi	
Diagnosis	Spinal Muscular Atrophy
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy from pretreatment baseline status as demonstrated by the most recent results from one of the following exams:

1.1 One of the following HINE-2 milestones: [2]

- Improvement or maintenance of previous improvement of at least a 2 point (or maximal score) increase in ability to kick
- Improvement or maintenance of previous improvement of at least a 1 point increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp
- Patient exhibited improvement, or maintenance of previous improvement in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement)
- Patient has achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

OR

1.2 One of the following HFMSE milestones: [8]

- Improvement or maintenance of a previous improvement of at least a 3 point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

OR

1.3 One of the following RULM test milestones: [2, 8-9]

- Improvement or maintenance of a previous improvement of at least a 2 point increase in score from pretreatment baseline

- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

OR

1.4 One of the following CHOP INTEND milestones: [2]

- Improvement or maintenance of a previous improvement of at least a 4 point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

OR

1.5 One of the following MFM-32 milestones: [2]

- Improvement or maintenance of a previous improvement of at least a 3 point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

OR

1.6 Improvement in the ability to sit without support for at least 5 seconds as assessed by item 22 of the Gross Motor Scale of the Bayley Scales of Infant and Toddler Development Third Edition (BSID-III) [2-3]

AND

2 - Patient continues to not be dependent on invasive ventilation or tracheostomy [2-3, D]

AND

3 - Patient continues to not be dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep [3, D]

AND

4 - Prescribed by or in consultation with a neurologist with expertise in the diagnosis and treatment of SMA

AND

5 - Patient is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Spinraza) [2-3, 10, F]

AND

6 - One of the following: [2-3, 10, F]

6.1 Patient has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma)

OR

6.2 Both of the following:

- Patient has previously received gene therapy for the treatment of SMA (e.g., Zolgensma)
- Documentation of inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months)

3 . Endnotes

A. There were two major Phase 2/3 trials that the FDA assessed when determining Evrysdi's clinical efficacy and subsequent approval (SUNFISH and FIREFISH). SUNFISH only enrolled patients with SMA Types 2 and 3 and FIREFISH only enrolled patients with SMA Type 1. [2-3]
B. This is the definition that the clinical trials SUNFISH and FIREFISH used. Also consistent with clinical guidelines. [2-7]
C. FIREFISH required patients to have 2 copies of SMN2, and SUNFISH only enrolled patients with 2-4 copies of SMN2. [2-3]

D. Invasive ventilation or tracheostomy was an exclusion criteria in both the SUNFISH and FIREFISH trials. Use of non-invasive ventilation beyond use for naps and nighttime sleep was only an exclusion criteria in FIREFISH. [2-3]
E. MFM-32 was included in Evrysdi criteria but not Spinraza because Spinraza did not study MFM-32 as an endpoint. Baseline motor score standards was only used as an inclusion criterion for SUNFISH. Revised upper limb module (RULM) entry item A (Brooke score) equal to or greater than 2 AND MFM-32 (Item 9) scores equal to or greater than 1 were required. As this was only for the SUNFISH trial and only applied to some of the motor scores, it was deemed unnecessary to include as a criterion. [2]
F. A recent European ad-hoc consensus statement on SMA stated that there currently is no published evidence that the combination of two disease modifying therapies (e.g., Evrysdi and Zolgensma) is superior to any single treatment alone. Both FIREFISH and SUNFISH excluded patients that were on concomitant or previous treatment with either SMN2-targeting antisense oligonucleotide, or gene therapy (e.g., Spinraza or Zolgensma). JEWELFISH is an ongoing open label phase 2 trial that included patients previously treated with another SMA targeted therapy (e.g., Zolgensma, Spinraza). JEWELFISH is scheduled to be completed in January 2025. [2-3,10-11]

4 . References

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10. Kirschner J, Butoianu N, Goemans N, et al. European ad-hoc consensus statement on gene replacement therapy for spinal muscular atrophy. Eur J Paediatr Neurol. 2020. https://doi.org/10.1016/j.ejpn.2020.07.001
11. Evrysdi [AMCP dossier]; South San Francisco, CA: Genentech; September 2020.

5 . Revision History

Date	Notes
10/7/2022	Update Guideline

Prior Authorization Guideline

Guideline Name	Extended Release Tramadol Products

Guideline Note:

Effective Date:	11/1/2022
P&T Approval Date:	11/16/2017
P&T Revision Date:	09/16/2020 ; 01/20/2021 ; 11/18/2021 ; 10/19/2022

1 . Indications

Drug Name: Conzip
Pain Indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.
Drug Name: Tramadol Extended Release (ER)
Pain Indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

2 . Criteria

Product Name: ConZip, tramadol ER	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to moderately severe chronic pain

AND

2 - Trial and failure (of a minimum 30 day supply) or intolerance to an immediate release tramadol containing product [e.g., Ultram (tramadol), Ultracet (tramadol/acetaminophen)]

3 . References

1. Conzip prescribing information. Vectical Pharmaceuticals, LLC. Bridgewater, NJ. September 2021.
2. Tramadol Extended Release prescribing information. Lupin Pharmaceuticals, Inc. Baltimore, MD. September 2021.

4 . Revision History

Date	Notes
10/19/2022	Annual review with no changes to criteria

Prior Authorization Guideline

Guideline Name	Eysuvis (loteprednol etabonate ophthalmic suspension)

Guideline Note:

Effective Date:	1/11/2022
P&T Approval Date:	2/18/2021
P&T Revision Date:	05/20/2021

1 . Indications

Drug Name: Eysuvis (loteprednol etabonate ophthalmic suspension)
Dry eye disease (DED) Indicated for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease.

2 . Criteria

Product Name: Eysuvis	
Diagnosis	Dry Eye Disease
Approval Length	14 Day(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of dry eye disease

AND

2 - Prescribed by or in consultation with one of the following:

- Ophthalmologist
- Optometrist

Product Name: Eysuvis	
Diagnosis	Dry Eye Disease
Approval Length	14 Day(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., improvement in dry eye symptoms)

AND

2 - Prescribed by or in consultation with one of the following:

- Ophthalmologist
- Optometrist

3 . References

1. Eysuvis prescribing information. Kala Pharmaceuticals, Inc. Watertown, MA. November 2020.
2. Per clinical consult with ophthalmologist, December 21, 2020.
3. Shtein, RM. Dry eye disease. In: Post T, ed. UpToDate. UpToDate; 2020. Accessed December 16, 2020. www.uptodate.com

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4 . Revision History

Date	Notes
1/10/2022	Updated to add EHB formulary, no changes to criteria

Prior Authorization Guideline

Guideline Name	Fabrazyme (agalsidase beta)

Guideline Note:

Effective Date:	12/1/2022
P&T Approval Date:	
P&T Revision Date:	10/16/2019 ; 10/21/2020 ; 05/20/2021 ; 10/20/2021 ; 10/19/2022

1 . Indications

Drug Name: Fabrazyme (agalsidase beta)
Fabry disease Indicated for the treatment of adult and pediatric patients 2 years of age and older with confirmed Fabry disease.

2 . Criteria

Product Name: Fabrazyme	
Approval Length	60 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Fabry disease	

AND

2 - Patient is 2 years of age or older

AND

3 - One of the following: [3, 4]

- Detection of pathogenic mutations in the GLA gene by molecular genetic testing
- Deficiency in α-galactosidase A (α-Gal A) enzyme activity in plasma, isolated leukocytes, or dried blood spots (DBS)
- Significant clinical manifestations (e.g., neuropathic pain, cardiomyopathy, renal insufficiency, angiokeratomas, cornea verticillata)

AND

4 - Will not be used in combination with Galafold (migalastat) [A]

3 . Endnotes

A. The safety and effectiveness of concomitant use of Galafold (migalastat) and Fabrazyme (agalsidase beta) has not been established. [2]

4 . References

1. Fabrazyme prescribing information. Genzyme Corporation. Cambridge, MA. August 2021.
2. Per clinical consultation with geneticist. October 11, 2018.
3. Ortiz A, Germain DP, Desnick RJ, et al. Fabry disease revisited: Management and treatment recommendations for adult patients. Mol Genet Metab. 2018;123(4):416-427. doi:10.1016/j.ymgme.2018.02.014.
4. Michaud M, Mauhin W, Belmatoug N, et al. When and How to Diagnose Fabry Disease in Clinical Pratice. Am J Med Sci. 2020;360(6):641-649. doi:10.1016/j.amjms.2020.07.011.

5 . Revision History

Date	Notes
9/30/2022	2022 UM Annual Review.

Prior Authorization Guideline

Guideline Name	Ferriprox (deferiprone)

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	4/10/2012
P&T Revision Date:	10/16/2019 ; 04/15/2020 ; 09/16/2020 ; 11/12/2020 ; 04/21/2021 ; 07/21/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Ferriprox (deferiprone) Tablets
Iron Overload Indicated for the treatment of transfusional iron overload in adult and pediatric patients 8 years of age and older with thalassemia syndromes, sickle cell disease or other anemias.
Drug Name: Ferriprox (deferiprone) Oral Solution
Iron Overload Indicated for the treatment of transfusional iron overload in adult and pediatric patients 3 years of age and older with thalassemia syndromes, sickle cell disease or other anemias.

2 . Criteria

Product Name: Ferriprox oral solution, Generic deferiprone tablet	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of transfusional iron overload due to one of the following: [1]

- Thalassemia syndromes
- Sickle cell disease
- Other transfusion-dependent anemias

AND

2 - One of the following:

2.1 For Ferriprox oral solution, patient is 3 years of age or older

OR

2.2 For generic deferiprone tablet, patient is 8 years of age or older

AND

3 - One of the following:

3.1 Trial (of a minimum 30 day supply) and failure, defined by a serum ferritin > 2,500 mcg/L, to one of the following chelation therapy: [A]

- Generic deferoxamine
- Generic deferasirox

OR

3.2 History of contraindication or intolerance to one of the following chelation therapy:

- Generic deferoxamine
- Generic deferasirox

AND

4 - Absolute Neutrophil Count (ANC) greater than 1.5 x 10^9/L

Product Name: Brand Ferriprox tablet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of transfusional iron overload due to one of the following: [1]

- Thalassemia syndromes
- Sickle cell disease
- Other transfusion-dependent anemias

AND

2 - Patient is 8 years of age or older

AND

3 - One of the following:

3.1 Trial (of a minimum 30 day supply) and failure, defined by a serum ferritin > 2,500 mcg/L, to one of the following chelation therapy: [A]

- Generic deferoxamine
- Generic deferasirox

OR

3.2 History of contraindication or intolerance to one of the following chelation therapy:

- Generic deferoxamine

- Generic deferasirox

AND

4 - Absolute Neutrophil Count (ANC) greater than 1.5 x 10^9/L

AND

5 - Trial and failure, or intolerance to generic deferiprone tablets*

Notes	*Product may require prior authorization

Product Name: Brand Ferriprox tablet, Ferriprox oral solution, Generic deferiprone tablet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced greater than or equal to 20% decline in serum ferritin levels from baseline

AND

2 - Absolute Neutrophil Count (ANC) greater than 1.5 x 10^9/L

3 . Endnotes

A. Failure to prior chelation therapy is defined as serum ferritin > 2,500 mcg/L. [1]

4 . References

1. Ferriprox tablets prescribing information. Apotex Inc., Toronto, Canada. November 2021.

2. Ferriprox solution prescribing information. Apotex Inc., Toronto, Canada. August 2021.
3. Deferiprone prescribing information. Taro Pharmaceutical Industries Ltd. Haifa Bay, Israel. November 2022.

5 . Revision History

Date	Notes
3/8/2023	2023 UM Annual Review. Added age criteria to align with package in sert. Removed SP formulary and kept only standard formulary attach ed to guideline. Updated references

Prior Authorization Guideline

Guideline Name	Fibric Acid Derivatives

Guideline Note:

Effective Date:	11/1/2022
P&T Approval Date:	11/20/1998
P&T Revision Date:	09/18/2019 ; 9/21/2022

1 . Indications

Drug Name: Fibricor and Triglide
Primary Hypercholesterolemia or Mixed Dyslipidemia Indicated as adjunctive therapy to diet to reduce elevated low-density lipoprotein cholesterol (LDL-C), total cholesterol (Total-C), triglycerides (TG), and apolipoprotein B (Apo B), and to increase high-density lipoprotein (HDL-C) in adult patients with primary hypercholesterolemia or mixed dyslipidemia. Limitations of Use: Fenofibrate was not shown to reduce coronary heart disease morbidity and mortality in patients with type 2 diabetes mellitus. **Severe Hypertriglyceridemia** Indicated as adjunctive therapy to diet for treatment of adult patients with severe hypertriglyceridemia. Improving glycemic control in diabetic patients showing fasting chylomicronemia will usually reduce fasting triglycerides and eliminate chylomicronemia thereby obviating the need forpharmacologic intervention. Markedly elevated levels of serum triglycerides (eg, > 2000 mg/dL) may increase the risk of developing pancreatitis. The effect of fenofibrate therapy on reducing this risk has not been adequately studied. Limitations of Use: Fenofibrate was not shown to reduce coronary heart disease morbidity and mortality in patients with type 2 diabetes mellitus.

2 . Criteria

Product Name: Brand Fibricor, or Brand Triglide	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure or intolerance to one of the following generics:

- fenofibrate micronized capsule
- fenofibrate tablet
- fenofibric capsule
- fenofibric acid tablet

3 . References

1. Triglide Prescribing Information. Casper Pharma, LLC. East Brunswick, NJ. April 2019.
2. Fibricor Prescribing Information. Athena Bioscience, LLC. Athena, GA. May 2019.

4 . Revision History

Date	Notes
9/1/2022	2022 Annual Review - added criteria "Requested drug is being used f or a Food and Drug Administration (FDA)-approved indication"

Prior Authorization Guideline

Guideline Name	Flurazepam

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	7/10/2012
P&T Revision Date:	03/18/2020 ; 03/17/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Flurazepam
Insomnia Indicated for the treatment of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings, and/or early morning awakening. Since insomnia is often transient and intermittent, short-term use is usually sufficient. Prolonged use of hypnotics is usually not indicated and should only be undertaken concomitantly with appropriate evaluation of the patient.

2 . Criteria

Product Name: Flurazepam	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of insomnia

AND

2 - Trial and failure, contraindication, or intolerance to two of the following benzodiazepines: [A]

- Estazolam
- Halcion (triazolam)
- Restoril (temazepam)

3 . Endnotes

A. Flurazepam, estazolam, triazolam, and temazepam are only recommended for patients < 65 years old. These drugs are included on the American Geriatrics Society 2019 Beers Criteria update. [2]

4 . References

1. Flurazepam Prescribing Information. Mylan Pharmaceuticals Inc. Morgantown, WV. February 2021.
2. The 2019 American Geriatrics Society Beers Criteria Update Expert Panel. American Geriatrics Society 2019 Updated AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc. 2019;67(4):674-694.

5 . Revision History

Date	Notes
3/16/2023	Annual review: no changes to criteria.

Prior Authorization Guideline

Guideline ID	GL-117663
Guideline Name	Folotyn (pralatrexate)

Guideline Note:

Effective Date:	2/1/2023
P&T Approval Date:	4/6/2010
P&T Revision Date:	07/21/2021 ; 08/18/2022 ; 1/18/2023

1 . Indications

Drug Name: Folotyn (pralatrexate)
Peripheral T-cell Lymphoma (PTCL) Indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL). This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

2 . Criteria

Product Name: Folotyn, Brand Pralatrexate	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsed or refractory peripheral T-cell lymphoma (PTCL)

AND

2 - Verification that patient is receiving folic acid and vitamin B12 supplementation [A]

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Folotyn, Brand Pralatrexate	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient shows no evidence of progressive disease or unacceptable toxicity

AND

2 - Verification that patient is receiving folic acid and vitamin B12 supplementation [A]

3 . Endnotes

A. Patients should be instructed to take folic acid and receive vitamin B12 to potentially reduce treatment-related hematological toxicity and mucositis. [1]

4 . References

1. Folotyn Prescribing Information. Acrotech Biopharma LLC. East Windsor, NJ. September, 2020.
2. Pralatrexate Prescribing Information. Fresenius Kabi LLC. Lake Zurich, IL. September, 2022.

5 . Revision History

Date	Notes
12/8/2022	Added Pralatrexate to guideline

Prior Authorization Guideline

Guideline Name	Galafold (migalastat)

Guideline Note:

Effective Date:	12/1/2022
P&T Approval Date:	
P&T Revision Date:	10/16/2019 ; 10/21/2020 ; 10/20/2021 ; 10/19/2022

1 . Indications

Drug Name: Galafold (migalastat)
Fabry Disease Indicated for the treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data. This indication is approved based on reduction in kidney interstitial capillary cell globotriaosylceramide (KIC GL-3) substrate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

2 . Criteria

Product Name: Galafold	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Fabry Disease

AND

2 - One of the following: [3, 4]

- Detection of pathogenic mutations in the GLA gene by molecular genetic testing
- Deficiency in α-galactosidase A (α-Gal A) enzyme activity in plasma, isolated leukocytes, or dried blood spots (DBS)
- Significant clinical manifestations (e.g., neuropathic pain, cardiomyopathy, renal insufficiency, angiokeratomas, cornea verticillata)

AND

3 - Patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data [A]

AND

4 - Will not be used in combination with Fabrazyme (agalsidase beta) [B]

Product Name: Galafold	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by one of the following: [3, 4]

- Reduction in plasma or urinary sediment lyso-GL-3, GL-3 compared to baseline

- Reduction in number of GL-3 inclusions per kidney interstitial capillary (KIC) in renal biopsy samples compared to baseline
- Improvement and/or stabilization in symptoms (e.g., renal function, neuropathic pain)

AND

2 - Will not be used in combination with Fabrazyme (agalsidase beta) [B]

3 . Endnotes

A. In an in vitro assay (HEK-293 assay), Human Embryonic Kidney (HEK-293) cell lines were transfected with specific GLA variants (mutations) which produced mutant alpha-Gal A proteins. A GLA variant was categorized as amenable if the resultant mutant alpha-Gal A activity (measured in the cell lysates) met two criteria: 1) it showed a relative increase of at least 20% compared to the pre-treatment alpha-Gal A activity, and 2) it showed an absolute increase of at least 3% of the wild-type (normal) alpha-Gal A activity. Whether a certain amenable GLA variant in a patient with Fabry disease is disease-causing or not should be determined by the prescribing physician (in consultation with a clinical genetics professional, if needed) prior to treatment initiation. [1]
B. The safety and effectiveness of concomitant use of Galafold and Fabrazyme (agalsidase beta) has not been established. [2]

4 . References

1. Galafold prescribing information. Amicus Therapeutics U.S., Inc. Cranbury, NJ. February 2021.
2. Per clinical consultation with geneticist. October 11, 2018.
3. Ortiz A, Germain DP, Desnick RJ, et al. Fabry disease revisited: Management and treatment recommendations for adult patients. Mol Genet Metab. 2018;123(4):416-427. doi:10.1016/j.ymgme.2018.02.014.
4. Michaud M, Mauhin W, Belmatoug N, et al. When and How to Diagnose Fabry Disease in Clinical Pratice. Am J Med Sci. 2020;360(6):641-649. doi:10.1016/j.amjms.2020.07.011.

5 . Revision History

Date	Notes

9/30/2022	2022 UM Annual Review.

Prior Authorization Guideline

Guideline Name	Gamifant (emapalumab-lzsg)

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	
P&T Revision Date:	02/13/2020 ; 02/18/2021 ; 02/17/2022 ; 2/16/2023

1 . Indications

Drug Name: Gamifant (emapalumab-lzsg)
Primary Hemophagocytic Lymphohistiocytosis (HLH) Indicated for the treatment of adult and pediatric (newborn and older) patients with primary HLH with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy.

2 . Criteria

Product Name: Gamifant	
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary hemophagocytic lymphohistiocytosis (HLH)

AND

2 - One of the following:

2.1 Disease is one of the following:

- Refractory
- Recurrent
- Progressive

OR

2.2 Trial and failure, contraindication, or intolerance to conventional HLH therapy (e.g., etoposide, dexamethasone, cyclosporine A, intrathecal methotrexate)

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

AND

4 - Patient has not received hematopoietic stem cell transplantation (HSCT)

Product Name: Gamifant	
Approval Length	6 Months [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., improvement in

hemoglobin/lymphocyte/platelet counts, afebrile, normalization of inflammatory factors/markers) **AND** **2** - Patient has not received HSCT

3 . Endnotes

A. Per clinical consultation, it is appropriate to limit authorization duration to no more than 6 months at a time, given that the ultimate goal in therapy is to receive HSCT and treatment with Gamifant should be viewed as bridge therapy to HSCT. Pivotal trial data duration was also less than 3 months. [2]

4 . References

1. Gamifant Prescribing Information. Sobi Inc. Waltham, MA. June 2020.
2. Per clinical consult with a pediatric hematologist/oncologist, January 18, 2019.

5 . Revision History

Date	Notes
1/15/2023	Annual Review - no criteria changes

Prior Authorization Guideline

Guideline Name	Gattex (teduglutide)

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	2/19/2013
P&T Revision Date:	01/15/2020 ; 01/20/2021 ; 01/19/2022 ; 06/15/2022 ; 2/16/2023

1 . Indications

Drug Name: Gattex (teduglutide)
Short Bowel Syndrome (SBS) Indicated for the treatment of adults and pediatric patients 1 year of age and older with Short Bowel Syndrome (SBS) who are dependent on parenteral support.

2 . Criteria

Product Name: Gattex	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of short bowel syndrome

AND

2 - Patient is 1 year of age and older

AND

3 - Documentation that the patient is dependent on parenteral nutrition/intravenous (PN/IV) support for at least 12 consecutive months [A]

AND

4 - Prescribed by or in consultation with a gastroenterologist [C]

Product Name: Gattex	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that the patient has had a reduction in weekly parenteral nutrition/intravenous (PN/IV) support from baseline while on Gattex therapy [B]

AND

2 - Prescribed by or in consultation with a gastroenterologist [C]

3 . Endnotes

A. Twelve consecutive months on parenteral nutrition is an inclusion criterion in clinical trials. [1]
B. In clinical trial data, treatment with Gattex has been shown to reduce the volume and number of days that patients with short bowel syndrome require parenteral nutrition/intravenous (PN/IV) support, with some patients remaining on Gattex therapy even if PN/IV support was no longer required. [1, 6-8]
C. Patients with short bowel syndrome (SBS) have undergone one or more surgical bowel resections due to underlying disease, congenital defects, or other trauma. These resections lead to inadequate digestion and absorption, requiring patients to become dependent on parenteral nutrition and/or intravenous (PN/IV) support. The management of PN/IV is complex and must be individualized to each patient as the degree of malabsorption can vary among patients with SBS. Long-term use of PN/IV can often lead to other complications, such as bacterial infections, blood clots, gallbladder disease, and liver and kidney problems. For SBS patients on chronic PN/IV, the goal of treatment is to reduce the need for PN/IV in order to improve the patients' quality of life and reduce the risk of any life-threatening complications. Careful monitoring of patients treated with Gattex is recommended in order to assess continued safety and manage any adverse effects or complications. [1-7]

4 . References

1. Gattex Prescribing Information. Takeda Pharmaceuticals America, Inc. Lexington, MA. October 2022.
2. Van Gossum A, Cabre E, Hébuterne X, et al. ESPEN Guidelines on Parenteral Nutrition: gastroenterology. Clin Nutr. 2009;28(4):415-27.
3. Nightingale J, Woodward JM on behalf of the Small Bowel and Nutrition Committee of the British Society of Gastroenterology. Guidelines for management of patients with a short bowel. Gut. 2006;55(Suppl 4):iv1-12.
4. National Institute of Diabetes and Digestive and Kidney Diseases. Short Bowel Syndrome. https://www.niddk.nih.gov/health-information/digestive-diseases/short-bowel-syndrome. Accessed December 7, 2020.
5. Buchman AL, Scolapio J, Fryer J. AGA technical review on short bowel syndrome and intestinal transplantation. Gastroenterology. 2003;124(4):1111-34.
6. Jeppesen PB, Pertkiewicz M, Messing B, et al. Teduglutide reduces need for parenteral support among patients with short bowel syndrome with intestinal failure. Gastroenterology. 2012;143(6):1473-1481.
7. Seidner DL, Schwartz LK, Winkler MF, Jeejeebhoy K, Boullata JI, Tappenden KA. Increased intestinal absorption in the era of teduglutide and its impact on management strategies in patients with short bowel syndrome-associated intestinal failure. J Parenter Enteral Nutr. 2013;37(2):201-11.
8. Naberhuis JK, Tappenden KA. Teduglutide for safe reduction of parenteral nutrient and/or fluid requirements in adults: a systematic review. J Parenter Enteral Nutr. 2016;40(8):1096-1105.
9. DiBaise, J. UptoDate. Management of the short bowel syndrome in adults. November 2022. Available at: https://www.uptodate.com/contents/management-of-the-short-bowel-syndrome-in-adults?search=GATTEX&source=search_result&selectedTitle=2~8&usage_type=default&display_rank=1. Accessed December 30, 2022.

10. Stamm, D., Duggan, C. UptoDate. Management of short bowel syndrome in children. November 2022. Available at: https://www.uptodate.com/contents/management-of-short-bowel-syndrome-in-children?search=GATTEX&source=search_result&selectedTitle=3~8&usage_type=default&display_rank=2. Accessed December 30, 2022.
11. Iyer, K., DiBaise, J., et al. AGA Clinical Practice Update on Management of Short Bowel Syndrome: Expert Review. June 2022. Available at: https://www.cghjournal.org/article/S1542-3565(22)00561-4/fulltext#pageBody. Accessed December 30, 2022.

5 . Revision History

Date	Notes
12/30/2022	2023 Annual Review

Prior Authorization Guideline

Guideline Name	Gaucher Disease Agents

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	11/20/2000
P&T Revision Date:	02/13/2020 ; 02/18/2021 ; 02/17/2022 ; 05/19/2022 ; 2/16/2023

1 . Indications

Drug Name: Cerezyme (imiglucerase for injection)
Type 1 Gaucher Disease Indicated for treatment of adults and pediatric patients 2 years of age and older with Type 1 Gaucher disease that results in one or more of the following conditions: - anemia - thrombocytopenia - bone disease - hepatomegaly or splenomegaly
Drug Name: Elelyso (taliglucerase alfa) for injection
Type 1 Gaucher Disease Indicated for the treatment of patients 4 years and older with a confirmed diagnosis of Type 1 Gaucher disease.
Drug Name: VPRIV (velaglucerase alfa for injection)
Type 1 Gaucher Disease Indicated for long-term enzyme replacement therapy (ERT) for patients with type 1 Gaucher disease.
Drug Name: Cerdelga (eliglustat)
Type 1 Gaucher Disease Indicated for the long-term treatment of adult patients with Gaucher disease type 1 (GD1) who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test. Limitations of Use: Patients who are CYP2D6 ultra-rapid metabolizers (URMs) may not

achieve adequate concentrations of CERDELGA to achieve a therapeutic effect. A specific dosage cannot be recommended for those patients whose CYP2D6 genotype cannot be determined (indeterminate metabolizers).
Drug Name: Zavesca (miglustat)
Type 1 Gaucher Disease Indicated as monotherapy for the treatment of adult patients with mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option (e.g., due to allergy, hypersensitivity, or poor venous access).

2 . Criteria

Product Name: Cerezyme, Elelyso, or VPRIV	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Type 1 Gaucher disease

AND

2 - Patient has evidence of symptomatic disease (e.g., moderate to severe anemia [A], thrombocytopenia [B], bone disease [C], hepatomegaly [D], or splenomegaly [D])

AND

3 - One of the following:

3.1 Patient is 4 years of age or older (applies to Elelyso and VPRIV only)

OR

3.2 Patient is 2 years of age or older (applies to Cerezyme only)

Product Name: Cerdelga	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Type 1 Gaucher disease

AND

2 - Patient is an extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) of cytochrome P450 enzyme (CYP) 2D6 as detected by an FDA-cleared test

AND

3 - Patient is 18 years of age or older

Product Name: Generic miglustat or Brand Zavesca	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mild to moderate Type 1 Gaucher disease [E]

AND

2 - Patient is 18 years of age or older

3 . Endnotes

A. Goals of treatment with anemia are to increase hemoglobin to greater than or equal to 12.0 g/dL for males (greater than 12 years of age), and to greater than or equal to 11.0 g/dL for both children (less than or equal to 12 years of age) and females (greater than 12 years of age). [6, 8]
B. Moderate thrombocytopenia is defined as a platelet count of 60,000 to 120,000/microliter. A platelet count of 120,000/microliter to meet the criterion of thrombocytopenia is based on the upper end of the range that defines moderate thrombocytopenia. [6]
C. In bone disease, the goal is to lessen or eliminate bone pain and prevent bone crises. Bone disease can be diagnosed using MRI, bone scan, and X-ray. [6-8]
D. Hepatomegaly is defined as a liver mass of greater than 1.25 times normal value. Splenomegaly is defined as a splenic mass greater than the normal, and moderate splenomegaly is considered a spleen volume of greater than 5 and less than or equal to 15 times normal. [6]
E. Zavesca may be prescribed only by physicians knowledgeable in the management of Gaucher disease (GD). In order to prescribe Zavesca, physicians must read the letter to doctors from Actelion, then sign and fax the one-page physician statement affirming that they are qualified to manage patients with GD and that they have read the Zavesca review booklet containing the full prescribing information. Zavesca is dispensed exclusively by Accredo specialty pharmacy. [10]

4 . References

1. Cerezyme Prescribing Information. Genzyme Corporation. Cambridge, MA. December 2021.
2. Elelyso Prescribing Information. Pfizer, Inc. New York, NY. August 2022.
3. VPRIV Prescribing Information. Takeda Pharmaceuticals U.S.A., Inc. Lexington, MA. September 2021.
4. Cerdelga Prescribing Information. Genzyme Ireland, Ltd. Waterford, Ireland. July 2021.
5. Zavesca Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. August 2022.
6. Pastores GM, Weinreb NJ, Aerts H, et al. Therapeutic goals in the treatment of Gaucher disease. Semin Hematol. 2004;41(4 Suppl 5):4-14.
7. Weinreb NJ, Aggio MC, Andersson HC, et al. Gaucher disease type 1: revised recommendations on evaluations and monitoring for adult patients. Semin Hematol. 2004;41(suppl 5):15-22.
8. Weinreb N, Taylor J, Cox T, et al. A benchmark analysis of the achievement of therapeutic goals for type 1 Gaucher disease patients treated with imiglucerase. Am J Hematol. 2008;83:890-895.
9. Hollak CE, vom Dahl S, Aerts JM, et al. Force majeure: therapeutic measures in response to restricted supply of imiglucerase (Cerezyme) for patients with Gaucher disease. Blood Cells Mol Dis. 2010;44(1):41-7.
10. Actelion Pharmaceuticals US, Inc. Zavesca (miglustat). Available at: https://www.zavesca.com/hcp-home.html. Accessed on January 5, 2023.
11. Per clinical consult with geneticist, November 11, 2010.

5 . Revision History

Date	Notes
2/17/2023	Annual review - no criteria changes.

Prior Authorization Guideline

Guideline Name	Gazyva (obinutuzumab)

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	2/18/2014
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/21/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Gazyva (obinutuzumab)
Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with previously untreated chronic lymphocytic leukemia (CLL) in combination with chlorambucil. **Follicular Lymphoma (FL)** 1) Indicated in combination with bendamustine followed by Gazyva monotherapy for the treatment of patients with follicular lymphoma (FL) who relapsed after, or are refractory to, a rituximab-containing regimen. 2) Indicated for the treatment of adult patients with previously untreated stage II bulky, III or IV follicular lymphoma in combination with chemotherapy followed by Gazyva monotherapy in patients achieving at least a partial remission. **Off Label Uses: Small Lymphocytic Lymphoma (SLL) [2]**

2 . Criteria

Product Name: Gazyva

Diagnosis	Chronic Lymphocytic Leukemia (CLL)/ Small Lymphocytic Leukemia (SLL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

- Diagnosis of chronic lymphocytic leukemia (CLL) and is previously untreated for CLL
- Diagnosis of small lymphocytic leukemia (SLL) and previously untreated for SLL [A]

AND

2 - Used in combination with chlorambucil [2,3]

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Gazyva	
Diagnosis	Follicular Lymphoma (FL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of follicular lymphoma (FL)

AND

2 - One of the following:

2.1 All of the following:

2.1.1 Relapsed or refractory to a rituximab-containing regimen [B]

AND

2.1.2 Will be used in combination with bendamustine for six cycles prior to maintenance treatment with Gazyva monotherapy

OR

2.2 All of the following:

2.2.1 Diagnosis of stage II bulky, III or IV follicular lymphoma

AND

2.2.2 Patient has not been treated with prior therapy

AND

2.2.3 Both of the following:

- Used in combination with chemotherapy until at least partial remission has been achieved
- Followed by Gazyva monotherapy

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Gazyva	
Diagnosis	All Indications

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. The National Comprehensive Cancer Network (NCCN) guidelines support the use of obinutuzumab for the treatment of small lymphocytic leukemia (SLL). One clinical trial showed the combination of obinutuzumab plus chlorambucil resulted in significant improvement in the median progression free survival (PFS) compared to chlorambucil alone (26.7 months vs 11.1 months, respectively). [2]
B. NCCN supports use of obinutuzumab in the treatment of follicular lymphoma as maintenance therapy for rituximab refractory disease in patients with indications for treatment as second-line extended dosing. [2]

4 . References

1. Gazyva Prescribing Information, Genentech Inc. San Francisco, CA. July 2022.
2. NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 10, 2023.
3. National Comprehensive Cancer Network(NCCN) Practice Guidelines in Oncology. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma v3.2021. Available at: https://www.nccn.org/professionals/physician_gls/ pdf/cll.pdf. Accessed March 10, 2023.
4. Sharman JP, Banerji V, Fogliatto LM, et al. ELEVATE TN: Phase 3 study of acalabrutinib combined with obinutuzumab (O) or alone vs O plus chlorambucil (Clb) in patients (Pts) with treatment-naïve chronic lymphocytic leukemia (CLL). Blood. 2019;134 (Supplement_1):31.

5 . Revision History

Date	Notes
4/4/2023	Annual review - updated references.

Prior Authorization Guideline

Guideline Name	Generic-First Step Program

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	
P&T Revision Date:	11/14/2019 ; 12/18/2019 ; 01/15/2020 ; 01/15/2020 ; 02/13/2020 ; 08/13/2020 ; 11/12/2020 ; 07/21/2021 ; 10/20/2021 ; 11/18/2021 ; 12/15/2021 ; 03/16/2022 ; 04/20/2022 ; 08/18/2022 ; 08/18/2022 ; 10/19/2022 ; 04/20/2022 ; 02/16/2023 ; 03/15/2023 ; 04/19/2023 ; 4/19/2023

1 . Criteria

Product Name: Brand contraceptive drug which has a generic counterpart	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - One of the following:

1.1 Both of the following:

- Patient is using the prescribed drug for contraception or other FDA-approved condition*
- The requested product is medically necessary**

OR

1.2 Both of the following:

- Patient is using the prescribed drug for contraception or other FDA-approved condition*
- Trial and failure of a minimum 30 day supply, or intolerance to target's generic counterpart

Notes	*Examples of non-contraception uses: (1) Abnormal or excessive bleeding disorders (eg, amenorrhea, oligomenorrhea, menorrhagia, dysfunctional uterine bleeding); (2) Acne; (3) Decrease in bone mineral density; (4) Dysmennorrhea; (5) Endometriosis; (6) Hirsutism; (7) Irregular menses / cycles; (8) Ovarian cysts; (9) Perimenopausal symptoms; (10) History of Pelvic Inflammatory Disease (PID); (11) Polycystic Ovarian Syndrome (PCO or PCOS); (12) Premenstrual Syndrome (PMS); (13) Premenstrual Dysphoric Disorder (PMDD); (14) Prevention of endometrial and/or ovarian cancer; (15) Prevention of menstrual migraines; (16) Turner's syndrome; (17) Uterine fibroids or adenomyosis. **Any justification of medical necessity/appropriateness provided by the prescriber is adequate to approve access.

Product Name: Brand drug which has a generic counterpart	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure of a minimum 30 day supply, or intolerance to target's generic counterpart

2 . Background

Benefit/Coverage/Program Information
Table of Target Drugs which require trial and failure or intolerance to generic counterpart

ABILIFY	592500150003**
ALTACE	361000500001**
ARIMIDEX	21402810000310
ARTHROTEC 75 TAB	66109902200630
ATACAND	361500201003**
AVAPRO	361500300003**
AVODART CAP 0.5MG	56851020000120
AZOPT	86802320001820
BRISDELLE CAP 7.5MG	62226060300110
BYSTOLIC	332000401003**
CANASA SUP 1000MG	52500030005240
CARBATROL	726000200069**
CARDIZEM LA	340000101275**
CARNITOR SOL 1GM/10ML	30903045102010

CARNITOR TAB 330MG	30903045100330
CATAPRES-TTS	362010100088**
CELEXA	581600201003**
CIALIS	403040800003**
CIALIS TAB 2.5MG	40304080000302
CIALIS TAB 5MG	40304080000305
CLARINEX TAB 5MG	41550021000320
CLIMARA	240000350088**
CLOBEX LOT 0.05%	90550025104110
CLOBEX SHA 0.05%	90550025104520
CLOBEX SPR 0.05%	90550025100910
COLESTID	391000201027**
COLESTID	391000201030**
COLESTID TAB 1GM	39100020100320
COREG	333000070003**
COREG CR	333000072070**
CORTEF	221000250003**
COSOPT SOL 22.3-6.8	86259902202020

COSOPT PF SOL	86259902202060
COZAAR	361500402003**
DELESTROGEN INJ	240000352017**
DEPAKOTE ER	725000101075**
DEPAKOTE	725000101006**
DEPAKOTE SPR CAP 125MG	7250001010H120
DYAZIDE	37990002300105
EFFEXOR XR	581800901070**
EPIDUO GEL 0.1-2.5%	90059902034020
ESTRACE	240000350003**
ESTRACE VAG CRE 0.01%	55350020003705
EXFORGE	369930021003**
FIORICET CAP	64991003100108
FIORICET CAP CODEINE	65991004100113
FLOMAX CAP 0.4MG	56852070100110
GENERESS FE CHW	25990003600540
GOLYTELY	469920053021**
HYZAAR	369940024503**
IMITREX INJ	6740607010D5**

IMITREX INJ	6740607010E2**
IMITREX INJ 6MG/0.5	674060701020**
IMITREX SPRAY	674060700020**
IMITREX TABLET	674060701003**
KEPPRA	726000430003**
KEPPRA SOL 100MG/ML	72600043002020
KEPPRA XR	726000430075**
KLONOPIN	721000100003**
KLONOPIN TAB 2MG	72100010000315
K-TAB	797000300004**
LAMICTAL	726000400003**
LAMICTAL	726000400005**
LAMICTAL KIT START 35	72600040006420
LAMICTAL KIT START 49	72600040006430
LAMICTAL KIT START 98	72600040006435
LAMICTAL ODT	726000400072**
LAMICTAL ODT KIT	72600040006450
LAMICTAL ODT KIT	72600040006455

LAMICTAL ODT KIT	72600040006460
LAMICTAL XR	726000400075**
LASIX	372000300003**
LOESTRIN TAB 1/20-21	25990002600310
LOESTRIN 21 TAB 1.5/30	25990002600320
LOESTRIN FE TAB 1.5/30	25990003610320
LOESTRIN FE TAB 1/20	25990003610310
LOTREL	369915022001**
LYRICA	726000570001**
LYRICA CAP 300MG	72600057000160
LYRICA SOL 20MG/ML	72600057002020
MAXALT	674060601003**
MAXALT-MLT	674060601072**
MICARDIS	361500700003**
MICARDIS HCT	369940026003**
MOBIC	661000520003**
NALFON CAP 400MG	66100010100120
NALFON TAB 600MG	66100010100305

NATROBA SUS 0.9%	90900048001820
NEURONTIN	726000300001**
NEURONTIN	726000300003**
NEURONTIN SOL 250/5ML	72600030002020
NIASPAN	394500500004**
ORTHO MICRON TAB 0.35MG	25100010000305
ORTHO-NOVUM TAB 1/35	25990002500320
ORTHO-NOVUM TAB 7/7/7	25992002200310
PATADAY SOL 0.2%	86802065102030
PATANOL SOL 0.1% OP	86802065102020
PAXIL	581600600003**
PAXIL CR	581600600075**
PLAQUENIL TAB 200MG	13000020100305
PLAVIX	851580201003**
PRED FORTE SUS 1% OP	86300050101815
PRINIVIL	361000300003**
QUESTRAN	391000100029**

RANEXA	322000400074**
RELPAX	674060251003**
RENAGEL	528000701003**
RESTORIL	602010300001**
RISPERDAL	590700700003**
RISPERDAL SOL 1MG/ML	59070070002010
SAFYRAL TAB	25990003200330
SEASONIQUE TAB	25993002300330
SEROQUEL	591530701003**
SEROQUEL TAB 300MG	59153070100340
SEROQUEL TAB 400MG	59153070100350
SEROQUEL XR	591530701075**
SEROQUEL XR TAB 200MG	59153070107520
SILVADENE CRE 1%	90450030003710
SKELAXIN TAB 800MG	75100060000320
SOMA	751000200003**
SUBOXONE MIS 12-3MG	65200010208250

SUBOXONE MIS 2-0.5MG	65200010208220
SUBOXONE MIS 4-1MG	65200010208230
SUBOXONE MIS 8-2MG	65200010208240
TAMIFLU SUS 6MG/ML	12504060201910
TEGRETOL SUS 100/5ML	72600020001810
TEGRETOL TAB 200MG	72600020000305
TEGRETOL-XR	726000200074**
TENORMIN	332000200003**
TIKOSYN	354000250001**
TIMOPTIC SOL 0.25% OP	86250030102005
TIMOPTIC SOL 0.5% OP	86250030102010
TIMOPTIC OCU SOL 0.25% OP	86250030102006
TIMOPTIC OCU SOL 0.5% OP	86250030102011
TIMOPTIC-XE SOL 0.5% OP	86250030107630
TIMOPTIC-XE SOL 0.25% OP	86250030107620
TOPAMAX	726000750003**

TOPAMAX SPR	726000750068**
TRAVATAN Z	86330070002025
TRICOR TAB 145MG	39200025000323
TRICOR TAB 48MG	39200025000310
TRILEPTAL	726000460003**
TRILEPTAL SUS 300MG/5M	72600046001820
UCERIS TAB 9MG	22100012007530
VALTREX	124050851003**
VANADOM	75100020000305
VECTICAL OIN 3MCG/GM	90250028004220
VESICARE	541000552003**
VIGAMOX DRO 0.5%	86101038102020
WELCHOL PAK 3.75GM	39100016103040
WELCHOL TAB 625MG	39100016100330
XALATAN SOL 0.005%	86330050002020
YASMIN 28 TAB 3-0.03MG	25990002150320
ZANAFLEX	751000901001**

ZANAFLEX TAB 4MG	75100090100320
ZESTRIL	361000300003**
ZONEGRAN	726000900001**
ZOVIRAX CRE 5%	90350010003720
ZYPREXA	591570600003**
ZYPREXA INJ 10MG	59157060002120
BROVANA	442010121025**
NITRO-DUR	321000300085**
LATISSE	90734020002020
NITROSTAT	32100030000710
NITROSTAT	32100030000715
NITROSTAT	32100030000720
TOPICORT	90550040000910
ARTHROTEC 50	66109902200620
PROPECIA	90736030000310
ZOVIRAX	90350010004205
HALOG	90550070003710
DILANTIN-125	72200030001810
COMBIGAN	862599021520**
ZOLOFT	581600701003**
ACZONE	90051015004020
ACZONE	90051015004030

VIMPAT	726000360003**
VIMPAT	72600036002020
VIMPAT	72600036002060
PENTASA	52500030000220
KENALOG-40	22100050101810

3 . Revision History

Date	Notes
4/20/2023	Added Effexor XR, brand Arimidex, Depakote and Plaquenil as target drugs to guideline

Prior Authorization Guideline

Guideline Name	Gilenya (fingolimod) - PA, NF

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	12/14/2022
P&T Revision Date:	

1 . Indications

Drug Name: Gilenya (fingolimod)
Multiple Sclerosis Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older.

2 . Criteria

Product Name: Generic fingolimod, Brand Gilenya 0.25mg	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A-D]

AND

2 - Not used in combination with another disease-modifying therapy for MS [E, 5, 6]

AND

3 - Prescribed by or in consultation with a neurologist

Product Name: Brand Gilenya 0.5mg	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A-D]

AND

2 - Failure after a trial of at least 4 weeks, or intolerance to generic fingolimod

AND

3 - Not used in combination with another disease-modifying therapy for MS [E, 5, 6]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Brand Gilenya, generic fingolimod	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Failure after a trial of at least 4 weeks, or intolerance to generic fingolimod (applies to Brand Gilenya 0.5mg only)

AND

3 - Not used in combination with another disease-modifying therapy for MS [E, 5, 6]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Brand Gilenya 0.5mg	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A-D]

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming failure after a trial of at least 4 weeks, or intolerance to generic fingolimod

AND

3 - Not used in combination with another disease-modifying therapy for MS [E, 5, 6]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Brand Gilenya 0.5mg	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming failure after a trial of at least 4 weeks, or intolerance to generic fingolimod

AND

3 - Not used in combination with another disease-modifying therapy for MS [E, 5, 6]

AND

4 - Prescribed by or in consultation with a neurologist

3 . Endnotes

A. According to the National MS Society, of the four disease courses that have been identified in MS, relapsing-remitting MS (RRMS) is characterized primarily by relapses, and secondary-progressive MS (SPMS) has both relapsing and progressive characteristics. These two constitute “relapsing forms of MS” if they describe a disease course that is characterized by the occurrence of relapses. [3] The effectiveness of interferon beta in SPMS patients without relapses is uncertain. [2]
B. Initiation of treatment with an interferon beta medication or glatiramer acetate should be considered as soon as possible following a definite diagnosis of MS with active, relapsing disease, and may also be considered for selected patients with a first attack who are at high risk of MS. [2]
C. Based on several years of experience with glatiramer acetate and interferon beta 1a and 1b, it is the consensus of researchers and clinicians with expertise in MS that these agents are likely to reduce future disease activity and improve quality of life for many individuals with relapsing forms of MS, including those with secondary progressive disease who continue to have relapses. For those who are appropriate candidates for one of these drugs, treatment must be sustained for years. Cessation of treatment may result in a resumption of pre-treatment disease activity. [2]
D. MS specialists will use Copaxone in relapsing forms of disease, including SPMS with relapses. While there have been no trials of Copaxone in SPMS (so we have no evidenced-based data upon which to make decisions or recommendations), it's clear that where there are relapses, the injectable therapies are partially effective – they reduce relapses and new lesions on MRI. In SPMS, the trials suggest that the interferons work better in earlier, more inflammatory (i.e. those with relapses prior to the trial and with gadolinium-enhancing lesions, which is the MRI equivalent of active inflammation). Since Copaxone and the interferons appear to have rather similar efficacy in the head-to-head trials, most assume that Copaxone has a similar efficacy in SPMS: where there are relapses or active inflammation on MRI, it will likely have some benefit. Thus, most MS specialists will use Copaxone in patients with SPMS who have persistent relapses. [4]
E. The advantage of using combination disease-modifying therapy (DMT) compared to monotherapy DMT use has not been demonstrated, but there are safety concerns, such as reduced efficacy or disease aggravation, with combination use. [5, 6]

4 . References

1. Gilenya Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. December 2019.
2. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline: Disease-modifying therapies for adults with multiple sclerosis. Neurology 2018;90:777-788.
3. National Multiple Sclerosis Society. Types of MS. Available at: https://www.nationalmssociety.org/What-is-MS/Types-of-MS. Accessed March 29, 2019.
4. Per clinical consultation with MS specialist, December 29, 2010.
5. Wingerchuk, D., & Carter, J. (2014). Multiple Sclerosis: Current and Emerging Disease-Modifying Therapies and Treatment Strategies. Mayo Clinic Proceedings, 89(2), 225-240.
6. Sorensen, P., Lycke, J., Erälinna, J., Edland, A., Wu, X., & Frederiksen, J. et al. (2011). Simvastatin as add-on therapy to interferon beta-1a for relapsing-remitting multiple sclerosis (SIMCOMBIN study): a placebo-controlled randomised phase 4 trial. The Lancet Neurology, 10(8), 691-701.

5 . Revision History

Date	Notes
4/28/2023	Addition of NF criteria for Brand Gilenya 0.5mg

Prior Authorization Guideline

Guideline Name	Gilotrif (afatinib)

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	10/8/2013
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Gilotrif (afatinib)
EGFR Mutation-Positive, Metastatic Non-Small Cell Lung Cancer (NSCLC) Indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test. Limitation of Use: Safety and efficacy of Gilotrif have not been established in patients whose tumors have resistant EGFR mutations. **Previously Treated, Metastatic Squamous Non-Small Cell Lung Cancer (NSCLC)** Indicated for the treatment of patients with metastatic, squamous non-small cell lung cancer (NSCLC) progressing after platinum-based chemotherapy.

2 . Criteria

Product Name: Gilotrif	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced or metastatic (stage IIIB or IV) non-small cell lung cancer (NSCLC)

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Tumors have non-resistant epidermal growth factor (EGFR) mutations as detected by an U.S. Food and Drug Administration (FDA) -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).

AND

2.1.2 Gilotrif will be used as first-line treatment

OR

2.2 Both of the following:

2.2.1 Diagnosis of squamous NSCLC

AND

2.2.2 Disease progressed after platinum-based chemotherapy (e.g., cisplatin, carboplatin)

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Gilotrif	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Gilotrif Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. April 2022.

4 . Revision History

Date	Notes
4/10/2023	2023 Annual Review - references updated

Prior Authorization Guideline

Guideline Name	Gleevec (imatinib mesylate) - PA, NF

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	8/24/2001
P&T Revision Date:	12/18/2019 ; 09/15/2021 ; 03/16/2022 ; 09/21/2022 ; 5/18/2023

1 . Indications

Drug Name: Gleevec (imatinib mesylate)
Chronic myelogenous/myeloid leukemia (CML) Indicated for the treatment of newly diagnosed adult and pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia in chronic phase. Gleevec is also indicated for the treatment of patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in blast crisis (BC), accelerated phase (AP), or in chronic phase (CP) after failure of interferon-alpha therapy. **Acute lymphoblastic leukemia/ Acute lymphoblastic lymphoma (ALL)** Indicated for the treatment of adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL). Gleevec is also indicated for the treatment of pediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy. **Myelodysplastic/myeloproliferative diseases (MDS/MPD)** Indicated for the treatment of adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements. **Aggressive systemic mastocytosis (ASM)** Indicated for the treatment of adult patients with aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation or with c-Kit mutational status unknown.

Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) Indicated for the treatment of adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) who have the FIP1L1-PDGFRa fusion kinase (mutational analysis or fluorescence in situ hybridization [FISH] demonstration of CHIC2 allele deletion) and for patients with HES and/or CEL who are FIP1L1-PDGFRa fusion kinase negative or unknown.

Dermatofibrosarcoma protuberans (DFSP) Indicated for the treatment of adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP).

Gastrointestinal stromal tumors (GIST) Indicated for the treatment of patients with Kit (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST). Gleevec is also indicated for the adjuvant treatment of adult patients following complete gross resection of Kit (CD117) positive GIST.

2 . Criteria

Product Name: Brand Gleevec	
Diagnosis	Chronic Myelogenous/Myeloid Leukemia (CML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome/BCR ABL-positive (Ph+/BCR ABL+) chronic myelogenous/myeloid leukemia (CML)

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Trial and failure, or intolerance to generic imatinib

Product Name: Brand Gleevec	
Diagnosis	Chronic Myelogenous/Myeloid Leukemia (CML)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Philadelphia chromosome/BCR ABL-positive (Ph+/BCR ABL+) chronic myelogenous/myeloid leukemia (CML)

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

Product Name: Generic imatinib	
Diagnosis	Chronic Myelogenous/Myeloid Leukemia (CML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome/BCR ABL-positive (Ph+/BCR ABL+) chronic myelogenous/myeloid leukemia (CML)

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Brand Gleevec	
Diagnosis	Acute lymphoblastic leukemia/ Acute lymphoblastic lymphoma (ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Ph+/BCR ABL+ acute lymphoblastic leukemia (ALL)

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Trial and failure, or intolerance to generic imatinib

Product Name: Brand Gleevec	
Diagnosis	Acute lymphoblastic leukemia/ Acute lymphoblastic lymphoma (ALL)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Ph+/BCR ABL+ acute lymphoblastic leukemia (ALL)

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

Product Name: Generic imatinib	
Diagnosis	Acute lymphoblastic leukemia/ Acute lymphoblastic lymphoma (ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Ph+/BCR ABL+ acute lymphoblastic leukemia (ALL)

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Brand Gleevec	
Diagnosis	Myelodysplastic Disease (MDS)/Myeloproliferative Disease (MPD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myelodysplastic/myeloproliferative disease (MDS/MPD)

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Trial and failure, or intolerance to generic imatinib

Product Name: Brand Gleevec	
Diagnosis	Myelodysplastic Disease (MDS)/Myeloproliferative Disease (MPD)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of myelodysplastic/myeloproliferative disease (MDS/MPD)

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

Product Name: Generic imatinib	
Diagnosis	Myelodysplastic Disease (MDS)/Myeloproliferative Disease (MPD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myelodysplastic/myeloproliferative disease (MDS/MPD)

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Brand Gleevec	
Diagnosis	Aggressive Systemic Mastocytosis (ASM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of aggressive systemic mastocytosis (ASM)

AND

2 - Prescribed by or in consultation with one of the following:

- hematologist/oncologist
- allergist/immunologist

AND

3 - Trial and failure, or intolerance to generic imatinib

Product Name: Brand Gleevec	
Diagnosis	Aggressive Systemic Mastocytosis (ASM)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of aggressive systemic mastocytosis (ASM)

AND

2 - Prescribed by or in consultation with one of the following:

- hematologist/oncologist
- allergist/immunologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

Product Name: Generic imatinib	
Diagnosis	Aggressive Systemic Mastocytosis (ASM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of aggressive systemic mastocytosis (ASM)

AND

2 - Prescribed by or in consultation with one of the following:

- hematologist/oncologist
- allergist/immunologist

Product Name: Brand Gleevec	
Diagnosis	Hypereosinophilic Syndrome (HES) and/or Chronic Eosinophilic Leukemia (CEL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of at least one of the following:

- Hypereosinophilic syndrome (HES)
- Chronic eosinophilic leukemia (CEL)

AND

2 - Prescribed by or in consultation with one of the following:

- hematologist/oncologist
- allergist/immunologist

AND

3 - Trial and failure, or intolerance to generic imatinib

Product Name: Brand Gleevec	
Diagnosis	Hypereosinophilic Syndrome (HES) and/or Chronic Eosinophilic Leukemia (CEL)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of at least one of the following:

- Hypereosinophilic syndrome (HES)
- Chronic eosinophilic leukemia (CEL)

AND

2 - Prescribed by or in consultation with one of the following:

- hematologist/oncologist
- allergist/immunologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

Product Name: Generic imatinib	
Diagnosis	Hypereosinophilic Syndrome (HES) and/or Chronic Eosinophilic Leukemia (CEL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of at least one of the following:

- Hypereosinophilic syndrome (HES)
- Chronic eosinophilic leukemia (CEL)

AND

2 - Prescribed by or in consultation with one of the following:

- hematologist/oncologist
- allergist/immunologist

Product Name: Brand Gleevec	
Diagnosis	Dermatofibrosarcoma Protuberans (DFSP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of unresectable, recurrent, or metastatic dermatofibrosarcoma protuberans (DFSP)

AND

2 - Prescribed by or in consultation with one of the following:

- oncologist
- dermatologist

AND

3 - Trial and failure, or intolerance to generic imatinib

Product Name: Brand Gleevec	
Diagnosis	Dermatofibrosarcoma Protuberans (DFSP)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of unresectable, recurrent, or metastatic dermatofibrosarcoma protuberans (DFSP)

AND

2 - Prescribed by or in consultation with one of the following:

- oncologist
- dermatologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

Product Name: Generic imatinib	
Diagnosis	Dermatofibrosarcoma Protuberans (DFSP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of unresectable, recurrent, or metastatic dermatofibrosarcoma protuberans (DFSP)

AND

2 - Prescribed by or in consultation with one of the following:

- oncologist
- dermatologist

Product Name: Brand Gleevec	
Diagnosis	Gastrointestinal Stromal Tumors (GIST)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumors (GIST)

AND

2 - Prescribed by or in consultation with one of the following:

- oncologist
- gastroenterologist

AND

3 - Trial and failure, or intolerance to generic imatinib

Product Name: Brand Gleevec	
Diagnosis	Gastrointestinal Stromal Tumors (GIST)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumors (GIST)

AND

2 - Prescribed by or in consultation with one of the following:

- oncologist
- gastroenterologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

Product Name: Generic imatinib	
Diagnosis	Gastrointestinal Stromal Tumors (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumors (GIST)

AND

2 - Prescribed by or in consultation with one of the following:

- oncologist
- gastroenterologist

Product Name: Brand Gleevec, Generic imatinib	
Diagnosis	All Indications Listed Above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Gleevec Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. July 2021.

4 . Revision History

Date	Notes
4/28/2023	Program update to for MDS/MPD, ASM, GIST criteria to remove requ irement associated with genetic status.

Prior Authorization Guideline

Guideline Name	GLP-1 Agonists

Guideline Note:

Effective Date:	2/1/2023
P&T Approval Date:	6/7/2005
P&T Revision Date:	03/18/2020 ; 05/14/2020 ; 10/21/2020 ; 04/21/2021 ; 06/16/2021 ; 05/19/2022 ; 06/15/2022 ; 1/18/2023

1 . Indications

Drug Name: Byetta (exenatide injection)
Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: 1) Byetta is not indicated for use in patients with type 1 diabetes, 2) Byetta contains exenatide and should not be used with other products containing the active ingredient exenatide. 3) Byetta has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
Drug Name: Bydureon (exenatide extended-release)
Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus. Limitations of use: 1) Bydureon is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of the rat thyroid C-cell tumor findings to humans, 2) Bydureon is not indicated for use in patients with type 1 diabetes mellitus, 3) Bydureon is an extended-release formulation of exenatide and should not be used with other products containing the active ingredient exenatide, 4) Bydureon has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.

Drug Name: Bydureon BCise (exenatide extended-release)
Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus. Limitations of Use: 1) Bydureon BCise is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of the rat thyroid C-cell tumor findings to humans, 2) Bydureon BCise is not indicated for use in patients with type 1 diabetes mellitus, 3) Bydureon BCise is an extended-release formulation of exenatide and should not be used with other products containing the active ingredient exenatide, 4) Bydureon BCise has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
Drug Name: Trulicity (dulaglutide)
Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus, and is indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors. Limitations of Use: 1) Trulicity has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis, 2) should not be used in patients with type 1 diabetes mellitus, 3) has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis and is therefore not recommended in these patients.
Drug Name: Ozempic (semaglutide)
Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus, and is indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease. Limitations of use: 1) Ozempic has not been studied in patients with a history of pancreatitis. Consider another antidiabetic therapy in patients with a history of pancreatitis, 2) Ozempic is not indicated for use in patients with type 1 diabetes mellitus.
Drug Name: Victoza (liraglutide injection)
Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in patients 10 years and older with type 2 diabetes mellitus, and is indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease. Limitations of Use: 1) Victoza should not be used in patients with type 1 diabetes mellitus, 2) contains liraglutide and should not be coadministered with other liraglutide-containing products.

2 . Criteria

Product Name: Byetta, Bydureon/Bydureon BCise, Ozempic, Trulicity, Victoza	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Drug is not solely being used for weight loss

AND

3 - Trial and failure, contraindication, or intolerance to one of the following generics:

- Metformin
- Metformin ER
- Glipizide-metformin
- Glyburide-metformin
- Pioglitazone-metformin

3 . References

1. Byetta Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. November 2021.
2. Victoza Prescribing Information. Novo Nordisk Inc. Plainsboro, NJ. December 2021.
3. Bydureon Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. July 2021.
4. Trulicity Prescribing Information. Eli Lily and Company. Indianapolis, IN. December 2021.
5. Bydureon BCise Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. July 2021.
6. Ozempic Prescribing Information. Novo Nordisk Inc. Plainsboro, NJ. March 2022.

4 . Revision History

Date	Notes
1/4/2023	Added new GPI for Ozempic 0.25 or 0.5mg/dose pen

Prior Authorization Guideline

Guideline Name	Glumetza (metformin ER tablets)

Guideline Note:

Effective Date:	8/1/2022
P&T Approval Date:	5/17/2011
P&T Revision Date:	05/14/2020 ; 06/16/2021 ; 6/15/2022

1 . Indications

Drug Name: Glumetza (metformin ER tablets)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

2 . Criteria

Product Name: Brand Glumetza, Generic metformin ER 24 HR tablet [Generic Glumetza]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - One of the following:

1.1 Both of the following:

1.1.1 History of greater than or equal to 12 week trial of metformin extended-release (generic Glucophage XR) [A]

AND

1.1.2 Documented history of an inadequate response to metformin extended-release (generic Glucophage XR) as evidenced by Hemoglobin A1c level above patient's goal

OR

1.2 Documented history of intolerance to metformin extended-release (generic Glucophage XR) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g., dose reduction)

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 History of greater than or equal to 12 week trial of metformin immediate-release

AND

2.1.2 Documented history of an inadequate response to metformin immediate-release as evidenced by Hemoglobin A1c level above patient's goal

OR

2.2 Documented history of intolerance to metformin immediate-release which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g., dose reduction)

Product Name: Brand Glumetza, Generic metformin ER 24 HR tablet [Generic Glumetza]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has experienced an objective response to therapy demonstrated by an improvement in HbA1c from baseline	

3 . Endnotes

A. Prior authorization promotes use of cost-effective metformin options prior to approval of Glumetza (metformin extended release). Glucophage XR (metformin extended release) is also a 24 hour tablet preparation and is available generically.

4 . References

1. Glumetza Prescribing Information. Salix Pharmaceuticals. Bridgewater, NJ. August 2019.

5 . Revision History

Date	Notes
6/17/2022	Annual review: no changes.

Prior Authorization Guideline

Guideline Name	Gonadotropin-Releasing Hormone Agonists

Guideline Note:

Effective Date:	2/1/2023
P&T Approval Date:	12/12/2005
P&T Revision Date:	12/18/2019 ; 02/13/2020 ; 07/15/2020 ; 09/16/2020 ; 01/20/2021 ; 09/15/2021 ; 06/15/2022 ; 08/18/2022 ; 09/21/2022 ; 1/18/2023

1 . Indications

Drug Name: Lupron Depot (leuprolide acetate) 1-Month 7.5 mg, Lupron Depot 3-Month 22.5 mg, Lupron Depot 4-Month 30 mg, Lupron Depot 6-Month 45 mg
Prostate Cancer Indicated for treatment of advanced prostatic cancer. **Off Label Uses: Gender Dysphoria [18, 19]** Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [18] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [19]
Drug Name: Lupron Depot 3.75 mg
Endometriosis Indicated for the management of endometriosis, including pain relief and reduction of endometriotic lesions. In combination with a norethindrone acetate, it is also indicated for initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms. Limitations of Use: The total duration of therapy with LUPRON DEPOT 3.75 mg plus add-back therapy should not exceed 12 months due to

concerns about adverse impact on bone mineral density.

Uterine Leiomyomata (Fibroids) Indicated for concomitant use with iron therapy for preoperative hematologic improvement of women with anemia caused by fibroids for whom three months of hormonal suppression is deemed necessary. Limitations of Use: Not indicated for combination use with norethindrone acetate add-back therapy for the preoperative hematologic improvement of women with anemia caused by heavy menstrual bleeding due to fibroids.

Off Label Uses: Gender Dysphoria [18, 19] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [18] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would.

Drug Name: Lupron Depot 3-Month 11.25 mg

Endometriosis Indicated for the management of endometriosis, including pain relief and reduction of endometriotic lesions. In combination with a norethindrone acetate, it is also indicated for initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms. Limitations of Use: The total duration of therapy with LUPRON DEPOT 11.25 mg plus add-back therapy should not exceed 12 months due to concerns about adverse impact on bone mineral density.

Uterine Leiomyomata (Fibroids) Indicated for concomitant use with iron therapy for preoperative hematologic improvement of women with anemia caused by fibroids for whom three months of hormonal suppression is deemed necessary. Limitations of Use: Not indicated for combination use with norethindrone acetate add-back therapy for the preoperative hematologic improvement of women with anemia caused by heavy menstrual bleeding due to fibroids.

Off Label Uses: Gender Dysphoria [18, 19] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [18] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would.

Drug Name: Leuprolide Acetate

Prostate Cancer Indicated for the palliative treatment of advanced prostatic cancer.

Off Label Uses: Infertility Used for controlled ovarian hyperstimulation to enhance the in vitro fertilization-embryo transfer (IVF-ET) procedure. [6]

Gender Dysphoria [18, 19] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [18] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [19]

Drug Name: Leuprolide Acetate Depot

Prostate Cancer Indicated for the palliative treatment of advanced prostate cancer.

Off Label Uses: Gender Dysphoria [18, 19] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [18] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [19]

Drug Name: Lupron Depot-PED (leuprolide acetate)

Central Precocious Puberty (CPP) Indicated in the treatment of pediatric patients with central precocious puberty (CPP).

Off Label Uses: Gender Dysphoria [18, 19] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [18] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [19]

Drug Name: Lupaneta Pack (leuprolide acetate inj; norethindrone acetate tablets) 1-Month 3.75mg, 3-Month 11.25 mg

Endometriosis Indicated for initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms. Limitation of use: Duration of use is limited due to concerns about adverse impact on bone mineral density. The initial treatment course of Lupaneta Pack is limited to 6 months. A single retreatment course of not more than 6 months may be administered after the initial course of treatment if symptoms recur. Use of Lupaneta for longer than a total of 12 months is not recommended.

Drug Name: Camcevi (leuprolide)

Prostate Cancer Indicated for the treatment of adult patients with advanced prostate cancer.

Drug Name: Eligard (leuprolide acetate)
Prostate Cancer Indicated for the palliative treatment of advanced prostate cancer. **Gender Dysphoria [18, 19]** Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [18] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [19]
Drug Name: Fensolvi (leuprolide acetate)
Central Precocious Puberty (CPP) Indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP).
Drug Name: Supprelin LA (histrelin acetate)
Central Precocious Puberty (CPP) Indicated for the treatment of children with CPP. Children with CPP (neurogenic or idiopathic) have an early onset of secondary sexual characteristics (earlier than 8 years of age in females and 9 years of age in males). They also show a significantly advanced bone age that can result in diminished adult height attainment. Prior to initiation of treatment a clinical diagnosis of CPP should be confirmed by measurement of blood concentrations of total sex steroids, luteinizing hormone (LH) and follicle stimulating hormone (FSH) following stimulation with a GnRH analog, and assessment of bone age versus chronological age. Baseline evaluations should include height and weight measurements, diagnostic imaging of the brain (to rule out intracranial tumor), pelvic/testicular/adrenal ultrasound (to rule out steroid secreting tumors), human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor), and adrenal steroids to exclude congenital adrenal hyperplasia. **Gender Dysphoria [18, 19]** Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [18] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [19]
Drug Name: Trelstar (triptorelin pamoate)
Prostate Cancer Indicated for the palliative treatment of advanced prostate cancer. **Gender Dysphoria [18, 19]** Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-

acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [18] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [19]

Drug Name: Triptodur (triptorelin)

Central Precocious Puberty (CPP) Indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP).

Gender Dysphoria [18, 19] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [18] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [19]

Drug Name: Vantas (histrelin acetate)

Prostate Cancer Indicated for the palliative treatment of advanced prostate cancer.

2 . Criteria

Product Name: Lupron Depot (3.75 mg and 11.25 mg)	
Diagnosis	Endometriosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endometriosis

AND

2 - One of the following: [9, 13]

2.1 History of inadequate pain control response following a trial of at least 6 months, or history of intolerance or contraindication to one of the following:

- Danazol
- Combination (estrogen/progestin) oral contraceptive
- Progestins

OR

2.2 Patient has had surgical ablation to prevent recurrence

Product Name: Lupron Depot (3.75 mg and 11.25 mg)	
Diagnosis	Endometriosis
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Recurrence of symptoms following a trial of at least 6 months with leuprolide acetate

AND

2 - Used in combination with one of the following:

- Norethindrone 5 mg daily
- Other "add-back" sex-hormones (e.g., estrogen, medroxyprogesterone)
- Other bone-sparing agents (e.g., bisphosphonates)

Product Name: Lupron Depot (3.75 mg and 11.25 mg)	
Diagnosis	Uterine Leiomyomata (Fibroids) - For the reduction of the size of fibroids [off-label]
Approval Length	4 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For use prior to surgery to reduce the size of fibroids to facilitate a surgical procedure (e.g., myomectomy, hysterectomy) [6]

Product Name: Lupron Depot (3.75 mg and 11.25 mg)	
Diagnosis	Uterine Leiomyomata (Fibroids) - Anemia [5,7]
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For the treatment of anemia

AND

2 - Anemia is caused by uterine leiomyomata (fibroids)

AND

3 - Patient has tried and had an inadequate response to at least 1 month of monotherapy with iron

AND

4 - Used in combination with iron therapy

AND

5 - For use prior to surgery

Product Name: Fensolvi, Lupron Depot-PED, Supprelin LA, Triptodur	
Diagnosis	Central Precocious Puberty (CPP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of central precocious puberty (idiopathic or neurogenic)

AND

2 - Early onset of secondary sexual characteristics in one of the following:

- Females less than 8 years of age
- Males less than 9 years of age

AND

3 - Advanced bone age of at least one year compared with chronological age

AND

4 - One of the following:

4.1 Both of the following:

- Patient has undergone gonadotropin-releasing hormone agonist (GnRHa) testing
- Peak luteinizing hormone (LH) level above pre-pubertal range

OR

4.2 Patient has a random LH level in the pubertal range

AND

5 - One of the following:

5.1 Patient had one of the following diagnostic evaluations to rule out tumors, when suspected:

- Diagnostic imaging of the brain (MRI or CT scan) (in patients with symptoms suggestive of a brain tumor or in those 6 years of age or younger)
- Pelvic/testicular/adrenal ultrasound (if steroid levels suggest suspicion)
- Adrenal steroids to rule out congenital adrenal hyperplasia (when pubarche precedes thelarche or gonadarche)

OR

5.2 Patient has no suspected tumors

AND

6 - Prescribed by or in consultation with a pediatric endocrinologist

Product Name: Fensolvi, Lupron Depot-PED, Supprelin LA, Triptodur	
Diagnosis	Central Precocious Puberty (CPP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - LH levels have been suppressed to pre-pubertal levels

AND

2 - Prescribed by or in consultation with a pediatric endocrinologist

Product Name: Generic leuprolide acetate*	
Diagnosis	Treatment of Infertility (off-label) [6]
Approval Length	2 Month [A] (or per plan benefit design)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of infertility

AND

2 - Used as part of an assisted reproductive technology (ART) protocol

Notes	*Please consult client-specific resources to confirm whether benefit ex clusions should be reviewed for medical necessity.

Product Name: Eligard, Leuprolide Acetate, generic leuprolide acetate, Trelstar, Vantas	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced or metastatic prostate cancer [6, 16]

AND

2 - Trial and failure, contraindication, or intolerance to any brand Lupron formulation

Product Name: Camcevi, Lupron Depot (7.5 mg, 22.5 mg, 30 mg and 45 mg)	
Diagnosis	Prostate Cancer

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced or metastatic prostate cancer [6, 16]

Product Name: Camcevi, Eligard, Leuprolide Acetate, generic leuprolide acetate, Lupron Depot (7.5 mg, 22.5 mg, 30 mg and 45 mg), Trelstar, Vantas	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Lupaneta Pack	
Diagnosis	Endometriosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endometriosis

AND

2 - One of the following: [9, 13]

2.1 History of inadequate pain control response following a trial of at least 6 months, or history of intolerance or contraindication to one of the following:

- Danazol
- Combination (estrogen/progestin) oral contraceptive
- Progestins

OR

2.2 Patient has had surgical ablation to prevent recurrence

Product Name: Lupaneta Pack	
Diagnosis	Endometriosis
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Recurrence of symptoms following a trial of at least 6 months with leuprolide therapy

Product Name: Lupron Depot, Lupron Depot-PED, Leuprolide Acetate, generic leuprolide acetate, Eligard, Supprelin LA, Trelstar, Triptodur	
Diagnosis	Gender Dysphoria/Gender Incongruence (off-label) [18, 19]
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Using gonadotropin for suppression of puberty [18,19]

AND

2 - Diagnosis of gender dysphoria/gender incongruence

3 . Endnotes

A. Sixty days would be a reasonable length of authorization for the treatment of infertility. [14]

4 . References

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19. Coleman E, Bockting W, Botzer M et al. Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7. International Journal of Transgenderism. 13:165-232, 2011.
20. Triptodur prescribing information. Arbor Pharmaceuticals, LLC. Atlanta, GA. April 2022.
21. Fensolvi prescribing information. Tolmar Pharmaceuticals, Inc. Fort Collins, CO. April 2022.
22. Camcevi Prescriber Information. Accord BioPharma, Inc. Durham, NC. May 2021.
23. Leuprolide Acetate Depot Prescribing Information. Cipla USA, Inc. Warren, NJ. May 2022.

5 . Revision History

Date	Notes
12/20/2022	Updated guideline to include new formulations, leuprolide acetate de pot and generic leuprolide kit.

Prior Authorization Guideline

Guideline Name	Growth Hormones - PA, NF

Guideline Note:

Effective Date:	12/21/2022
P&T Approval Date:	3/17/2000
P&T Revision Date:	08/15/2019 ; 05/14/2020 ; 08/13/2020 ; 08/19/2021 ; 12/15/2021 ; 06/15/2022 ; 08/18/2022 ; 1/18/2023

1 . Indications

Drug Name: Genotropin, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, and Zomacton
Pediatric Growth Hormone Deficiency Indicated for the treatment of pediatric patients with growth failure due to inadequate secretion of endogenous growth hormone.
Drug Name: Skytrofa
Pediatric Growth Hormone Deficiency Indicated for the treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone (GH).
Drug Name: Genotropin and Omnitrope
Prader-Willi Syndrome (PWS) Indicated for the treatment of pediatric patients who have growth failure due to Prader-Willi Syndrome (PWS). The diagnosis of PWS should be confirmed by appropriate genetic testing. **Small for Gestational Age (SGA)** Indicated for the treatment of growth failure in children born small for gestational age (SGA) who fail to manifest catch-up growth by age 2.

Drug Name: Norditropin Flexpro, Humatrope, and Zomacton
Small for Gestational Age (SGA) Indicated for the treatment of pediatric patients with short stature born small for gestational age (SGA) with no catch-up growth by 2 years to 4 years of age.
Drug Name: Genotropin, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, and Zomacton
Turner Syndrome Indicated for the treatment of pediatric patients with short stature associated with Turner syndrome.
Drug Name: Humatrope and Zomacton
SHOX Deficiency Indicated for the treatment of pediatric patients with short stature or growth failure in short stature homeobox-containing gene (SHOX) deficiency.
Drug Name: Nutropin AQ NuSpin
Growth Failure Secondary to Chronic Kidney Disease (CKD) Indicated for the treatment of growth failure associated with CKD up to the time of renal transplantation. Nutropin AQ therapy should be used in conjunction with optimal management of CKD.
Drug Name: Norditropin Flexpro
Noonan Syndrome Indicated for the treatment of pediatric patients with short stature associated with Noonan Syndrome. **Prader-Willi Syndrome** Indicated for the treatment of pediatric patients with growth failure due to Prader-Willi syndrome (PWS).
Drug Name: Genotropin, Nutropin AQ NuSpin, and Omnitrope
[Non-Approvable Use] Idiopathic Short Stature (ISS) [E] Indicated for the treatment of idiopathic short stature, also called non-growth hormone-deficient short stature, defined by height SDS less than or equal to -2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range, in pediatric patients whose epiphyses are not closed and for whom diagnostic evaluation excludes other causes associated with short stature that should be observed or treated by other means. **Please Note: The request for growth hormone (GH) injections to treat idiopathic short stature (ISS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy.
Drug Name: Norditropin Flexpro and Humatrope
[Non-Approvable Use] Idiopathic Short Stature (ISS) [E] Indicated for the treatment of pediatric patients with Idiopathic Short Stature (ISS), height standard deviation score (SDS) less than -2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range. **Please Note: The request for growth hormone (GH) injections to treat

idiopathic short stature (ISS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy.

Drug Name: Genotropin, Nutropin AQ NuSpin, Omnitrope, and Saizen

Adult Growth Hormone Deficiency Indicated for replacement of endogenous growth hormone in adults with growth hormone deficiency who meet either of the following two criteria: Adult-Onset: Patients who have growth hormone deficiency, either alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma; or Childhood-Onset: Patients who were growth hormone deficient during childhood as a result of congenital, genetic, acquired, or idiopathic causes. Patients who were treated with somatropin for growth hormone deficiency in childhood and whose epiphyses are closed should be reevaluated before continuation of somatropin therapy at the reduced dose level recommended for growth hormone deficient adults. Confirmation of the diagnosis of adult growth hormone deficiency in both groups involves an appropriate growth hormone provocative test with two exceptions: (1) patients with multiple other pituitary hormone deficiencies due to organic disease; and (2) patients with congenital/genetic growth hormone deficiency.

Drug Name: Norditropin Flexpro, Humatrope, and Zomacton

Adult Growth Hormone Deficiency Indicated for the replacement of endogenous GH in adults with GH deficiency.

Drug Name: Serostim

AIDS Wasting or Cachexia Indicated for the treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance. Concomitant antiretroviral therapy is necessary.

Drug Name: Zorbtive

Short Bowel Syndrome Indicated for the treatment of short bowel syndrome in adult patients receiving specialized nutritional support.

Drug Name: Zomacton

[Non-Approvable Use] Idiopathic Short Stature (ISS) [E] Indicated for the treatment of pediatric patients with Idiopathic Short Stature (ISS), height standard deviation score (SDS) less than or equal to -2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range. **Please Note: The request for growth hormone (GH) injections to treat idiopathic short stature (ISS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy.

2 . Criteria

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 One of the following: [12]

1.1.1 Both of the following: [24-26]

- Infant is < 4 months of age
- Infant has suspected GH deficiency based on clinical presentation (e.g., persistent neonatal hypoglycemia, persistent or prolonged neonatal jaundice/elevated bilirubin, male infant with microgenitalia, midline anatomical defects, failure to thrive, etc.)

OR

1.1.2 History of neonatal hypoglycemia associated with pituitary disease

OR

1.1.3 Diagnosis of panhypopituitarism

OR

1.2 All of the following:

1.2.1 Diagnosis of pediatric GH deficiency as confirmed by one of the following: [10, 11, 12]

1.2.1.1 Height is documented by one of the following (utilizing age and gender growth charts related to height): [11]

- Height is > 2.0 standard deviations [SD] below midparental height
- Height is > 2.25 SD below population mean (below the 1.2 percentile for age and gender)

OR

1.2.1.2 Growth velocity is > 2 SD below mean for age and gender

OR

1.2.1.3 Delayed skeletal maturation of > 2 SD below mean for age and gender (e.g., delayed > 2 years compared with chronological age)

AND

1.2.2 Documentation of one of the following: [22]

1.2.2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

1.2.3 One of the following:

1.2.3.1 Both of the following: [10, 11, 12]

1.2.3.1.1 Patient has undergone two of the following provocative GH stimulation tests:

- Arginine

- Clonidine
- Glucagon
- Insulin
- Levodopa

AND

1.2.3.1.2 Both GH response values are < 10 mcg/L

OR

1.2.3.2 Both of the following: [11]

1.2.3.2.1 Patient is < 1 year of age

AND

1.2.3.2.2 One of the following is below the age and gender adjusted normal range as provided by the physician's lab: [A, 13, 14]

- Insulin-like Growth Factor 1 (IGF-1/Somatomedin-C)
- Insulin Growth Factor Binding Protein-3 (IGFBP-3)

AND

2 - Prescribed by or in consultation with an endocrinologist

Notes	Includes children who have undergone brain radiation. If patient is a T ransition Phase Adolescent or Adult who had childhood onset GH defi ciency, utilize criteria for Transition Phase Adolescent or Adult GH Def iciency. NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22, 23]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	Includes children who have undergone brain radiation. If patient is a T ransition Phase Adolescent or Adult who had childhood onset GH defi ciency, utilize criteria for Transition Phase Adolescent or Adult GH Def iciency.

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 One of the following: [12]

1.1.1 Both of the following: [24-26]

- Infant is < 4 months of age
- Suspected GHD based on clinical presentation (e.g., persistent neonatal hypoglycemia that is not responsive to treatment, persistent or prolonged neonatal jaundice/elevated bilirubin, male infant with microgenitalia, midline anatomical defects, etc.)

OR

1.1.2 History of neonatal hypoglycemia associated with pituitary disease

OR

1.1.3 Diagnosis of panhypopituitarism

OR

1.2 All of the following:

1.2.1 Diagnosis of pediatric GH deficiency as confirmed by one of the following: [10, 11, 12]

1.2.1.1 Height is documented by one of the following (utilizing age and gender growth charts related to height): [11]

- Height is > 2.0 standard deviations [SD] below midparental height
- Height is > 2.25 SD below population mean (below the 1.2 percentile for age and gender)

OR

1.2.1.2 Growth velocity is > 2 SD below mean for age and gender

OR

1.2.1.3 Delayed skeletal maturation of > 2 SD below mean for age and gender (e.g., delayed > 2 years compared with chronological age)

AND

1.2.2 Documentation of one of the following: [22]

1.2.2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

1.2.3 One of the following:

1.2.3.1 Both of the following: [10, 11, 12]

1.2.3.1.1 Patient has undergone two of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa

AND

1.2.3.1.2 Both GH response values are < 10 mcg/L

OR

1.2.3.2 Both of the following: [11]

1.2.3.2.1 Patient is < 1 year of age

AND

1.2.3.2.2 One of the following is below the age and gender adjusted normal range as provided by the physician's lab: [A, 13, 14]

- Insulin-like Growth Factor 1 (IGF-1/Somatomedin-C)
- Insulin Growth Factor Binding Protein-3 (IGFBP-3)

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Notes	Includes children who have undergone brain radiation. If patient is a T ransition Phase Adolescent or Adult who had childhood onset GH defi ciency, utilize criteria for Transition Phase Adolescent or Adult GH Def iciency. NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22, 23]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following:

1.1 One of the following: [12]

1.1.1 Both of the following: [24-26]

- Infant is < 4 months of age
- Suspected GHD based on clinical presentation (e.g., persistent neonatal hypoglycemia that is not responsive to treatment, persistent or prolonged neonatal jaundice/elevated bilirubin, male infant with microgenitalia, midline anatomical defects, etc.)

OR

1.1.2 History of neonatal hypoglycemia associated with pituitary disease

OR

1.1.3 Diagnosis of panhypopituitarism

OR

1.2 Submission of medical records (e.g., chart notes) documenting all of the following:

1.2.1 Diagnosis of pediatric GH deficiency as confirmed by one of the following: [10, 11, 12]

1.2.1.1 Height is documented by one of the following (utilizing age and gender growth charts related to height): [11]

- Height is > 2.0 standard deviations [SD] below midparental height
- Height is > 2.25 SD below population mean (below the 1.2 percentile for age and gender)

OR

1.2.1.2 Growth velocity is > 2 SD below mean for age and gender

OR

1.2.1.3 Delayed skeletal maturation of > 2 SD below mean for age and gender (e.g., delayed > 2 years compared with chronological age)

AND

1.2.2 One of the following: [22]

1.2.2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

1.2.3 One of the following:

1.2.3.1 Both of the following: [10, 11, 12]

1.2.3.1.1 Patient has undergone two of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa

AND

1.2.3.1.2 Both GH response values are < 10 mcg/L

OR

1.2.3.2 Both of the following: [11]

1.2.3.2.1 Patient is < 1 year of age

AND

1.2.3.2.2 One of the following is below the age and gender adjusted normal range as provided by the physician's lab: [A, 13, 14]

- Insulin-like Growth Factor 1 (IGF-1/Somatomedin-C)
- Insulin Growth Factor Binding Protein-3 (IGFBP-3)

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Notes	Includes children who have undergone brain radiation. If patient is a T ransition Phase Adolescent or Adult who had childhood onset GH defi ciency, utilize criteria for Transition Phase Adolescent or Adult GH Def iciency.

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting height increase of at least

2 cm/year over the previous year of treatment as documented by both of the following: [22, 23]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Submission of medical records (e.g., chart notes) documenting both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Skytrofa	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 One of the following: [12]

1.1.1 History of neonatal hypoglycemia associated with pituitary disease

OR

1.1.2 Diagnosis of panhypopituitarism

OR

1.2 All of the following:

1.2.1 Diagnosis of pediatric GH deficiency as confirmed by one of the following: [10, 11, 12]

1.2.1.1 Height is documented by one of the following (utilizing age and gender growth charts related to height): [11]

- Height is > 2.0 standard deviations [SD] below midparental height
- Height is > 2.25 SD below population mean (below the 1.2 percentile for age and gender)

OR

1.2.1.2 Growth velocity is > 2 SD below mean for age and gender

OR

1.2.1.3 Delayed skeletal maturation of > 2 SD below mean for age and gender (e.g., delayed > 2 years compared with chronological age)

AND

1.2.2 Documentation of one of the following: [22]

1.2.2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

1.2.3 Both of the following: [10, 11, 12]

1.2.3.1 Patient has undergone two of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa

AND

1.2.3.2 Both GH response values are < 10 mcg/L

AND

2 - Patient is 1 year of age or older

AND

3 - Patient weight is 11.5 kg or greater

AND

4 - Prescribed by or in consultation with an endocrinologist

AND

5 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Notes	NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name: Skytrofa	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22, 23]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Skytrofa	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following:

1.1 One of the following: [12]

1.1.1 History of neonatal hypoglycemia associated with pituitary disease

OR

1.1.2 Diagnosis of panhypopituitarism

OR

1.2 All of the following:

1.2.1 Submission of medical records (e.g., chart notes) documenting diagnosis of pediatric GH deficiency as confirmed by one of the following: [10, 11, 12]

1.2.1.1 Height is documented by one of the following (utilizing age and gender growth charts related to height): [11]

- Height is > 2.0 standard deviations [SD] below midparental height
- Height is > 2.25 SD below population mean (below the 1.2 percentile for age and gender)

OR

1.2.1.2 Growth velocity is > 2 SD below mean for age and gender

OR

1.2.1.3 Delayed skeletal maturation of > 2 SD below mean for age and gender (e.g., delayed > 2 years compared with chronological age)

AND

1.2.2 One of the following: [22]

1.2.2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

1.2.3 Both of the following: [10, 11, 12]

1.2.3.1 Patient has undergone two of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon

- Insulin
- Levodopa

AND

1.2.3.2 Both GH response values are < 10 mcg/L

AND

2 - Patient is 1 year of age or older

AND

3 - Patient weight is 11.5 kg or greater

AND

4 - Prescribed by or in consultation with an endocrinologist

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Notes	NOTE: Documentation of previous height, current height and goal exp ected adult height will be required for renewal.

Product Name: Skytrofa	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22, 23]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Submission of medical records (e.g., chart notes) documenting both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin [off-label] [B, 11]	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Prader-Willi Syndrome [10, 11]

AND

2 - Prescribed by or in consultation with an endocrinologist

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin [off-label] [B, 11]	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Evidence of positive response to therapy (e.g., increase in total lean body mass, decrease in fat mass)

OR

1.2 Both of the following:

1.2.1 Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

1.2.2 Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

2 - Prescribed by or in consultation with an endocrinologist

Product Name: Genotropin, Humatrope [off-label], Saizen [off-label], Zomacton [off-label] [B, 11], or Omnitrope	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Prader-Willi Syndrome [10, 11]

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope [off-label], Saizen [off-label], Zomacton [off-label] [B, 11], or Omnitrope	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Evidence of positive response to therapy (e.g., increase in total lean body mass, decrease in fat mass)

OR

1.2 Both of the following:

1.2.1 Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

1.2.2 Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope [off-label], Saizen [off-label], Zomacton [off-label] [B, 11], or Omnitrope	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Prader-Willi Syndrome [10, 11]

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope [off-label], Saizen [off-label], Zomacton [off-label] [B, 11], or Omnitrope	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following:

1.1 Evidence of positive response to therapy (e.g., increase in total lean body mass, decrease in fat mass)

OR

1.2 Submission of medical records (e.g., chart notes) documenting both of the following:

1.2.1 Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

1.2.2 Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin [off-label] [B, 11]	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of SGA based on demonstration of catch up growth failure in the first 24 months of life using a 0-36 month growth chart as confirmed by the following criterion: [10]

1.1 One of the following is below the 3rd percentile for gestational age (more than 2 SD below population mean):

- Birth weight
- Birth length

AND

2 - Height remains less than or equal to 3rd percentile (more than 2 SD below population mean) [10]

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	NOTE: Documentation of previous height, current height and goal exp ected adult height will be required for renewal.

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin [off-label] [B, 11]	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

Product Name: Genotropin, Humatrope, Saizen [off-label] [B, 11], Zomacton, or Omnitrope	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of SGA based on demonstration of catch up growth failure in the first 24 months of life using a 0-36 month growth chart as confirmed by the following criterion: [10]

1.1 One of the following is below the 3rd percentile for gestational age (more than 2 SD below the population mean):

- Birth weight
- Birth length

AND

2 - Height remains less than or equal to 3rd percentile (more than 2 SD below population mean) [10]

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Notes	NOTE: Documentation of previous height, current height and goal exp ected adult height will be required for renewal.

Product Name: Genotropin, Humatrope, Saizen [off-label] [B, 11], Zomacton, or Omnitrope	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [28]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope, Saizen [off-label] [B, 11], Zomacton, or Omnitrope	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of SGA based on demonstration of catch up growth failure in the first 24 months of life using a 0-36 month growth chart as confirmed by the following criterion: [10]

1.1 Submission of medical records (e.g., chart notes) documenting one of the following is below the 3rd percentile for gestational age (more than 2 SD below the population mean):

- Birth weight
- Birth length

AND

2 - Submission of medical records (e.g., chart notes) documenting height remains less than or equal to 3rd percentile (more than 2 SD below population mean) [10]

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope, Saizen [off-label] [B, 11], Zomacton, or Omnitrope	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [28]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Submission of medical records (e.g., chart notes) documenting both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Turner Syndrome or Noonan Syndrome [off-label except for Norditropin] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with one of the following: [10, 22]

1.1 Both of the following:

1.1.1 Turner Syndrome (Gonadal Dysgenesis)

AND

1.1.2 Documentation of both of the following:

- Patient is female
- Bone age < 14 years

OR

1.2 Both of the following:

1.2.1 Noonan Syndrome

AND

1.2.2 Documentation of one of the following:

1.2.2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

2 - Height is below the 5th percentile on growth charts for age and gender [10]

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	NOTE: Documentation of previous height, current height and goal exp ected adult height will be required for renewal

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Turner Syndrome or Noonan Syndrome [off-label except for Norditropin] [B, 11]
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Turner Syndrome [off-label for Saizen] or Noonan Syndrome [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with one of the following: [10, 22]

1.1 Both of the following:

1.1.1 Turner Syndrome (Gonadal Dysgenesis)

AND

1.1.2 Documentation of both of the following:

- Patient is female
- Bone age < 14 years

OR

1.2 Both of the following:

1.2.1 Noonan Syndrome

AND

1.2.2 Documentation of one of the following:

1.2.2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

2 - Height is below the 5th percentile on growth charts for age and gender [10]

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Notes	NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Turner Syndrome [off-label for Saizen] or Noonan Syndrome [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Turner Syndrome [off-label for Saizen] or Noonan Syndrome [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with one of the following: [10, 22]

1.1 Both of the following:

1.1.1 Turner Syndrome (Gonadal Dysgenesis)

AND

1.1.2 Submission of medical records (e.g., chart notes) documenting both of the following:

- Patient is female
- Bone age < 14 years

OR

1.2 Both of the following:

1.2.1 Noonan Syndrome

AND

1.2.2 Submission of medical records (e.g., chart notes) documenting one of the following:

1.2.2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

2 - Submission of medical records (e.g., chart notes) documenting height below the 5th percentile on growth charts for age and gender [10]

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Turner Syndrome [off-label for Saizen] or Noonan Syndrome [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Submission of medical records (e.g., chart notes) documenting both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claim or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin

Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure with short stature homeobox (SHOX) gene deficiency as confirmed by genetic testing [2]

AND

2 - Documentation of one of the following: [22]

2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	NOTE: Documentation of previous height, current height and goal exp ected adult height will be required for renewal.

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

Product Name: Genotropin [off-label], Humatrope, Saizen [off-label], Zomacton, or Omnitrope [off-label] [B, 11]	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure with short stature homeobox (SHOX) gene deficiency as confirmed by genetic testing [2]

AND

2 - Documentation of one of the following: [22]

2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Notes	NOTE: Documentation of previous height, current height and goal exp ected adult height will be required for renewal.

Product Name: Genotropin [off-label], Humatrope, Saizen [off-label], Zomacton, or Omnitrope [off-label] [B, 11]	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin [off-label], Humatrope, Saizen [off-label], Zomacton, or Omnitrope [off-label] [B, 11]	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of pediatric growth failure with short stature homeobox (SHOX) gene deficiency as confirmed by genetic testing [2]

AND

2 - Submission of medical records (e.g., chart notes) documenting one of the following: [22]

2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin [off-label], Humatrope, Saizen [off-label], Zomacton, or Omnitrope [off-label] [B, 11]	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Submission of medical records (e.g., chart notes) documenting both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Norditropin Flexpro [off-label] [B, 11] or Nutropin AQ NuSpin	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with chronic renal insufficiency [10]

AND

2 - Documentation of one of the following: [22]

2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Nephrologist

Notes	NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name: Norditropin Flexpro [off-label] [B, 11] or Nutropin AQ NuSpin	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Nephrologist

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with chronic renal insufficiency [10]

AND

2 - Documentation of one of the following: [22]

2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Nephrologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Notes	NOTE: Documentation of previous height, current height and goal exp ected adult height will be required for renewal.

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency [off-label] [B, 11]
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Nephrologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency [off-label] [B, 11]
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with chronic renal insufficiency [10]

AND

2 - Submission of medical records (e.g., chart notes) documenting one of the following: [22]

2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Nephrologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Submission of medical records (e.g., chart notes) documenting both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Nephrologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of adult GH deficiency as a result of one of the following: [10, 12, 21]

1.1 Clinical records supporting a diagnosis of childhood-onset GHD

OR

1.2 Both of the following:

1.2.1 Adult-onset GHD

AND

1.2.2 Clinical records documenting that hormone deficiency is a result of hypothalamic-pituitary disease from organic or known causes (e.g., damage from surgery, cranial irradiation, head trauma, or subarachnoid hemorrhage)

AND

2 - One of the following: [10, 12, 20-21]

2.1 Both of the following:

2.1.1 Patient has undergone one of the following GH stimulation tests to confirm adult GH deficiency:

- Insulin tolerance test (ITT)
- Glucagon
- Macimorelin

AND

2.1.2 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 Both of the following:

2.2.1 Documented deficiency of three of the following anterior pituitary hormones:

- Prolactin
- Adrenocorticotropic hormone (ACTH)
- Thyroid stimulating hormone (TSH)
- Follicle-stimulating hormone/luteinizing hormone (FSH/LH)

AND

2.2.2 IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	Use the following criteria for child- and adult-onset with pituitary disea se; use Isolated GHD in Adult criteria for patients without pituitary dise ase.

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Evidence of ongoing monitoring as demonstrated by documentation within the past 12 months of an IGF-1/Somatomedin C level [10, 12, 21]

AND

2 - Prescribed by or in consultation with an endocrinologist

Notes	Use the following criteria for child- and adult-onset with pituitary disea se; use Isolated GHD in Adult criteria for patients without pituitary dise ase.

Product Name: Genotropin, Humatrope, Saizen, Zomacton [B, 21], or Omnitrope	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of adult GH deficiency as a result of one of the following: [10, 12, 21]

1.1 Clinical records supporting a diagnosis of childhood-onset GHD

OR

1.2 Both of the following:

1.2.1 Adult-onset GHD

AND

1.2.2 Clinical records documenting that hormone deficiency is a result of hypothalamic-

pituitary disease from organic or known causes (e.g., damage from surgery, cranial irradiation, head trauma, or subarachnoid hemorrhage)

AND

2 - One of the following: [10, 12, 21]

2.1 Both of the following:

2.1.1 Patient has undergone one of the following GH stimulation tests to confirm adult GH deficiency:

- Insulin tolerance test (ITT)
- Glucagon
- Macimorelin

AND

2.1.2 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 Both of the following:

2.2.1 Documented deficiency of three of the following anterior pituitary hormones:

- Prolactin
- ACTH
- TSH
- FSH/LH

AND

2.2.2 IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Notes	Use the following criteria for child- and adult-onset with pituitary disea se; use Isolated GHD in Adult criteria for patients without pituitary dise ase.

Product Name: Genotropin, Humatrope, Saizen, Zomacton [B, 21], or Omnitrope	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Evidence of ongoing monitoring as demonstrated by documentation within the past 12 months of an IGF-1/Somatomedin C level [10, 12, 21]

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Notes	Use the following criteria for child- and adult-onset with pituitary disea se; use Isolated GHD in Adult criteria for patients without pituitary dise ase.

Product Name: Genotropin, Humatrope, Saizen, Zomacton [B, 21], or Omnitrope	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of adult GH deficiency as a result of one of the following: [10, 12, 21]

1.1 Submission of medical records (e.g., chart notes) supporting a diagnosis of childhood-onset GHD

OR

1.2 Both of the following:

1.2.1 Adult-onset GHD

AND

1.2.2 Submission of medical records (e.g., chart notes) documenting that hormone deficiency is a result of hypothalamic-pituitary disease from organic or known causes (e.g., damage from surgery, cranial irradiation, head trauma, or subarachnoid hemorrhage)

AND

2 - One of the following: [10, 12, 21]

2.1 Both of the following:

2.1.1 Patient has undergone one of the following GH stimulation tests to confirm adult GH deficiency:

- Insulin tolerance test (ITT)
- Glucagon
- Macimorelin

AND

2.1.2 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 Both of the following:

2.2.1 Submission of medical records (e.g., chart notes) documenting deficiency of three of the following anterior pituitary hormones:

- Prolactin
- ACTH
- TSH
- FSH/LH

AND

2.2.2 IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Notes	Use the following criteria for child- and adult-onset with pituitary disea se; use Isolated GHD in Adult criteria for patients without pituitary dise ase.

Product Name: Genotropin, Humatrope, Saizen, Zomacton [B, 21], or Omnitrope	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting evidence of ongoing monitoring within the past 12 months of an IGF-1/Somatomedin C level [10, 12, 21]

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Notes	Use the following criteria for child- and adult-onset with pituitary disea se; use Isolated GHD in Adult criteria for patients without pituitary dise ase.

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Transition Phase Adolescent Patients
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following: [21]

- Attained expected adult height
- Closed epiphyses on bone radiograph

AND

2 - One of the following: [20, 21]

2.1 Both of the following:

2.1.1 Documentation of high risk of GH deficiency due to GH deficiency in childhood from one of the following:

2.1.1.1 Embryopathic/congenital defects

OR

2.1.1.2 Genetic mutations

OR

2.1.1.3 Irreversible structural hypothalamic-pituitary disease

OR

2.1.1.4 Panhypopituitarism

OR

2.1.1.5 Deficiency of three of the following anterior pituitary hormones:

- ACTH
- TSH
- Prolactin
- FSH/LH

AND

2.1.2 One of the following:

2.1.2.1 IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

OR

2.1.2.2 All of the following:

2.1.2.2.1 Patient does not have a low IGF-1/Somatomedin C level

AND

2.1.2.2.2 Discontinued GH therapy for at least 1 month

AND

2.1.2.2.3 Patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT

- Glucagon
- Macimorelin

AND

2.1.2.2.4 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 All of the following:

2.2.1 At low risk of severe GH deficiency (e.g., due to isolated and/or idiopathic GH deficiency)

AND

2.2.2 Discontinued GH therapy for at least 1 month

AND

2.2.3 Patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- Glucagon
- Macimorelin

AND

2.2.4 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L

- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

AND

3 - Prescribed by or in consultation with an endocrinologist

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Transition Phase Adolescent Patients
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Evidence of positive response to therapy (e.g., increase in total lean body mass, exercise capacity or IGF-1 and IGFBP-3 levels)

AND

2 - Prescribed by or in consultation with an endocrinologist

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Transition Phase Adolescent Patients [off-label] [B]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following: [21]

- Attained expected adult height

- Closed epiphyses on bone radiograph

AND

2 - One of the following: [20, 21]

2.1 Both of the following:

2.1.1 Documentation of high risk of GH deficiency due to GH deficiency in childhood from one of the following:

2.1.1.1 Embryopathic/congenital defects

OR

2.1.1.2 Genetic mutations

OR

2.1.1.3 Irreversible structural hypothalamic-pituitary disease

OR

2.1.1.4 Panhypopituitarism

OR

2.1.1.5 Deficiency of three of the following anterior pituitary hormones:

- ACTH
- TSH
- Prolactin
- FSH/LH

AND

2.1.2 One of the following:

2.1.2.1 IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

OR

2.1.2.2 All of the following:

2.1.2.2.1 Patient does not have a low IGF-1/Somatomedin C level

AND

2.1.2.2.2 Discontinued GH therapy for at least 1 month

AND

2.1.2.2.3 Patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- Glucagon
- Macimorelin

AND

2.1.2.2.4 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 All of the following:

2.2.1 At low risk of severe GH deficiency (e.g., due to isolated and/or idiopathic GH deficiency)

AND

2.2.2 Discontinued GH therapy for at least 1 month

AND

2.2.3 Patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- Glucagon
- Macimorelin

AND

2.2.4 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Transition Phase Adolescent Patients [off-label] [B]

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Evidence of positive response to therapy (e.g., increase in total lean body mass, exercise capacity or IGF-1 and IGFBP-3 levels)

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Transition Phase Adolescent Patients [off-label] [B]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting one of the following: [21]

- Attained expected adult height
- Closed epiphyses on bone radiograph

AND

2 - Submission of medical records (e.g., chart notes) documenting one of the following: [20, 21]

2.1 Both of the following:

2.1.1 Documentation of high risk of GH deficiency due to GH deficiency in childhood from one of the following:

2.1.1.1 Embryopathic/congenital defects

OR

2.1.1.2 Genetic mutations

OR

2.1.1.3 Irreversible structural hypothalamic-pituitary disease

OR

2.1.1.4 Panhypopituitarism

OR

2.1.1.5 Deficiency of three of the following anterior pituitary hormones:

- ACTH
- TSH
- Prolactin
- FSH/LH

AND

2.1.2 One of the following:

2.1.2.1 IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

OR

2.1.2.2 All of the following:

2.1.2.2.1 Patient does not have a low IGF-1/Somatomedin C level

AND

2.1.2.2.2 Discontinued GH therapy for at least 1 month

AND

2.1.2.2.3 Patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- Glucagon
- Macimorelin

AND

2.1.2.2.4 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 All of the following:

2.2.1 At low risk of severe GH deficiency (e.g., due to isolated and/or idiopathic GH deficiency)

AND

2.2.2 Discontinued GH therapy for at least 1 month

AND

2.2.3 Patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- Glucagon
- Macimorelin

AND

2.2.4 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Serostim	
Diagnosis	Human Immunodeficiency Virus (HIV)-Associated Cachexia
Approval Length	3 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HIV-associated wasting syndrome or cachexia [7, 15, 18, 19]

AND

2 - One of the following: [7, 15, 18, 19, C]

2.1 Unintentional weight loss of > 10% over the last 12 months

OR

2.2 Unintentional weight loss of > 7.5% over the last 6 months

OR

2.3 Loss of 5% body cell mass (BCM) within 6 months

OR

2.4 Body mass index (BMI) < 20 kg/m^2

OR

2.5 All of the following

- Patient is male
- BCM < 35% of total body weight
- BMI < 27 kg/m^2

OR

2.6 All of the following

- Patient is female
- BCM < 23% of total body weight
- BMI < 27 kg/m^2

AND

3 - Nutritional evaluation since onset of wasting first occurred [7, 15, 18, 19]

AND

4 - Patient has not had weight loss as a result of other underlying treatable conditions (e.g., depression, mycobacterium avium complex, chronic infectious diarrhea, or malignancy with the exception of Kaposi's sarcoma limited to skin or mucous membranes) [7, 15, 18, 19]

AND

5 - Anti-retroviral therapy has been optimized to decrease the viral load [7, 15, 18, 19]

Product Name: Serostim	
Diagnosis	Human Immunodeficiency Virus (HIV)-Associated Cachexia
Approval Length	6 months [D]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Evidence of positive response to therapy (i.e., greater than or equal to 2% increase in body weight and/or BCM) [17, 18]

AND

2 - One of the following targets or goals has not been achieved: [17, 18]

- Weight
- BCM
- BMI

Product Name: Zorbtive	
Diagnosis	Short Bowel Syndrome
Approval Length	4 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Short Bowel Syndrome [9, 16]

AND

2 - Patient is currently receiving specialized nutritional support (e.g., intravenous parenteral nutrition, fluid, and micronutrient supplements) [9, 16]

AND

3 - Patient has not previously received 4 weeks of treatment with Zorbtive [9, 16]

Notes	NOTE: Treatment with Zorbtive will not be authorized beyond 4 weeks . Administration for more than 4 weeks has not been adequately studi ed.

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Isolated Growth Hormone Deficiency in Adults
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documented deficiency of GH as demonstrated by both of the following: [20-21]

1.1 Patient has undergone two of the following GH stimulation tests:

- ITT
- Glucagon
- Macimorelin

AND

1.2 Patient has two of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

AND

2 - Prescribed by or in consultation with an endocrinologist

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Isolated Growth Hormone Deficiency in Adults
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Evidence of ongoing monitoring as demonstrated by documentation within the past 12 months of an IGF-1/Somatomedin C level [10, 12, 21]

AND

2 - Prescribed by or in consultation with an endocrinologist

Product Name: Genotropin, Humatrope, Saizen, Zomacton [off-label] [B, 21], or Omnitrope	
Diagnosis	Isolated Growth Hormone Deficiency in Adults
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documented deficiency of GH as demonstrated by both of the following: [20-21]

1.1 Patient has undergone two of the following GH stimulation tests:

- ITT
- Glucagon
- Macimorelin

AND

1.2 Patient has two of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton [off-label] [B, 21], or Omnitrope	
Diagnosis	Isolated Growth Hormone Deficiency in Adults
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Evidence of ongoing monitoring as demonstrated by documentation within the past 12 months of an IGF-1/Somatomedin C level [10, 12, 21]

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton [off-label] [B, 21], or Omnitrope	
Diagnosis	Isolated Growth Hormone Deficiency in Adults
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting deficiency of GH as demonstrated by both of the following: [20-21]

1.1 Patient has undergone two of the following GH stimulation tests:

- ITT
- Glucagon
- Macimorelin

AND

1.2 Patient has two of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton [off-label] [B, 21], or Omnitrope	
Diagnosis	Isolated Growth Hormone Deficiency in Adults
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting evidence of ongoing monitoring within the past 12 months of an IGF-1/Somatomedin C level [10, 12, 21]

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: All Products	
Guideline Type	Prior Authorization, Non Formulary
Approval Criteria **1** - Requests for coverage of growth hormone for the diagnosis of Idiopathic Short Stature (ISS) are not authorized and will not be approved. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. [E]	
Notes	Approval Length: N/A - Requests for non-approvable diagnoses shoul d not be approved

3 . Endnotes

A. Several recent review articles in the literature have suggested that GH stimulation tests should no longer be used to diagnose GHD. [13,14] The authors argue that GH stimulation test may have side effects, lack precision, accuracy, and do not predict response to GH therapy. It has been suggested that newer diagnostic procedures such as serum IGF-1, IGFBP-3 concentrations, genetic testing and neuroimaging could provide an alternative approach to the diagnosis of GHD in childhood.
B. Overall, there are no observable differences in the results obtained among the different preparations as long as the regimen follows currently approved daily injections. Many of the products are available in a variety of injection devices that are meant to make administration more appealing and easier. Currently, there is no evidence that clinical

outcome differs among the various injection systems, although there may be patient and parent preferences for some of these devices. [11, 21]

C. Even a 5% weight loss in persons with HIV infection indicates a poor prognosis. [2]
D. Patients with HIV-associated wasting may begin an initial 12-week course of therapy with Serostim, 6 mg/day s.c. The clinician should monitor treatment responses by obtaining serial body weights and BCM measurements by BIA. A positive response to therapy probably should be considered as a 2% increase in body weight and/or BCM. Maintenance therapy may continue on a monthly basis as long as wasting is still evident. Once BCM has normalized, therapy can be stopped, with the patient being observed for an 8-week period. Over these 8 weeks, body weight, BCM, and any appearance of wasting symptoms can be monitored. If wasting reappears, therapy can be restarted. [17]
E. Guidelines for idiopathic short stature recommend against the routine use of GH in every child with height standard deviation score ≤ - 2.25. [23]

4 . References

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5. Omnitrope Prescribing Information. Sandoz Inc. Princeton, NJ. June 2019.
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5 . Revision History

Date	Notes
12/21/2022	Due to Norditropin shortage, formulary strategy for non-preferred age nts that previously required a trial of Norditropin and Nutropin will be updated to require a trial of one agent.

Prior Authorization Guideline

Guideline Name	Halaven (eribulin mesylate)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	4/5/2011
P&T Revision Date:	12/18/2019 ; 03/18/2020 ; 03/17/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Halaven (eribulin mesylate)
Metastatic Breast Cancer Indicated for the treatment of patients with metastatic breast cancer who have previously received at least two chemotherapeutic regimens for the treatment of metastatic disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting. **Liposarcoma** Indicated for the treatment of patients with unresectable or metastatic liposarcoma who have received a prior anthracycline-containing regimen.

2 . Criteria

Product Name: Halaven	
Diagnosis	Breast cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Disease is one of the following: [1-2]

- Recurrent
- Metastatic

AND

3 - Previous treatment with both of the following:

- One anthracycline [e.g., doxorubicin, Ellence (epirubicin)]
- One taxane [e.g., paclitaxel, Taxotere (docetaxel)]

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Halaven	
Diagnosis	Liposarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of liposarcoma

AND

2 - Disease is one of the following:

- Unresectable
- Metastatic

AND

3 - Previous treatment with one anthracycline-containing regimen (e.g., doxorubicin, epirubicin)

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Halaven	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Halaven Prescribing Information. Eisai Inc.,Woodcliff Lake, NJ. September 2021.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at www.nccn.org. Accessed Februrary 27, 2023.

4 . Revision History

Date	Notes
2/27/2023	2023 Annual Review

Prior Authorization Guideline

Guideline Name	Halcinonide cream

Guideline Note:

Effective Date:	9/1/2022
P&T Approval Date:	7/21/2021
P&T Revision Date:	7/20/2022

1 . Indications

Drug Name: Halcinonide cream
Corticosteroid-responsive dermatoses Indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

2 . Criteria

Product Name: Halcinonide cream	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria	

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure, contraindication, or intolerance to three of the following generics:

- betamethasone dipropionate 0.05% ointment
- betamethasone augmented 0.05% cream
- desoximetasone 0.25% cream
- fluocinonide 0.05% solution
- fluocinonide 0.05% cream
- fluocinonide 0.05% gel
- fluocinonide 0.05% ointment

3 . References

1. Halcinonide Prescribing Information. Glasshouse Pharmaceuticals Limited Canada. Ontario, Canada. October 2020.

4 . Revision History

Date	Notes
7/7/2022	Annual review: Updated criteria and background.

Prior Authorization Guideline

Guideline Name	Harvoni (ledipasvir/sofosbuvir) - PA, NF

Guideline Note:

Effective Date:	8/23/2022
P&T Approval Date:	10/14/2014
P&T Revision Date:	11/14/2019 ; 05/14/2020 ; 08/13/2020 ; 01/20/2021 ; 06/16/2021 ; 01/19/2022 ; 06/15/2022 ; 6/15/2022

1 . Indications

Drug Name: Harvoni (ledipasvir/sofosbuvir)
Chronic Hepatitis C Indicated for the treatment of adults and pediatric patients 3 years of age and older with chronic hepatitis C virus (HCV)]: - Genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis; - Genotype 1 infection with decompensated cirrhosis, for use in combination with ribavirin; - Genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, for use in combination with ribavirin

2 . Criteria

Product Name: Harvoni*, Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1 - Treatment Naive without Cirrhosis - Pre-Treatment HCV RNA less than 6 Million IU/mL
Approval Length	8 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1

AND

2 - Patient is without cirrhosis

AND

3 - Patient is treatment-naive

AND

4 - Pre-treatment HCV RNA less than 6 million IU/mL

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

7 - One of the following (applies to brand ledipasvir/sofosbuvir only):

7.1 Both of the following:

7.1.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 For continuation of prior brand ledipasvir/sofosbuvir

Notes	*Approve brand Harvoni at NDC level (i.e., closed NDC) if criteria are met.

Product Name: Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1 - Treatment Naive without Cirrhosis - Pre-Treatment HCV RNA less than 6 Million IU/mL
Approval Length	8 Week(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C genotype 1

AND

2 - Patient is without cirrhosis

AND

3 - Patient is treatment-naive

AND

4 - Submission of medical records documenting pre-treatment HCV RNA less than 6 million IU/mL

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

7 - One of the following:

7.1 Both of the following:

7.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Harvoni*, Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1 - Treatment Naive without Cirrhosis - Pre-Treatment HCV RNA greater than or equal to 6 Million IU/mL
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1

AND

2 - Patient is without cirrhosis

AND

3 - Patient is treatment-naive

AND

4 - Pre-treatment HCV RNA greater than or equal to 6 million IU/mL

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

7 - One of the following (applies to brand ledipasvir/sofosbuvir only):

7.1 Both of the following:

7.1.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 For continuation of prior brand ledipasvir/sofosbuvir

Notes	*Approve brand Harvoni at NDC level (i.e., closed NDC) if criteria are met.

Product Name: Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1 - Treatment Naive without Cirrhosis - Pre-Treatment HCV RNA greater than or equal to 6 Million IU/mL
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C genotype 1

AND

2 - Patient is without cirrhosis

AND

3 - Patient is treatment-naive

AND

4 - Submission of medical records documenting pre-treatment HCV RNA greater than or equal to 6 million IU/mL

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

7 - One of the following:

7.1 Both of the following:

7.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Harvoni*, Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 - Treatment-Naive or PegIFN/RBV-experienced or PegIFN/RBV/protease inhibitor-experienced (No Decompensated Cirrhosis)
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 4, 5, or 6

AND

2 - One of the following:

- Patient is treatment-naive
- Patient has prior failure to peginterferon alfa plus ribavirin treatment
- Patient has prior failure to treatment with peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, or telaprevir)

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - One of the following (applies to brand ledipasvir/sofosbuvir only):

6.1 Both of the following:

6.1.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)

- Brand Harvoni (ledipasvir/sofosbuvir)

AND

6.1.2 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

6.2 For continuation of prior brand ledipasvir/sofosbuvir

Notes	*Approve brand Harvoni at NDC level (i.e., closed NDC) if criteria are met.

Product Name: Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 - Treatment-Naive or PegIFN/RBV-experienced or PegIFN/RBV/protease inhibitor-experienced (No Decompensated Cirrhosis)
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C genotype 1, 4, 5, or 6

AND

2 - One of the following:

- Patient is treatment-naive
- Patient has prior failure to peginterferon alfa plus ribavirin treatment
- Patient has prior failure to treatment with peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, or telaprevir)

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - One of the following:

6.1 Both of the following:

6.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

6.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Harvoni*, Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Post-Liver Transplant
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6

AND

2 - Patient is a liver transplant recipient

AND

3 - One of the following:

3.1 Patient is without cirrhosis or has compensated cirrhosis (Child-Pugh Class A)

OR

3.2 Both of the following:

- Patient has decompensated cirrhosis (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist

- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - One of the following (applies to brand ledipasvir/sofosbuvir only):

6.1 Both of the following:

6.1.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

6.1.2 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

6.2 For continuation of prior brand ledipasvir/sofosbuvir

Notes	*Approve brand Harvoni at NDC level (i.e., closed NDC) if criteria are met.

Product Name: Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Post-Liver Transplant
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6

AND

2 - Patient is a liver transplant recipient

AND

3 - One of the following:

3.1 Patient is without cirrhosis or has compensated cirrhosis (Child-Pugh Class A)

OR

3.2 Both of the following:

- Patient has decompensated cirrhosis (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - One of the following:

6.1 Both of the following:

6.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

6.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Harvoni*, Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Decompensated Cirrhosis - Ribavirin Eligible
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6

AND

2 - Patient has decompensated cirrhosis (e.g., Child-Pugh Class B or C)

AND

3 - Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - Trial and failure, contraindication, or intolerance to ONE of the following (applies to brand ledipasvir/sofosbuvir only):

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

Notes	*Approve brand Harvoni at NDC level (i.e., closed NDC) if criteria are met.

Product Name: Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Decompensated Cirrhosis - Ribavirin Eligible
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has decompensated cirrhosis (e.g., Child-Pugh Class B or C)

AND

3 - Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

Product Name: Harvoni*, Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Decompensated Cirrhosis; Ribavirin Ineligible OR Prior Sovaldi or NS5A-Based Treatment Failure
Approval Length	24 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6

AND

2 - Patient has decompensated cirrhosis (e.g., Child-Pugh Class B or C)

AND

3 - One of the following:

3.1 Patient is ribavirin ineligible

OR

3.2 Both of the following:

- Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based therapy
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist

- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - Trial and failure, contraindication, or intolerance to ONE of the following (applies to brand ledipasvir/sofosbuvir only):

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

Notes	*Approve brand Harvoni at NDC level (i.e., closed NDC) if criteria are met.

Product Name: Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Decompensated Cirrhosis; Ribavirin Ineligible OR Prior Sovaldi or NS5A-Based Treatment Failure
Approval Length	24 Week(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has decompensated cirrhosis (e.g., Child-Pugh Class B or C)

AND

3 - One of the following:

3.1 Patient is ribavirin ineligible

OR

3.2 Both of the following:

- Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based therapy
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

3 . References

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4 . Revision History

Date	Notes
8/23/2022	Background update

Prior Authorization Guideline

Guideline Name	Healthcare Reform Copay Waiver Review

Guideline Note:

Effective Date:	1/5/2023
P&T Approval Date:	11/14/2019
P&T Revision Date:	

Note:

The intent of this policy is to allow patients to receive medications/products that are not on the Healthcare Reform (HCR) preventative drug list (but are in the same drug class) at no cost-share. First and foremost, the patient must meet the basic HCR criteria (as described below) in order to qualify for zero cost-share.

1 . Criteria

Product Name: Fluoride supplementation products	
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria **1** - Patient is between 6 months of age to 16 years of age*	

AND

2 - Requested product is a prescription (single ingredient only) oral fluoride supplementation product (does not include topical fluoride products such as toothpaste or rinses, etc.)

AND

3 - There is a clinical reason why the patient cannot take two products on the HCR preventive drug list** (e.g., the patient has had an allergic reaction or intolerance to an inactive ingredient or has experienced an inadequate response)

Notes	*Benefit exclusion if age not met. **The HCR preventive drug list is posted at: https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS%20Guidelines/Healthcare%20Reform%20Supporting%20Document.

Product Name: Folic acid supplementation products	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - Patient is of childbearing potential who is planning pregnancy*

AND

2 - Requested product is a prescription or OTC folic acid product (with prescription), including prenatal vitamins containing folic acid*

AND

3 - Requested product contains between 0.4 mg to 0.8 mg of folic acid**

AND

4 - There is a clinical reason why the patient cannot take two products on the HCR preventive drug list** (e.g., the patient has had an allergic reaction or intolerance to an inactive ingredient or has experienced an inadequate response)

Notes	*Benefit exclusion if not for childbearing or for multivitamins without folic acid. **Greater than 0.8mg is allowed for medical necessity. ***The HCR preventive drug list is posted at: https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS%20Guidelines/Healthcare%20Reform%20Supporting%20Document.

Product Name: Smoking Cessation products	
Approval Length	6 months per 12 months for zero copay with deductible bypass
Guideline Type	Administrative

Approval Criteria

1 - Patient is 18 years of age or older*

AND

2 - For use as an aid to smoking cessation treatment*

AND

3 - Any requested HCR $0 Rx or OTC smoking cessation product and quantity requested does not exceed the following quantities:

- Maximum of 180 days of therapy per year for all smoking cessation products
- Brand or Generic Chantix (varenicline)/Apo-Varenicline: starter kits limited to one 53 tablet starter kit; Maximum Daily Dose (MDD) = 2 units per day for remainder of therapy
- Nicotrol NS: MDD = 4 mL per day
- Nicotrol Inhaler: MDD = 16 units per day
- Zyban/Buproban/bupropion 150 mg SR: MDD = 2
- Brand or Generic OTC Nicotine replacement patch: MDD = 1
- Brand or Generic OTC Nicotine replacement gum: MDD = 24
- Brand or Generic OTC Nicotine replacement lozenge: MDD = 20

AND

4 - If request is for Nicotrol inhaler, Nicotrol NS, or Apo-Varenicline, a history of both of the following:

4.1 Generic Zyban (bupropion)

AND

4.2 One of the following smoking cessation therapies:

- Nicotine gum
- Nicotine lozenge
- Nicotine transdermal patch
- Generic varenicline

AND

5 - If request is for brand Chantix, one of the following:

5.1 A history of generic varenicline

OR

5.2 Member has had a contraindication or intolerance to generic varenicline

Notes	*Benefit exclusion if age not met or not used for smoking cessation or used beyond 180 days.

Product Name: Contraceptives [E]	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - For medical necessity requests, to waive cost-sharing for a medication not included on a zero cost-sharing coverage list* BOTH of the following must be met:

1.1 Patient is using the prescribed drug for contraception**

AND

1.2 The requested product is medically necessary***

Notes	*Zero cost share contraceptive coverage lists are available at: https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS%20Guidelines/Healthcare%20Reform%20Supporting%20Document. FDA Contraceptive Methods available at: https://www.fda.gov/consumers/free-publications-women/birth-control. **Benefit exclusion if not for contraception. ***Any justification of medical necessity/appropriateness provided by the prescriber is adequate to approve access of a preferred product at $0 cost share, in accordance with the ACA's contraceptive mandate.

Product Name: Aspirin	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - Patient meets the following*:

1.1 Patient is using 81 mg aspirin for the prevention of morbidity and mortality from preeclampsia

AND

1.2 Requested product is a single agent oral OTC aspirin product (with prescription) (but does not include prescription aspirin products, non-oral aspirin products, or aspirin strengths greater than 81 mg)

Notes	*Benefit exclusion if any criterion is not met.

Product Name: Immunizations	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - Requested product is a single-entity or combination vaccination for one of the following:**

- Diphtheria
- Haemophilus influenzae type B (applies only to children less than 6 years of age)*
- Hepatitis A
- Hepatitis B (Heplisav B applies only to adults ages 18 years and older)*
- Herpes zoster (Shingrix applies to adults ages 19 years and older)*
- Human papillomavirus (applies only to children and adults 9 years to 26 years of age)*
- Polio
- Influenza (Flumist applies only to children and adults 2 years through 49 years of age. Fluzone HD Quad, Fluad Quad applies only to adults ages 65 years and older)*
- Measles
- Mumps
- Rubella
- Meningococcal infections
- Pertussis
- Pneumococcal infections
- Rotavirus (applies only to children less than 8 months)*
- Tetanus
- Varicella

OR

2 - All of the following:

2.1 Requested product is for Dengue vaccine:

AND

2.2 Member is between ages 9-16 living in a dengue endemic area (endemic areas include Puerto Rico, American Samoa, US Virgin Islands, Federated States of Micronesia, Republic of Marshall Islands, and the Republic of Palau)***

AND

2.3 Member has a laboratory confirmation of a previous dengue infection

Notes	*Benefit exclusion if age not met. **This list excludes vaccines not listed in the Advisory Committee on Immunization Practices (ACIP) Imm

	unization Schedules (http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/index.html). ***For updated guidance on dengue endemic areas and pre-vaccination laboratory testing see: https://www.cdc.gov/mmwr/volumes/70/rr/rr7006a1.htm and https://www.cdc.gov/dengue/vaccine/hcp/index.html

Product Name: Bowel preparation agents for colorectal cancer screening [F]	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - Requested product is a prescription bowel preparation agent used for primary preventative colorectal cancer screening (e.g., patient does not have a previous history of adenomatous polyps or previous colorectal cancer)*

AND

2 - There is a clinical reason why the patient cannot take two generic products on the HCR preventive drug list** (e.g., the patient has had an allergic reaction or intolerance to an inactive ingredient or has experienced an inadequate response). (Some examples of generic bowel prep products include: TriLyte, Gavilyte, PEG-3350/electrolytes)

AND

3 - Quantity requested does not exceed the QL of two primary preventive bowel prep products per year***

Notes	*Benefit exclusion if not for cancer screening. **The HCR preventive drug list is posted at: https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS%20Guidelines/Healthcare%20Reform%20Supporting%20Document. ***If a patient has an intolerance, allergic reaction, or an inadequate response to one of the products on the HCR preventative drug list, then the quantity limits will not apply for one time only per drug category (to allow for another product to be tried on the HCR preventative drug list).

Product Name: Arimidex (anastrozole) 1 mg, Aromasin (exemestane) 25 mg, Evista (raloxifene) 60 mg, Soltamox (tamoxifen) solution, Tamoxifen 20 mg tablets

Approval Length	60 Months: Authorization will be issued for zero copay with deductible bypass for a total of up to 60 months (please determine if member has already received some length of therapy and if so subtract from total approval period).
Guideline Type	Administrative

Approval Criteria

1 - Member is greater than or equal to 35 years of age*

AND

2 - Member has no prior diagnosis of any of the following:*

- breast cancer
- ductal carcinoma in situ (DCIS)

AND

3 - Member has no history of thromboembolic events (e.g.- deep venous thrombosis, pulmonary embolus, stroke or transient ischemic attack)*

AND

4 - Member has an estimated 5 year risk of breast cancer based on a breast cancer risk assessment tool of greater than or equal to 3% [11]*

AND

5 - One of the following:

5.1 Request is for tamoxifen 20 mg once daily

OR

5.2 Both of the following:

5.2.1 Member is post-menopausal

AND

5.2.2 One of the following:

5.2.2.1 Request is for raloxifene 60 mg once daily, exemestane 25 mg once daily, or anastrozole 1 mg once daily

OR

5.2.2.2 Request is for brand name Evista 60 mg, Aromasin 25 mg, and Arimidex 1 mg once daily and member has had failure, contraindication or adverse reaction to generic raloxifene, exemestane, or anastrozole

OR

5.3 Both of the following:

5.3.1 Request is for Soltamox 20 mg once daily*

AND

5.3.2 Member has had failure, contraindication or adverse reaction to tamoxifen tablets

Notes	*Benefit exclusion if age not met or has prior cancer diagnosis or has t hromboembolic events or less than 3% risk factor or requesting a diffe rent strength. This program is designed to meet Health Care Reform r equirements which require coverage of tamoxifen tablets, Soltamox (t amoxifen) solution, Evista (raloxifene), Aromasin (exemestane), and A rimidex (anastozole) at zero dollar cost share if being used for primary prevention of breast cancer and criteria are met.

Product Name: Generic Statins	
Approval Length	24 month(s)
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 Request is for atorvastatin 10 mg or 20 mg, simvastatin 5 mg, 10 mg, 20 mg, or 40mg*

OR

1.2 Both of the following:

1.2.1 Request is for another moderate or low dose statin (pravastatin 10 mg, 20 mg, 40 mg, or 80 mg; fluvastatin 20 mg or 40 mg; pitavastatin 1 mg, 2 mg, or 4 mg; rosuvastatin 5 mg or 10 mg) (D)*

AND

1.2.2 Patient is unable to take all of the following:

- atorvastatin 10 mg or 20 mg
- simvastatin 5 mg, 10 mg, 20 mg, or 40 mg
- lovastatin (any strength)

AND

2 - Patient is at least 40 years old and younger than 75 years old*

AND

3 - Medication is being used for primary prevention of cardiovascular disease (CVD) (e.g., member has no history of cardiovascular events)*

AND

4 - Patient has one or more risk factors for CVD (e.g., dyslipidemia, diabetes, hypertension, or smoking)*

AND **5** - Patient has an estimated 10-year risk of a cardiovascular event of 10% or greater*	
Notes	*Benefit exclusion if any criterion not met. The HCR preventive drug li st is posted at: https://uhgazure.sharepoint.com/sites/CST/CSDM/Sha red%20Documents/UMCS%20Guidelines/Healthcare%20Reform%20 Supporting%20Document.

Product Name: Erythromycin 0.5% ophthalmic ointment	
Approval Length	1 Month: Authorization will be issued for zero copay with deductible bypass for up to 1 month
Guideline Type	Administrative
Approval Criteria **1** - Member or health care provider intends to administer medication to newborn for the prophylaxis of gonococcal ophthalmia* **OR** **2** - Newborn is 0-1 month of age**	
Notes	*Please note, requests may be submitted before the infant's birth, and could be requested under the mother's account. **Benefit exclusion if age exceeded. This program is designed to meet Health Care Refor m requirements which require coverage of erythromycin 0.5% ophthal mic ointment at zero dollar cost share if being used for primary preven tion of gonococcal ophthalmia neonatorum (GON) and criteria are met . [H] The HCR preventive drug list is posted at: https://uhgazure.share point.com/sites/CST/CSDM/Shared%20Documents/UMCS%20Guideli nes/Healthcare%20Reform%20Supporting%20Document.

Product Name: Brand Truvada 200-300 mg, Generic emtricitabine-tenofovir disoproxil fumarate 200-300 mg, Brand Viread 300mg, generic tenofovir disoproxil fumarate 300mg, Descovy	
Approval Length	12 Months: Authorization will be issued for zero copay with deductible bypass for 12 months

Guideline Type	Administrative
Approval Criteria **1** - Member is taking as effective antiretroviral therapy for pre-exposure prophylaxis (PrEP) **AND** **2** - One of the following: **2.1** Request is for generic emtricitabine-tenofovir disoproxil fumarate 200-300 mg or generic tenofovir disoproxil fumarate 300mg **OR** **2.2** History of contraindication or intolerance to generic emtricitabine-tenofovir disoproxil fumarate 200-300 mg (Applies to Brand Truvada 200-300 mg and Descovy only) **OR** **2.3** History of contraindication or intolerance to generic tenofovir disoproxil fumarate 300mg (Applies to Brand Viread 300mg only)	
Notes	This program is designed to meet Health Care Reform requirements which require coverage of effective HIV Prep regimens at zero dollar c ost share if being used for pre-exposure prophylaxis (PrEP) and criteri a are met. [I] *The HCR preventive drug list is posted at: https://uhgaz ure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS% 20Guidelines/Healthcare%20Reform%20Supporting%20Document.

2 . Endnotes

A. Important Risk Factors for Breast Cancer [5]: (1) Family history of breast or ovarian cancer (especially among first-degree relatives and onset before age 50 years); (2) History of atypical hyperplasia; (3) Non-malignant high-risk breast lesions; (4) Previous breast biopsy; (5) Extremely dense breast tissue; (6) Increasing age; (7) Race or ethnicity; (8) Age at menarche; (9) Age at first live childbirth; (10) Ductal carcinoma in situ (DCIS); (11) Lobular carcinoma in situ (LCIS); (12) Body mass index; (13)

Menopause status or age; (14) Estrogen and progestin use; (15) Smoking; (16) Alcohol use; (17) Physical activity; (18) Diet.

B. The Affordable Care Act (ACA) requires private insurers to cover certain preventive services without any patient cost-sharing (i.e., copayments) when they are delivered by a network provider. The Department of Health and Human Services (HHS) has recognized several recommending bodies (e.g., United States Preventive Services Task Force [USPSTF], Advisory Committee on Immunization Practices [ACIP] http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/index.html, Health Resources and Services Administration [HRSA]) who have identified several medication categories that fall within the preventive health mandate.
C. Has developed a Healthcare Reform Preventative Drug List posted at: https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS%20Guidelines/Healthcare%20Reform%20Supporting%20Document that identifies which products are eligible for coverage without patient copayment. Some products may be excluded (such as brand oral contraceptives) unless the patient meets the criteria in this exceptions policy.
D. Here is a brief summary of the exceptions allowed in this policy (provided the patient meets all of the specified criteria): (1) The fluoride supplementation exception allows for brand name products at no cost-share, but not combination products; (2) The folic acid exception allows for brand name and Rx products at no cost-share; (3) The smoking cessation exception allows for Chantix, Nicotrol Inhaler, Nicotrol NS, and brand Zyban at no cost-share, but not additional quantities beyond the QLs; all other covered tobacco cessation products for members ages 18 years and older and not to exceed listed QLs; (4) The contraceptives exception allows for brand name products at no cost-share; (5) The bowel preparation agent exception allows for brand name Rx products at no cost-share but not beyond the QL; and (6) The statin exception allows for atorvastatin 10 mg or 20 mg, or simvastatin 5 mg, 10 mg, 20 mg, or 40mg generics at no cost-share. Other moderate to low dose statins include: pravastatin 10 mg, 20 mg, 40 mg, or 80 mg, fluvastatin 20 mg or 40 mg, pitavastatin 1 mg or 2 mg or 4 mg, rosuvastatin 5 mg or 10 mg.
E. Oral Contraceptives: In order to receive an oral contraceptive at zero cost-share, a woman must be of childbearing potential and must be requesting an oral contraceptive for contraception (and not for another use) or if provider states medical necessity (as well as meeting the other criteria noted at the beginning of the policy). In addition, the 21 or 28 day oral contraceptive packs should not be approved for continuous use because there are continuous use products already on the Healthcare Reform Preventative Drug List posted at: https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS%20Guidelines/Healthcare%20Reform%20Supporting%20Document.
F. F. Bowel Preparation Agents: It is important to distinguish between a screening and a surveillance or diagnostic colonoscopy. Screening is performed in asymptomatic patients with no history of colon cancer, polyps, and/or gastrointestinal disease. [1] Whereas, a surveillance colonoscopy can be performed at varying ages and intervals based on the patient's personal history of colon cancer, polyps, and/or gastrointestinal disease. Patients with a history of colon polyp(s) are not recommended for a screening colonoscopy, but for a surveillance colonoscopy. Per the USPSTF, when the screening test results in the diagnosis of clinically significant colorectal adenomas or cancer, the patient will be followed by a surveillance regimen, and recommendations for screening are no longer applicable. [6] According to the USPSTF, routine colorectal cancer screening is now recommended in adults beginning at age 45 and continuing only until age 75. The American Cancer Society, the U.S. Multi-Society Task Force on Colorectal

Cancer, and the American College of Radiology jointly recommended screening for colorectal cancer beginning at 45 years of age by 1) high-sensitivity FOBT or fecal immunochemical testing annually, 2) flexible sigmoidoscopy every 5 years, 3) CT colonography (virtual colonoscopy) every 5 years, 4) colonoscopy every 10 years, or 5) fecal DNA at an unspecified interval. Based on the collective information above, we have a quantity limit in place of two bowel preparation agents per year. (This quantity limit will not apply if patient was intolerant to, had an allergic reaction, or an inadequate response to one of the bowel prep products on the HCR preventative drug list.)

G. Breast Cancer Prevention: The USPSTF recommends that clinicians engage in shared, informed decision-making with women who are at increased risk for breast cancer about medications to reduce their risk. [5] For women who are at an increased risk for breast cancer and at low risk for adverse medication effects, clinicians should offer to prescribe risk-reducing medications, such as tamoxifen or raloxifene. The USPSTF recommends against the routine use of medications, such as tamoxifen or raloxifene, for risk reduction of primary breast cancer in women who are not at increased risk for breast cancer. The updated STAR trial results show diminished benefits of raloxifene compared to tamoxifen after cessation of therapy, making it a preferred risk reduction choice for most post-menopausal women desiring non-surgical risk reduction therapy. However, consideration of toxicity (e.g., endometrial cancer or uterine bleeding) may still lead to the choice of raloxifene over tamoxifen in some women.
H. Gonococcal Ophthalmia Neonatorum (GON) Prevention: The USPSTF recommends prophylactic ocular topical medication for all newborns to prevent gonococcal ophthalmia neonatorum (GON). [17] GON can cause corneal scarring, ocular perforation, and blindness as early as 24 hours after birth. Erythromycin ophthalmic ointment is the only FDA approved drug for the prophylaxis of GON. Ocular prophylaxis of newborns is mandated in most states and is considered standard neonatal care.
I. The USPSTF recommends that clinicians offer preexposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition. [19] Once-daily oral treatment with Truvada is the only formulation of PrEP approved by the US Food and Drug Administration (FDA) for use in the United States in persons at risk of sexual acquisition of HIV infection. However, several studies reviewed by the USPSTF found that tenofovir disoproxil fumarate alone was also effective as PrEP, and CDC guidelines note that, given these trial data, tenofovir disoproxil fumarate alone can be considered as an alternative regimen for high-risk heterosexually active men and women and persons who inject drugs. [19, 20]
J. The USPSTF recommends that clinicians offer to prescribe risk-reducing medications, such as tamoxifen, raloxifene, or aromatase inhibitors, to women who are at increased risk for breast cancer and at low risk for adverse medication effects. (B recommendation) The USPSTF recommends against the routine use of risk-reducing medications, such as tamoxifen, raloxifene, or aromatase inhibitors, in women who are not at increased risk for breast cancer. (D recommendation) This recommendation applies to asymptomatic women 35 years and older, including women with previous benign breast lesions on biopsy (such as atypical ductal or lobular hyperplasia and lobular carcinoma in situ). This recommendation does not apply to women who have a current or previous diagnosis of breast cancer or ductal carcinoma in situ.

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4 . Revision History

Date	Notes
1/5/2023	Update to change aspirins strength from 325 MG to 81 MG

Prior Authorization Guideline

Guideline Name	Hereditary Angioedema Agents

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	2/17/2009
P&T Revision Date:	09/18/2019 ; 03/18/2020 ; 07/15/2020 ; 12/16/2020 ; 02/18/2021 ; 04/21/2021 ; 08/19/2021 ; 10/20/2021 ; 10/20/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Berinert (C1 esterase inhibitor [Human])
Acute treatment of Hereditary Angioedema (HAE) Indicated for the treatment of acute abdominal, facial, or laryngeal attacks of HAE in adult and adolescent patients. The safety and efficacy of Berinert for prophylactic therapy have not been established.
Drug Name: Cinryze (C1 esterase inhibitor [Human])
Prophylaxis of Hereditary Angioedema (HAE) Indicated for routine prophylaxis against angioedema attacks in adults, adolescents and pediatric patients (6 years old and above) with HAE. **Off Label Uses: Acute treatment of Hereditary Angioedema (HAE)** Following treatment with nanofiltered C1 inhibitor concentrate (Cinryze) for an acute attack, the median time to response was 30 minutes in 82 patients with HAE. [3]
Drug Name: Firazyr (icatibant)

Acute treatment of Hereditary Angioedema (HAE) Indicated for the treatment of acute attacks of HAE in adults 18 years of age and older.
Drug Name: Haegarda (C1 esterase inhibitor [Human])
Prophylaxis of Hereditary Angioedema (HAE) Indicated for routine prophylaxis to prevent HAE attacks in patients 6 years of age and older.
Drug Name: Kalbitor (ecallantide)
Acute treatment of Hereditary Angioedema (HAE) Indicated for treatment of acute attacks of HAE in patients 12 years of age and older.
Drug Name: Orladeyo (berotralstat)
Prophylaxis of Hereditary Angioedema (HAE) Indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years of age and older. Limitations of Use: The safety and effectiveness of ORLADEYO for the treatment of acute HAE attacks have not been established. ORLADEYO should not be used for treatment of acute HAE attacks. Additional doses or doses of ORLADEYO higher than 150 mg once daily are not recommended due to the potential for QT prolongation.
Drug Name: Ruconest (C1 esterase inhibitor [Recombinant])
Acute treatment of Hereditary Angioedema (HAE) Indicated for the treatment of acute attacks in adult and adolescent patients with HAE. Limitation of Use: Effectiveness was not established in HAE patients with laryngeal attacks.
Drug Name: Takhzyro (lanadelumab-flyo)
Prophylaxis of Hereditary Angioedema (HAE) Indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients 2 years and older.
Drug Name: Sajazir (icatibant)
Acute treatment of Hereditary Angioedema (HAE) Indicated for the treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older.

2 . Criteria

Product Name: Cinryze, Haegarda, Orladeyo or Takhzyro	
Diagnosis	Prophylaxis of HAE attacks
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) [A]

AND

2 - Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following:

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

AND

3 - For prophylaxis against HAE attacks [3]

AND

4 - One of the following:

- Patient is 6 years of age or older (applies to Cinryze and Haegarda only)
- Patient is 12 years of age or older (applies to Orladeyo only)
- Patient is 2 years of age or older (applies to Takhzyro only)

AND

5 - Prescribed by or in consultation with one of the following: [B]

- Immunologist
- Allergist

Product Name: Cinryze [off-label], Brand Firazyr, Generic icatibant, Sajazir, or Ruconest	
Diagnosis	Treatment of acute HAE attacks

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) [3, A]

AND

2 - Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by one of the following:

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

AND

3 - For the treatment of acute HAE attacks [3, C]

AND

4 - Not used in combination with other approved treatments for acute HAE attacks

AND

5 - One of the following:

- Patient is 6 years of age or older (applies to Cinryze only)
- Patient is 18 years of age or older (applies to Brand Firazyr, generic icatibant, and Sajazir only)

AND

6 - Prescribed by or in consultation with one of the following: [B]

- Immunologist

- Allergist

AND

7 - Trial and failure or intolerance to one of the following (applies to brand Firazyr only):

- generic icatibant
- Sajazir

Product Name: Kalbitor	
Diagnosis	Treatment of acute HAE attacks
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) [A]

AND

2 - Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by one of the following:

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

AND

3 - For the treatment of acute HAE attacks

AND

4 - Patient is greater than or equal to 12 years of age [D]

AND

5 - Not used in combination with other approved treatments for acute HAE attacks

AND

6 - Prescribed by or in consultation with one of the following: [B]

- Immunologist
- Allergist

Product Name: Berinert	
Diagnosis	Treatment of acute HAE attacks
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) [3, A]

AND

2 - Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by one of the following:

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

AND

3 - For the treatment of acute HAE attacks [3, C]

AND

4 - Not used in combination with other approved treatments for acute HAE attacks

AND

5 - One of the following:

5.1 Trial and failure, contraindication, or intolerance to Ruconest

OR

5.2 One of the following:

- Patient is 12 years of age or younger
- Documentation that patient has history of laryngeal attacks

AND

6 - Prescribed by or in consultation with one of the following: [B]

- Immunologist
- Allergist

3 . Endnotes

A. HAE is a rare genetic disorder caused by a deficiency of C1-inhibitor and is inherited in an autosomal dominant manner. This condition is characterized by recurrent episodes of angioedema, without urticaria or pruritus, which most often affect the skin or mucosal tissues of the upper respiratory and gastrointestinal tracts. Diagnosis of HAE requires a blood test to confirm low or abnormal levels of C1-inhibitor. [10]

B. Includes immunologist and allergist specialties to ensure the requirement for proper diagnosing and assessing the severity of the symptoms. In the pivotal Cinryze trial, criteria for participation of long term prophylaxis included patients 9 years and older with documented HAE (based on: a low C4 level plus low C1 inhibitor antigenic level/or low C1 inhibitor functional level OR a known HAE causing mutation) AND a history of at

least two HAE attack per month. [1, 8] Berinert is approved for the treatment of acute attacks in patients who are 13 years and older. In the pivotal Berinert trial patients had laboratory-confirmed C1-inhibitor deficiency (type I or II HAE). [9]

C. Following treatment with nanofiltered C1 inhibitor concentrate (Cinryze) for an acute attack, the median time to response was 30 minutes in 82 patients with hereditary angioedema (median number of attacks per patient, 3; range, 1 to 57 attacks) in an open-label extension trial (median follow-up of 11 months). Additionally, 93% of attacks responded within 4 hr after C1 inhibitor concentrate treatment. [3]
D. Kalbitor carries a black box warning that states the following: "Anaphylaxis has been reported after administration of Kalbitor. Because of the risk of anaphylaxis, Kalbitor should only be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and hereditary angioedema (HAE). Healthcare professionals should be aware of the similarity of symptoms between hypersensitivity reactions and hereditary angioedema and patients should be monitored closely. Do not administer Kalbitor to patients with known clinical hypersensitivity to Kalbitor." In 255 HAE patients treated with intravenous or subcutaneous Kalbitor in clinical studies, 10 patients (3.9%) experienced anaphylaxis. For the subgroup of 187 patients treated with subcutaneous Kalbitor, 5 patients (2.7%) experienced anaphylaxis. Symptoms associated with these reactions have included chest discomfort, flushing, pharyngeal edema, pruritus, rhinorrhea, sneezing, nasal congestion, throat irritation, urticaria, wheezing, and hypotension. These reactions occurred within the first hour after dosing. Other adverse reactions indicative of hypersensitivity reactions included the following: pruritus (5.1%), rash (3.1%), and urticaria (2.0%). Patients should be observed for an appropriate period of time after administration of Kalbitor, taking into account the time to onset of anaphylaxis seen in clinical trials. In the Kalbitor HAE program, patients developed antibodies to ecallantide. Rates of seroconversion increased with exposure to ecallantide over time. Overall, 7.4% of patients seroconverted to anti-ecallantide antibodies. Neutralizing antibodies to ecallantide were determined in vitro to be present in 4.7% of patients. Anti-ecallantide and anti-Po pastoris IgE antibodies were also detected. While the long-term effects of antibodies to Kalbitor are not known, patients who seroconvert may be at a higher risk of a hypersensitivity reaction. The manufacturer developed a Risk Evaluation and Mitigation Strategy (REMS) program consisting of a Medication Guide and Communication Plan to notify healthcare professionals of the risk of anaphylaxis and the need to distinguish signs and symptoms of anaphylaxis and HAE attack as they may overlap. The presence of the black box warning necessitating administration by a healthcare professional; development of antibodies to ecallantide that may predispose patients to higher risks of hypersensitivity reactions; and the requirement for a REMS program offer compelling evidence to warrant the continued inclusion of an age criterion. [7]

4 . References

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3. Micromedex Healthcare Series [internet database]. Greenwood Village (CO): Thomson Reuters (Healthcare) Inc. Updated periodically. Available at: http://www.thomsonhc.com/. Accessed July 30, 2019.
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5. Ruconest Prescribing Information. Pharming Healthcare Inc. Bridgewater, NJ. April 2020.
6. Firazyr Prescribing Information. Shire Orphan Therapies LLC. Lexington, MA. October 2021.
7. Kalbitor Prescribing Information. Dyax Corp. Lexington, MA. November 2021.
8. FDA/CDER. Briefing Document for Blood products Advisory Committee. Presented May 2, 2008. Available at: http://www.fda.gov/. Accessed July 30, 2019.
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11. Takhzyro Prescribing Information. Dyax Corp. Lexington, MA. February 2023.
12. Orladeyo Prescribing Information. BioCryst Pharmaceuticals, Inc. Durham, NC. March 2022.
13. Sajazir Prescribing Information. Cipla Ltd., India. May 2022.

5 . Revision History

Date	Notes
4/5/2023	Annual review: Updated Takhzyro criteria age requirement. Added n ew 150 mg/mL syringe formulation of Takhzyro (GPI 8584204020E5 10) to existing Takhzyro criteria. Updated references and backgroun d/indications.

Prior Authorization Guideline

Guideline Name	Hetlioz, Hetlioz LQ (tasimelteon) - PA, NF

Guideline Note:

Effective Date:	3/1/2023
P&T Approval Date:	4/8/2014
P&T Revision Date:	09/18/2019 ; 09/16/2020 ; 02/18/2021 ; 06/16/2021 ; 08/19/2021 ; 07/20/2022 ; 2/16/2023

1 . Indications

Drug Name: Hetlioz (tasimelteon) capsule
Non-24-Hour Sleep-Wake Disorder (Non-24) Indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in adults. **Smith-Magenis Syndrome (SMS)** Indicated for the treatment of nighttime sleep disturbances in SMS in patients 16 years of age and older.
Drug Name: Hetlioz LQ (tasimelteon) suspension
Smith-Magenis Syndrome (SMS) Indicated for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in pediatric patients 3 to 15 years of age.

2 . Criteria

Product Name: Brand Hetlioz capsule, generic tasimelteon capsule

Diagnosis	Non-24-Hour Sleep-Wake Disorder (Non-24)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-24-hour sleep-wake disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernychthemeral syndrome) [2, 5-6, A]

AND

2 - Patient is totally blind (has no light perception) [2-8, B]

AND

3 - Trial and failure, contraindication, or intolerance to generic tasimelteon (Applies to Brand only)

AND

4 - Prescribed by or in consultation with one of the following:

- Specialist in sleep disorders
- Neurologist

Product Name: Brand Hetlioz capsule, generic tasimelteon capsule	
Diagnosis	Non-24-Hour Sleep-Wake Disorder (Non-24)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Brand Hetlioz capsule, generic tasimelteon capsule	
Diagnosis	Smith-Magenis Syndrome (SMS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Smith-Magenis Syndrome (SMS)

AND

2 - Patient is 16 years of age or older

AND

3 - Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking)

AND

4 - Trial and failure, contraindication, or intolerance to generic tasimelteon (Applies to Brand only)

AND

5 - Prescribed by or in consultation with one of the following:

- Specialist in sleep disorders
- Neurologist

Product Name: Hetlioz LQ suspension	
Diagnosis	Smith-Magenis Syndrome (SMS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Smith-Magenis Syndrome (SMS)

AND

2 - Patient is 3 through 15 years of age

AND

3 - Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking)

AND

4 - Prescribed by or in consultation with one of the following:

- Specialist in sleep disorders
- Neurologist

Product Name: Brand Hetlioz capsule, generic tasimelteon capsule, Hetlioz LQ suspension	
Diagnosis	Smith-Magenis Syndrome (SMS)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (i.e., improvement in nighttime total sleep time, improvement in nighttime sleep quality)

Product Name: Hetlioz capsule	
Diagnosis	Non-24-Hour Sleep-Wake Disorder (Non-24)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of non-24-hour sleep-wake disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernychthemeral syndrome) [2, 5-6, A]

AND

2 - Patient is totally blind (has no light perception) [2-8, B]

AND

3 - Trial and failure, contraindication, or intolerance to generic tasimelteon (Applies to Brand only)

AND

4 - Prescribed by or in consultation with one of the following:

- Specialist in sleep disorders
- Neurologist

Product Name: Hetlioz capsule	
Diagnosis	Smith-Magenis Syndrome (SMS)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Smith-Magenis Syndrome (SMS)

AND

2 - Patient is 16 years of age or older

AND

3 - Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking)

AND

4 - Trial and failure, contraindication, or intolerance to generic tasimelteon (Applies to Brand only)

AND

5 - Prescribed by or in consultation with one of the following:

- Specialist in sleep disorders
- Neurologist

Product Name: Hetlioz LQ suspension	
Diagnosis	Smith-Magenis Syndrome (SMS)

Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Smith-Magenis Syndrome (SMS)

AND

2 - Patient is 3 through 15 years of age

AND

3 - Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking)

AND

4 - Prescribed by or in consultation with one of the following:

- Specialist in sleep disorders
- Neurologist

3 . Endnotes

A. The International Classification of Sleep Disorders (an official publication of the American Academy of Sleep Medicine) defines non-24-hour sleep-wake disorder as a circadian rhythm sleep disorder characterized by complaints of insomnia or excessive sleepiness related to abnormal synchronization between the 24-hour light-dark cycle and the endogenous circadian rhythms of sleep and wake propensity, for a duration of 3 months. [2] Patients with non-24 experience a chronic steady pattern comprising 1- to 2-hour daily delays in sleep onset and wake times. As incremental phase delays in sleep occur, the complaint will consist of difficulty initiating sleep at night coupled with oversleeping into the daytime hours or inability to remain awake in the daytime. Therefore, over long periods of time, patients alternate between being symptomatic and asymptomatic, depending on the degree of synchrony between their internal biologic rhythm and the 24-hour world. [2] The condition is very rare in normally sighted people,

but quite common in the totally blind who have no access to the entraining effects of the light-dark cycle. [3] Of the estimated 1.3 million legally blind individuals in the United States, approximately 130,000 have no light perception. Epidemiologic studies have found that as many as 70% of this totally blind sub-population suffer from non-24. [4] Non-24 is considered a chronic condition and markedly decreases the quality of life for patients. To varying extents, individuals with non-24 are unable to function in scheduled social activities or hold conventional jobs. [2, 4]

B. Hetlioz was approved on the basis of two pivotal, randomized, double-masked, placebo-controlled, multicenter, parallel-group studies in totally blind patients with non-24-hour sleep-wake disorder. [1, 7] The Safety and Efficacy of Tasimelteon (SET) Trial [1,7] was conducted in 84 totally blind patients with non-24, aged 21-84 years. Subjects received either Hetlioz 20 mg or placebo, one hour prior to bedtime, at the same time every night for up to 6 months. The Randomized-withdrawal study of the Efficacy and Safety of Tasimelteon to treat non-24 (RESET) Trial [1,8] was conducted in 20 entrained totally blind patients with non-24, aged 28-70 years. Subjects were treated for approximately 12 weeks with Hetlioz 20 mg one hour prior to bedtime, at the same time every night. Patients in whom the calculated time of peak melatonin level (melatonin acrophase) occurred at approximately the same time of day (in contrast to the expected daily delay) during the run-in phase were randomized to receive placebo or continue treatment with Hetlioz 20 mg for 8 weeks.

C. Given the wide range of available dosing regimens for melatonin, the variability in response time to treatment with tasimelteon and melatonin, and the need for consistent monitoring and evaluation of patients' sleep-related symptoms, tasimelteon must be prescribed by or in consultation with a specialist in sleep disorders. [3]

4 . References

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2. International Classification of Sleep Disorders. 3rd ed. Darien, IL: American academy of sleep medicine; 2014.
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7. Lockley SW, Dressman MA, Xiao C, et al. Tasimelteon treatment entrains the circadian clock and demonstrates a clinically meaningful benefit in totally blind individuals with non-24-hour circadian rhythms [Poster abstract no. FP26-6]. 95th Annual Meeting of the Endocrine Society; 15-18 Jun 2013; San Francisco, CA.
8. Lockley SW, Dressman MA, Xiao C, Licamele L, Polymeropoulos MH. RESET study demonstrates that tasimelteon maintains entrainment of melatonin and cortisol in totally

blind individuals with non-24-hour circadian rhythms [Poster abstract no. SUN-137]. 95th Annual Meeting of the Endocrine Society; 15-18 Jun 2013; San Francisco, CA.
9. National Organization for Rare Disorders. Non-24-Hour Sleep-Wake Disorder Available at: https://rarediseases.org/rare-diseases/non-24-hour-sleep-wake-disorder/Accessed June 16, 2022.

5 . Revision History

Date	Notes
1/21/2023	update guideline

Prior Authorization Guideline

Guideline Name	High Dollar/Claim Dollar

Guideline Note:

Effective Date:	12/1/2022
P&T Approval Date:	3/26/2017
P&T Revision Date:	10/16/2019 ; 10/21/2020 ; 10/20/2021 ; 10/21/2021 ; 10/19/2022

Note:

The intent of this policy is to serve as guidance for clients who would like to implement a High Dollar program. When a prescription exceeds the claim or high dollar threshold, the prescribed drug will be considered for coverage under the pharmacy benefit when the following criteria are met.

1 . Criteria

Product Name: A drug (non-anti-cancer chemotherapeutic regimen) used for an off-label indication or FDA approved indication	
Approval Length	12 months, if no PA is on file. Approval duration is granted for length of current PA on file (if existing PA is on file).
Guideline Type	Administrative
Approval Criteria	

1 - One of the following:

1.1 Medication is being prescribed for an FDA-approved indication

OR

1.2 One of the following:

1.2.1 Diagnosis is supported as a use in American Hospital Formulary Service Drug Information (AHFS DI) [1]

OR

1.2.2 Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of IIb or better (see DRUGDEX Strength of Recommendation table in Background section) [1]

OR

1.2.3 The use is supported by clinical research in two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal**

AND

2 - One of the following:

2.1 The dosage quantity/duration of the medication is reasonably safe and effective based on information contained in the FDA approved labeling, peer-reviewed medical literature, or accepted standards of medical practice

OR

2.2 The dosage/quantity/duration of the medication is reasonably safe and effective based on one of the following compendia:

- American Hospital Formulary Service (AHFS) Compendium

• Thomson Reuters (Healthcare) Micromedex/DrugDex (not Drug Points) Compendium	
Notes	**May not apply to all benefit plans.

Product Name: A drug or biological in an anti-cancer chemotherapeutic regimen	
Approval Length	12 months, if no PA is on file. Approval duration is granted for length of current PA on file (if existing PA is on file).
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 Medication is being prescribed for an FDA-approved indication

OR

1.2 One of the following:

1.2.1 Diagnosis is supported as a use in American Hospital Formulary Service Drug Information (AHFS DI) [2]

OR

1.2.2 Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of IIb or better (see DRUGDEX Strength of Recommendation table in Background section) [2]

OR

1.2.3 Diagnosis is supported as a use in the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B (see NCCN Categories of Evidence and Consensus table in Background section) [2, B]

OR

1.2.4 Diagnosis is supported as an indication in Clinical Pharmacology [2]

OR

1.2.5 Off-label use is supported in one of the published, peer-reviewed medical literature listed below: [2, C]

- American Journal of Medicine
- Annals of Internal Medicine
- Annals of Oncology
- Annals of Surgical Oncology
- Biology of Blood and Marrow Transplantation
- Blood
- Bone Marrow Transplantation
- British Journal of Cancer
- British Journal of Hematology
- British Medical Journal
- Cancer
- Clinical Cancer Research
- Drugs
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology)
- Gynecologic Oncology
- International Journal of Radiation, Oncology, Biology, and Physics
- The Journal of the American Medical Association
- Journal of Clinical Oncology
- Journal of the National Cancer Institute
- Journal of the National Comprehensive Cancer Network (NCCN)
- Journal of Urology
- Lancet
- Lancet Oncology
- Leukemia
- The New England Journal of Medicine
- Radiation Oncology

OR

1.2.6 Diagnosis is supported as a use in Wolters Kluwer Lexi-Drugs rated as "Evidence Level A" with a "Strong" recommendation. (see Lexi-Drugs Strength of Recommendation table in Background section) [2, 4, 5]

AND

2 - One of the following:

2.1 The dosage quantity/duration of the medication is reasonably safe and effective based on information contained in the FDA approved labeling, peer-reviewed medical literature, or accepted standards of medical practice

OR

2.2 The dosage/quantity/duration of the medication is reasonably safe and effective based on one of the following compendia:

- American Hospital Formulary Service (AHFS) Compendium
- Thomson Reuters (Healthcare) Micromedex/DrugDex (not Drug Points) Compendium
- Elsevier Gold Standard's Clinical Pharmacology Compendium
- National Comprehensive Cancer Network Drugs and Biologics Compendium

Notes	**May not apply to all benefit plans.

2 . Background

Clinical Practice Guidelines

DRUGDEX Strength of Recommendation [5]

Class	Recommendation	Description
Class I	Recommended	The given test or treatment has been proven useful, and should be performed or administered.
Class IIa	Recommended, In Most Cases	The given test or treatment is generally considered to be useful, and is indicated in most cases.
Class IIb	Recommended, in Some Cases	The given test or treatment may be useful, and is indicated in some, but not most, cases.

Class III	Not Recommended	The given test or treatment is not useful, and should be avoided
Class Indeterminate	Evidence Inconclusive	

NCCN Categories of Evidence and Consensus [B]

Category	Level of Consensus
1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

Lexi-Drugs: Strength of Recommendation for Inclusion in Lexi-Drugs for Oncology Off-Label Use and Level of Evidence Scale for Oncology Off-Label Use [5]

Strength of Recommendation for Inclusion

Strong (for proposed off-label use)	The evidence persuasively supports the off-label use (ie, Level of Evidence A).
Equivocal (for proposed off-label use)	The evidence to support the off-label use is of uncertain clinical significance (ie, Level of Evidence B, C). Additional studies may be necessary to further define the role of this medication for the off-label use.
Against proposed off-label use	The evidence either advocates against the off-label use or suggests a lack of support for the off-label use (independent of Level of Evidence).

	Additional studies are necessary to define the role of this medication for the off-label use.

Level of Evidence Scale for Oncology Off-Label Use

A	Consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form (eg, results of the introduction of penicillin treatment) to support off-label use. Further research is unlikely to change confidence in the estimate of benefit.
B	Evidence from randomized, controlled trials with important limitations (eg, inconsistent results, methodologic flaws, indirect, imprecise); or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on confidence in the estimate of benefit and risk and may change the estimate.
C	Evidence from observational studies (eg, retrospective case series/reports providing significant impact on patient care); unsystematic clinical experience; or potentially flawed randomized, controlled trials (eg, when limited options exist for condition). Any estimate of effect is uncertain.
G	Use has been substantiated by inclusion in at least one evidence-based or consensus-based clinical practice guideline.

3 . Endnotes

A. Has high dollar criteria for clients who opt for such a program to help manage prescription costs. If the prescription cost exceeds the claim or high dollar threshold, then an administrative PA will be required. The pharmacist will review the prescription to see if it is in-line with FDA approved labeling or well supported by the approved compendia or a peer-reviewed medical journal.
B. NCCN Categories of Evidence and Consensus. Category 1: The recommendation is based on high-level evidence (i.e., high-powered randomized clinical trials or meta-analyses), and the NCCN Guideline Panel has reached uniform consensus that the recommendation is indicated. In this context, uniform means near unanimous positive support with some possible neutral positions. Category 2A: The recommendation is based on lower level evidence, but despite the absence of higher level studies, there is uniform consensus that the recommendation is appropriate. Lower level evidence is interpreted broadly, and runs the gamut from phase II to large cohort studies to case series to individual practitioner experience. Importantly, in many instances, the retrospective studies are derived from clinical experience of treating large numbers of

patients at a member institution, so NCCN Guideline Panel Members have first-hand knowledge of the data. Inevitably, some recommendations must address clinical situations for which limited or no data exist. In these instances the congruence of experience-based judgments provides an informed if not confirmed direction for optimizing patient care. These recommendations carry the implicit recognition that they may be superseded as higher level evidence becomes available or as outcomes-based information becomes more prevalent. Category 2B: The recommendation is based on lower level evidence, and there is nonuniform consensus that the recommendation should be made. In these instances, because the evidence is not conclusive, institutions take different approaches to the management of a particular clinical scenario. This nonuniform consensus does not represent a major disagreement, rather it recognizes that given imperfect information, institutions may adopt different approaches. A Category 2B designation should signal to the user that more than one approach can be inferred from the existing data. Category 3: Including the recommendation has engendered a major disagreement among the NCCN Guideline Panel Members. The level of evidence is not pertinent in this category, because experts can disagree about the significance of high level trials. Several circumstances can cause major disagreements. For example, if substantial data exist about two interventions but they have never been directly compared in a randomized trial, adherents to one set of data may not accept the interpretation of the other side's results. Another situation resulting in a Category 3 designation is when experts disagree about how trial data can be generalized. An example of this is the recommendation for internal mammary node radiation in postmastectomy radiation therapy. One side believed that because the randomized studies included this modality, it must be included in the recommendation. The other side believed, based on the documented additional morbidity and the role of internal mammary radiation therapy in other studies, that this was not necessary. A Category 3 designation alerts users to a major interpretation issue in the data and directs them to the manuscript for an explanation of the controversy. [3]

C. Abstracts (including meeting abstracts) are excluded from consideration. When evaluating peer-reviewed medical literature, the following (among other things) should be considered: 1) Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence 2) Whether the administered chemotherapy regimen is adequately represented in the published evidence. 3) Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. 4) Whether the study is appropriate to address the clinical question. The following should be considered: a) Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover.); b) That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and c) That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs. [2]

4 . References

1. Center for Medicaid & Medicare Services. Medicare Prescription Drug Benefit Manual. Chapter 6 – Part D Drugs and Formulary Requirements. Section 10.6. Available at:

https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. Accessed September 9, 2021.
2. Center for Medicaid & Medicare Services. Medicare Benefit Policy Manual. Chapter 15 - Covered Medical and Other Health Services. Section 50.4.5. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf. Accessed September 9, 2021.
3. National Comprehensive Cancer Network Categories of Evidence and Consensus. Available at: https://www.nccn.org/professionals/physician_gls/categories_of_consensus.aspx. Accessed September 9, 2021.
4. Center for Medicaid & Medicare Services. Medicare Benefit Policy Manual. Wolters Kluwer Clinical Drug Information Lexi-Drugs Compendium Revision Request - CAG-00443O. Available at: https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=31#decision. Accessed September 9, 2021.
5. Wolters Kluwer Clinical Drug Information's Request for CMS evaluation of Lexi-Drugs as a compendium for use in the determination of medically-accepted indications of drugs/biologicals used off-label in anti-cancer chemotherapeutic regimens. Available at: https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/downloads/covdoc31.pdf. Accessed September 9, 2021.
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5 . Revision History

Date	Notes
10/14/2022	2022 Annual Review

Prior Authorization Guideline

Guideline Name	Human Chorionic Gonadotropin (hCG)

Guideline Note:

Effective Date:	12/1/2022
P&T Approval Date:	7/20/2001
P&T Revision Date:	07/15/2020 ; 11/12/2020 ; 09/15/2021 ; 10/19/2022

1 . Indications

Drug Name: Novarel (chorionic gonadotropin), Pregnyl (chorionic gonadotropin)
Ovulation Induction (OI) Indicated for the induction of ovulation (OI) and pregnancy in the anovulatory, infertile woman in whom the cause of anovulation is secondary and not due to primary ovarian failure, and who has been appropriately pretreated with human menotropins. **Prepubertal Cryptorchidism** Indicated for prepubertal cryptorchidism not due to anatomic obstruction. In general, hCG is thought to induce testicular descent in situations when descent would have occurred at puberty. hCG thus may help to predict whether or not orchiopexy will be needed in the future. Although, in some cases, descent following hCG administration is permanent, in most cases the response is temporary. Therapy is usually instituted between the ages of 4 and 9. **Hypogonadotropic Hypogonadism** Indicated for the treatment of selected cases of hypogonadotropic hypogonadism (hypogonadism secondary to a pituitary deficiency) in males. **Off Label Uses: Infertile women undergoing Assisted Reproductive Technologies (ART)** Used for the induction of final follicular maturation and early luteinization in infertile women who have undergone pituitary desensitization and who have been appropriately pretreated

with follicle-stimulating hormones (FSH) as part of an assisted reproductive technology (ART) program such as in vitro fertilization and embryo transfer. [3]

Drug Name: Ovidrel (chorionic gonadotropin) PreFilled Syringe
Infertile women undergoing Assisted Reproductive Technologies (ART) Indicated for the induction of final follicular maturation and early luteinization in infertile women who have undergone pituitary desensitization and who have been appropriately pretreated with follicle-stimulating hormones (FSH) as part of an assisted reproductive technology (ART) program such as in vitro fertilization and embryo transfer. **Ovulation Induction (OI)** Indicated for the induction of ovulation (OI) and pregnancy in anovulatory infertile patients in whom the cause of infertility is functional and not due to primary ovarian failure.

2 . Criteria

Product Name: Pregnyl*	
Diagnosis	Ovulation Induction [4, 6]
Approval Length	2 Months (or per plan benefit design)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anovulatory infertility

AND

2 - Infertility is not due to primary ovarian failure

AND

3 - For induction of ovulation

AND

4 - Patient has been pre-treated with a follicular stimulating agent (e.g., gonadotropins, clomiphene citrate, letrozole)	
Notes	*Please consult client-specific resources to confirm whether benefit ex clusions should be reviewed for medical necessity.

Product Name: Pregnyl*	
Diagnosis	Controlled Ovarian Hyperstimulation
Approval Length	2 Months (or per plan benefit design)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of infertility

AND

2 - For the development of multiple follicles (controlled ovarian hyperstimulation)

AND

3 - Patient has been pre-treated with a follicular stimulating agent (e.g., gonadotropins, clomiphene citrate, letrozole)

Notes	*Please consult client-specific resources to confirm whether benefit ex clusions should be reviewed for medical necessity.

Product Name: Pregnyl	
Diagnosis	Prepubertal Cryptorchidism
Approval Length	6 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of prepubertal cryptorchidism not due to anatomical obstruction [A]

Product Name: Pregnyl	
Diagnosis	Male Hypogonadotropic Hypogonadism [4, 5]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of male hypogonadism secondary to pituitary deficiency

AND

2 - Low testosterone (below normal reference level provided by the physician's laboratory)

AND

3 - One of the following:

- Low LH (below normal reference level provided by the physician's laboratory)
- Low FSH (below normal reference level provided by the physician's laboratory)

Product Name: Pregnyl	
Diagnosis	Male Hypogonadotropic Hypogonadism [4, 5]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Generic chorionic gonadotropin*, Novarel*, Ovidrel*	
Diagnosis	Ovulation Induction [4, 6]
Approval Length	2 Months (or per plan benefit design)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anovulatory infertility

AND

2 - Infertility is not due to primary ovarian failure

AND

3 - For induction of ovulation

AND

4 - Patient has been pre-treated with a follicular stimulating agent (e.g., gonadotropins, clomiphene citrate, letrozole)

Notes	*Please consult client-specific resources to confirm whether benefit ex clusions should be reviewed for medical necessity.

Product Name: Generic chorionic gonadotropin*, Novarel*, Ovidrel*	
Diagnosis	Controlled Ovarian Hyperstimulation
Approval Length	2 Months (or per plan benefit design)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of infertility

AND

2 - For the development of multiple follicles (controlled ovarian hyperstimulation)

AND

3 - Patient has been pre-treated with a follicular stimulating agent (e.g., gonadotropins, clomiphene citrate, letrozole)

Notes	*Please consult client-specific resources to confirm whether benefit ex clusions should be reviewed for medical necessity.

Product Name: Generic chorionic gonadotropin, Novarel, Ovidrel	
Diagnosis	Prepubertal Cryptorchidism
Approval Length	6 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of prepubertal cryptorchidism not due to anatomical obstruction [A]

Product Name: Generic chorionic gonadotropin, Novarel, Ovidrel	
Diagnosis	Male Hypogonadotropic Hypogonadism [4, 5]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of male hypogonadism secondary to pituitary deficiency

AND

2 - Low testosterone (below normal reference level provided by the physician's laboratory)

AND

3 - One of the following:

- Low LH (below normal reference level provided by the physician's laboratory)
- Low FSH (below normal reference level provided by the physician's laboratory)

Product Name: Generic chorionic gonadotropin, Novarel, Ovidrel	
Diagnosis	Male Hypogonadotropic Hypogonadism [4, 5]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

3 . Endnotes

A. In general, hCG is thought to induce testicular descent in situations when descent would have occurred at puberty. hCG thus may help predict whether or not orchiopexy (operation to bring an undescended testicle into the scrotum) will be needed in the future. Although, in some cases, descent following hCG administration is permanent, in most cases, the response is temporary. Therapy is usually initiated between the ages of 4 and 9. [1, 2, 4]

4 . References

1. Novarel prescribing information. Ferring Pharmaceuticals Inc. Parsippany, NJ. November 2020.
2. Pregnyl prescribing information. Merck & Co., Inc. Whitehouse Station, NJ. June 2022.
3. Ovidrel prescribing information. EMD Serono, Inc. Rockland, MA. February 2022.
4. DRUGDEX System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Accessed August 9, 2021.
5. Petak SM, Nankin HR, Spark RF, Swerdloff RS, Rodriguez-Rigau LJ. American Association of Clinical Endocrinologists Medical Guidelines for clinical practice for the evaluation and treatment of hypogonadism in adult male patients – 2002 update. Endocr Pract. 2002;8:440-456.
6. The Practice Committee of the American Society for Reproductive Medicine. Use of exogenous gonadotropins in anovulatory women: a technical bulletin. Fertil Steril. 2008;90:S7-12.

5 . Revision History

Date	Notes
10/20/2022	Annual review: no criteria changes.

Prior Authorization Guideline

Guideline Name	Hydroxyprogesterone caproate injection products

Guideline Note:

Effective Date:	2/1/2023
P&T Approval Date:	5/17/2011
P&T Revision Date:	10/16/2019 ; 10/21/2020 ; 10/20/2021 ; 10/19/2022 ; 12/14/2022

1 . Indications

Drug Name: Makena (hydroxyprogesterone caproate injection)
Reduce Risk of Preterm Birth Indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. The effectiveness of Makena is based on improvement in the proportion of women who delivered less than 37 weeks of gestation. There are no controlled trials demonstrating a direct clinical benefit, such as improvement in neonatal mortality and morbidity. Limitation of use: While there are many risk factors for preterm birth, safety and efficacy of Makena has been demonstrated only in women with a prior spontaneous singleton preterm birth. It is not intended for use in women with multiple gestations or other risk factors for preterm birth.

Drug Name: Hydroxyprogesterone caproate injection (for non-pregnant women)
Amenorrhea Indicated in non-pregnant women for the management of amenorrhea (primary and secondary) and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as submucous fibroids or uterine cancer. **Production of secretory endometrium and desquamation** Indicated in non-pregnant women for the production of secretory endometrium and desquamation. **Adenocarcinoma of uterine corpus** Indicated in non-pregnant women for the treatment of advanced (Stage III or IV) adenocarcinoma of the uterine corpus.

Test for endogenous estrogen production Indicated as a test for endogenous estrogen production in nonpregnant women.

2 . Criteria

Product Name: Brand Makena, Generic Hydroxyprogesterone 250mg/mL caproate injection	
Diagnosis	Reduce Risk of Preterm birth
Approval Length	21 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient had a previous singleton (single offspring) spontaneous preterm birth

AND

2 - Patient is having a singleton pregnancy

AND

3 - Therapy will be started between 16 weeks, 0 days and 20 weeks, 6 days of gestation

AND

4 - Therapy will be continued until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first

AND

5 - Prescribed by or in consultation with one of the following:

- Gynecologist
- Obstetrician

AND

6 - Provider attests and is aware of the FDA's advisory committee recommendation to withdraw medication due to lack of efficacy shown in post-market data

Product Name: Hydroxyprogesterone 1.25g/5mL caproate injection (For Non-Pregnant Women)	
Diagnosis	Amenorrhea, Abnormal uterine bleeding
Approval Length	4 Month [B]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Primary or secondary amenorrhea
- Abnormal uterine bleeding

AND

2 - Amenorrhea or abnormal uterine bleeding is due to hormonal imbalance in the absence of organic pathology (e.g., submucous fibroids or uterine cancer)

AND

3 - Patient is not pregnant

Notes	Note: This product and its criteria do NOT apply to brand Makena or it s generic.

Product Name: Hydroxyprogesterone 1.25g/5mL caproate injection (For Non-Pregnant Women)

Diagnosis	Production of secretory endometrium and desquamation
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Used for production of secretory endometrium and desquamation

AND

2 - Patient is not pregnant

Notes	Note: This product and its criteria do NOT apply to brand Makena or it s generic.

Product Name: Hydroxyprogesterone 1.25g/5mL caproate injection (For Non-Pregnant Women)	
Diagnosis	Adenocarcinoma of uterine corpus
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Stage III or IV adenocarcinoma of the uterine corpus

AND

2 - Patient is not pregnant

AND

3 - Prescribed by or in consultation with an oncologist

Notes	Note: This product and its criteria do NOT apply to brand Makena or it s generic.

Product Name: Hydroxyprogesterone 1.25g/5mL caproate injection (For Non-Pregnant Women)	
Diagnosis	Adenocarcinoma of uterine corpus
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Patient is not pregnant

Notes	Note: This product and its criteria do NOT apply to brand Makena or it s generic.

Product Name: Hydroxyprogesterone 1.25g/5mL caproate injection (For Non-Pregnant Women)	
Diagnosis	Test for endogenous estrogen production
Approval Length	2 Month [C]
Guideline Type	Prior Authorization

Approval Criteria

1 - Used for the testing of endogenous estrogen production

AND

2 - Patient is not pregnant

Notes	Note: This product and its criteria do NOT apply to brand Makena or it s generic.

3 . Definitions

Definition	Description
Singleton spontaneous preterm birth	Delivery at less than 37 weeks of gestation following spontaneous preterm labor or premature rupture of membranes. [1]

4 . Endnotes

A. Pregnant women with a history of preterm birth may benefit from initiating Makena therapy later than the FDA-recommended initiation period (between 16 weeks, 0 days and 20 weeks, 6 days gestation). There are no significant safety concerns with late initiation of therapy. Available evidence suggests it would be reasonable to allow initiation as late as 26 weeks, 6 days. [1-5]
B. Hydroxyprogesterone caproate injection (for non-pregnant women) for amenorrhea can be given as a one-time dosage or as cyclic therapy as part of a 28-day cycle, with each cycle repeated every 4 weeks and stopped after 4 cycles. [6]
C. Hydroxyprogesterone caproate injection (for non-pregnant women) for estrogen testing can be started at any time, with a repeat dose given 4 weeks after the first injection for confirmation. Therapy should be stopped after the second injection. [6]

5 . References

1. Makena Prescribing Information. AMAG Pharmaceuticals, Inc. Waltham, MA. February 2018.
2. ACOG Committee Opinion number. Use of progesterone to reduce preterm birth. Obstet Gynecol. 2008 Oct;112(4):963-5.
3. Per clinical consult with women's health specialist. May 9, 2011.
4. How HY, Barton JR, Istwan NB, et al. Prophylaxis with 17 alpha-hydroxyprogesterone caproate for prevention of recurrent preterm delivery: does gestational age at initiation of treatment matter? Am J Obstet Gynecol. 2007;197(3):260.e1-4.
5. González-Quintero VH, Istwan NB, Rhea DJ, et al. Gestational age at initiation of 17-hydroxyprogesterone caproate (17P) and recurrent preterm delivery. J Matern Fetal Neonatal Med. 2007;20(3):249-52.
6. The choice of progestogen for the prevention of preterm birth in women with singleton pregnancy and prior preterm birth. Am J Obstet Gynecol. 2017;216(3):B11-B13. doi:10.1016/j.ajog.2017.01.022

7. Hydroxyprogesterone caproate injection Prescribing Information. AuroMedics Pharma LLC. Windsor, NJ. June 2022.
8. Prediction and prevention of spontaneous preterm birth. ACOG Practice Bulletin No. 234. American College of Obstetricians and Gynecologists. Obstet Gynecol 2021;138:e65–90.

6 . Revision History

Date	Notes
12/6/2022	Updated guideline

Prior Authorization Guideline

Guideline Name	HyQvia (immune globulin with recombinant human hyaluronidase)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	2/18/2015
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 5/18/2023

1 . Indications

Drug Name: HyQvia (immune globulin with recombinant human hyaluronidase) for subcutaneous administration
Primary Immunodeficiency Indicated for the treatment of Primary Immunodeficiency (PI) in adults and pediatric patients two years of age and older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies. Limitation of Use: Safety and efficacy of chronic use of recombinant human hyaluronidase in HyQvia have not been established in conditions other than PI.

2 . Criteria

Product Name: HyQvia	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For patients with a primary immunodeficiency syndrome

AND

2 - Patient is 2 years of age or older

AND

3 - Clinically significant functional deficiency of humoral immunity as evidenced by one of the following: [2]

3.1 Documented failure to produce antibodies to specific antigens

OR

3.2 History of significant recurrent infections

3 . References

1. HyQvia Prescribing Information. Baxalta US Inc. Lexington, MA. April 2023.
2. Bonilla FA, Bernstein L, Khan DA, et. al. Practice management for the diagnosis and management of primary immunodeficiency. Ann Allergy Asthma Immunol. 2005;94(suppl):S1-S63.

4 . Revision History

Date	Notes
5/3/2023	Addition of age criterion

Prior Authorization Guideline

Guideline Name	HyQvia (immune globulin with recombinant human hyaluronidase)

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	2/18/2015
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: HyQvia (immune globulin with recombinant human hyaluronidase) for subcutaneous administration
Primary Immunodeficiency Indicated for the treatment of primary immunodeficiency (PI) in adults. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies. Limitation of Use: Safety and efficacy of chronic use of recombinant human hyaluronidase in HyQvia have not been established in conditions other than PI.

2 . Criteria

Product Name: HyQvia	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For patients with a primary immunodeficiency syndrome

AND

2 - Clinically significant functional deficiency of humoral immunity as evidenced by one of the following: [2]

2.1 Documented failure to produce antibodies to specific antigens

OR

2.2 History of significant recurrent infections

3 . References

1. HyQvia Prescribing Information. Baxalta US Inc. Lexington, MA. March 2021.
2. Bonilla FA, Bernstein L, Khan DA, et. al. Practice management for the diagnosis and management of primary immunodeficiency. Ann Allergy Asthma Immunol. 2005;94(suppl):S1-S63.

4 . Revision History

Date	Notes
4/5/2023	Annual review: No updates required.

Prior Authorization Guideline

Guideline Name	Ibrance (palbociclib)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	4/14/2015
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 05/19/2022 ; 03/15/2023 ; 5/18/2023

1 . Indications

Drug Name: Ibrance (palbociclib)
Breast Cancer Indicated for the treatment of HR-positive, HER2-negative advanced or metastatic breast cancer in combination with: (1) an aromatase inhibitor as initial endocrine based therapy, or (2) fulvestrant in patients with disease progression following endocrine therapy.

2 . Criteria

Product Name: Ibrance	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced or metastatic breast cancer

AND

2 - Disease is hormone-receptor (HR)-positive [2]

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

4 - One of the following:

4.1 Used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane)

OR

4.2 Both of the following:

- Used in combination with Faslodex (fulvestrant)
- Disease has progressed following endocrine therapy

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Ibrance	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on therapy	

3 . References

1. Ibrance Prescribing Information. Pfizer Inc. New York, NY. December 2022.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Breast Cancer. v.2.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf Accessed April 15, 2022.

4 . Revision History

Date	Notes
4/11/2023	2023 Annual Review.

Prior Authorization Guideline

Guideline Name	IBS - Diarrhea

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	1/13/2003
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Lotronex (alosetron hydrochloride)
Severe Diarrhea-Predominant Irritable Bowel Syndrome (IBS) in Women Indicated only for women with severe diarrhea-predominant IBS who have: • chronic IBS symptoms (generally lasting 6 months or longer) • had anatomic or biochemical abnormalities of the gastrointestinal tract excluded, and • not responded adequately to conventional therapy. Diarrhea-predominant IBS is severe if it includes diarrhea and one or more of the following: • frequent and severe abdominal pain/discomfort • frequent bowel urgency or fecal incontinence • disability or restriction of daily activities due to IBS. Because of infrequent but serious gastrointestinal adverse reactions associated with Lotronex, the indication is restricted to those patients for whom the benefit-to-risk balance is most favorable. Clinical studies have not been performed to adequately confirm the benefits of Lotronex in men.
Drug Name: Viberzi (eluxadoline)
Irritable bowel syndrome with diarrhea (IBS-D) Indicated in adults for the treatment of IBS-D.

2 . Criteria

Product Name: Brand Lotronex, Generic alosetron	
Approval Length	12 Week(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS)

AND

2 - Symptoms for at least 6 months [A]

AND

3 - Patient is female

AND

4 - Patient is 18 years of age or older

AND

5 - Trial and failure, contraindication, or intolerance to both of the following:

- antispasmodic agent [eg, Bentyl (dicyclomine)] [2, 6, B]
- antidiarrheal agent [eg, loperamide] [2, 3, 6]

Product Name: Brand Lotronex, Generic alosetron	
Approval Length	6 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Symptoms of IBS continue to persist

AND

2 - Documentation of positive clinical response to therapy as evidenced by one of the following: [1]

- Relief of IBS abdominal pain and discomfort
- Improvement in stool consistency
- Decrease in daily stool frequency
- Moderate or substantial improvement as measured by the Global Improvement Scale [C]

Product Name: Viberzi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of irritable bowel syndrome with diarrhea

AND

2 - Trial and failure, contraindication, or intolerance to both of the following:

- antispasmodic agent [eg, Bentyl (dicyclomine)] [2, 6]
- antidiarrheal agent [eg, Lomotil (diphenoxylate and atropine)] [2, 3, 6]

Product Name: Viberzi

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

2 - Symptoms of IBS continue to persist

AND

2 - Documentation of positive clinical response to therapy as evidenced by both of the following: [D]

- Improvement in the daily worst abdominal pain score
- Reduction in the Bristol Stool Scale

3 . Endnotes

A. Lotronex was removed from the market in late 2000 due to reports of ischemic colitis and severe constipation but has since been re-released with a “black box” warning for use in select cases. [1, 3, 4, 5]
B. Lotronex should be used with caution in debilitated patients, elderly patients, patients with hepatic impairment, and patients taking medications that decrease gastrointestinal motility. [1]
C. The Global Improvement Scale (GIS) assesses multiple symptoms of Irritable Bowel Syndrome (IBS) using a 7-point Likert scale which ranges from symptoms substantially worse to substantially improved. GIS responders were defined as having moderate or substantial improvement in IBS symptoms. [1]
D. The primary endpoint in Studies 1 and 2 to assess the efficacy of Viberzi was defined by both the simultaneous improvement in the daily worse abdominal pain score by ≥30% as compared to the baseline weekly average AND a reduction in the BSS to <5 on at least 50% of the days within a 12-week time interval. [7]

4 . References

1. Lotronex Prescribing Information. Sebela Pharmaceuticals Inc. Roswell, Georgia, CA. July 2016.

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5 . Revision History

Date	Notes
3/23/2023	2023 UM Annual Review. No criteria changes. Updated references

Prior Authorization Guideline

Guideline Name	Iclusig (ponatinib)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	2/19/2013
P&T Revision Date:	11/14/2019 ; 11/12/2020 ; 11/12/2020 ; 02/18/2021 ; 11/18/2021 ; 11/17/2022 ; 5/18/2023

1 . Indications

Drug Name: Iclusig (ponatinib)
Chronic Myeloid Leukemia (CML) Indicated for the treatment of adult patients with chronic phase (CP) chronic myeloid leukemia (CML) with resistance or intolerance to at least two prior kinase inhibitors. **Accelerated phase (AP) or blast phase (BP) Chronic Myeloid Leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)** Indicated for the treatment of adult patients with Accelerated phase (AP) or blast phase (BP) Chronic Myeloid Leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) for whom no other kinase inhibitors are indicated. **T315I-positive Chronic Myeloid Leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)** Indicated for the treatment of adult patients with T315I-positive CML (chronic phase, accelerated phase, or blast phase) or T315I-positive Ph+ ALL.

2 . Criteria

Product Name: Iclusig	
Diagnosis	Chronic Myelogenous Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic myelogenous leukemia

AND

2 - Prescribed by or in consultation with a hematologist or oncologist

Product Name: Iclusig	
Diagnosis	Chronic Myelogenous Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Iclusig	
Diagnosis	Acute Lymphoblastic Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia

AND

2 - Prescribed by or in consultation with a hematologist or oncologist

Product Name: Iclusig	
Diagnosis	Acute Lymphoblastic Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Iclusig Prescribing Information. ARIAD Pharmaceuticals, Inc. Cambridge, MA. August 2021.

4 . Revision History

Date	Notes
4/28/2023	Program update to remove trial requirement of 2 TKI's or confirmation of T315I mutation status.

Prior Authorization Guideline

Guideline Name	Ilaris (canakinumab injection)

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	11/17/2009
P&T Revision Date:	08/15/2019 ; 08/13/2020 ; 08/19/2021 ; 08/18/2022 ; 10/19/2022

1 . Indications

Drug Name: Ilaris (canakinumab injection)
Periodic Fever Syndromes: Cryopyrin-Associated Periodic Syndromes (CAPS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), Familial Mediterranean Fever(FMF) Indicated for the treatment of the following autoinflammatory Periodic Fever Syndromes: Cryopyrin-Associated Periodic Syndromes (CAPS), in adults and children 4 years of age and older including, Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS); Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) in adult and pediatric patients; Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) in adult and pediatric patients; Familial Mediterranean Fever (FMF) in adult and pediatric patients. **Systemic Juvenile Idiopathic Arthritis (SJIA)** Indicated for the treatment of active Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older. **Still's disease (Adult-Onset Still's Disease [AOSD])** Indicated for the treatment of active Still's disease, including Adult-Onset Still's Disease (AOSD) in patients aged 2 years and older.

2 . Criteria

Product Name: Ilaris	
Diagnosis	Periodic Fever Syndromes [Cryopyrin-Associated Periodic Syndromes (CAPS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency(MKD), Familial Mediterranean Fever(FMF)]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following periodic fever syndromes:

- cryopyrin-associated periodic syndromes (CAPS), including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS)
- tumor necrosis factor (TNF) receptor associated periodic syndrome (TRAPS)
- hyperimmunoglobulin D (Hyper-IgD) syndrome (HIDS/mevalonate kinase deficiency (MKD)
- familial mediterranean fever (FMF)

AND

2 - Prescribed by or in consultation with one of the following:

- Immunologist
- Allergist
- Dermatologist
- Rheumatologist
- Neurologist
- Other medical specialist

AND

3 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab])

- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

Product Name: Ilaris	
Diagnosis	Periodic Fever Syndrome [CAPS, TRAPS, HIDS/MKD, FMF]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

Product Name: Ilaris	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active systemic juvenile idiopathic arthritis (SJIA)

AND

2 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [1, 2]:

- Minimum duration of a 3-month trial and failure of methotrexate
- Minimum duration of a 1-month trial of a nonsteroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, naproxen)
- Minimum duration of a 2-week trial of a systemic glucocorticoid (e.g., prednisone)

AND

3 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name: Ilaris	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 2]:

- Reduction in the total active (swollen and tender) joint count from baseline

- Improvement in clinical features or symptoms (e.g., pain, fever, inflammation, rash, lymphadenopathy, serositis) from baseline

AND

2 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

Product Name: Ilaris	
Diagnosis	Still's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Still’s Disease, including Adult-Onset Still’s Disease (AOSD)

AND

2 - Trial and failure, contraindication, or intolerance to one of the following: [1-3]

- Corticosteroids (e.g., prednisone)
- Methotrexate
- Nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen)

AND

3 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab])

- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name: Ilaris	
Diagnosis	Still's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

3 . Definitions

Definition	Description
Cryopyrin-Associated Periodic Syndromes (CAPS):	A group of rare, autosomal dominantly inherited auto-inflammatory conditions comprising of Familial-Cold Auto-inflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), Neonatal-Onset Multisystem Inflammatory Disease (NOMID) or also known as Chronic Infantile Neurologic Cutaneous Articular Syndrome

	(CINCA), which are caused by the CIAS1 gene mutation and characterized by recurrent symptoms (urticaria-like skin lesions, fever chills, arthralgia, profuse sweating, sensorineural hearing/vision loss, and increased inflammation markers the blood). Approximately 300 people in the United States are affected by CAPS. [1, 4, 5]
Familial Cold Autoinflammatory Syndrome (FCAS):	The mildest form of CAPS, is characterized by cold-induced, daylong episodes of fever associated with rash, arthralgia, headaches and less frequently conjunctivitis, but without other signs of CNS inflammation. Symptoms usually begin during the first 6 months of life and are predominantly triggered by cold exposure. Duration of episodes usually is less than 24 hours. [5]
Muckle-Wells Syndrome (MWS):	A subtype of CAPS, which is characterized by episodic attacks of inflammation associated with a generalized urticaria-like rash, fever, malaise, arthralgia, and progressive hearing loss. Duration of symptoms usually lasts from 24-48 hours. [5]

4 . References

1. Ilaris Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. September 2020.
2. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. Arthritis Rheumatol. 2022;74(4):553-569.
3. Mimura T, Kondo Y, Ohta A et al. Evidence-based clinical practice guideline for adult Still's disease. Mod Rheumatol. 2018;28(5):736-757.
4. Lachmann HJ, Kone-Paut I, Kuemmerle-Deschner JB, et al. Use of canakinumab in the cryopyrin-associated periodic syndrome. N Engl J Med. 2009;360(23):2416-25.
5. Aksentijevich I, Putnam CD, Remmers EF, et al. Clinical continuum of cryopyrinopathies: novel CIAS1 mutations in North-American patients and a new cryopyrin model. Arthritis Rheum. 2007;56(4):1273-85.

5 . Revision History

Date	Notes
10/23/2022	Further clinical detail added for SJIA

Prior Authorization Guideline

Guideline Name	Imbruvica (ibrutinib)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	2/18/2014
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 10/19/2022 ; 5/18/2023

1 . Indications

Drug Name: Imbruvica (ibrutinib)
Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) **Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) with 17p deletion** Indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic leukemia (SLL) with 17p deletion **Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma** Indicated for the treatment of adult patients with Waldenström’s macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma [2] **Chronic graft versus host disease (cGVHD)** Indicated for the treatment of adult and pediatric patients age 1 year and older with chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy.

2 . Criteria

Product Name: Imbruvica	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- chronic lymphocytic leukemia
- small lymphocytic lymphoma

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Imbruvica	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Imbruvica	
Diagnosis	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Waldenstrom's Macroglobulinemia

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Imbruvica	
Diagnosis	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Imbruvica, Imbruvica oral suspension	
Diagnosis	Chronic graft versus host disease (cGVHD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic graft versus host disease (cGVHD)

AND

2 - Patient is 1 year of age or older

AND

3 - Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids like prednisone or methylprednisolone, mycophenolate)

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist
- Physician experienced in the management of transplant patients

Product Name: Imbruvica, Imbruvica oral suspension	
Diagnosis	Chronic graft versus host disease (cGVHD)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Imbruvica Prescribing Information. Pharmacyclics, Inc. Sunnyvale, CA. August 2022.
2. National Comprehensive Cancer Network Practice Guidelines in Oncology. Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma. V1.2017. NCCN Web site. http://www.nccn.org/professionals/physician_gls/pdf/waldenstroms.pdf. Accessed March 18, 2020.

4 . Revision History

Date	Notes
4/10/2023	Annual Review - criteria for MCL and MZL removed

Prior Authorization Guideline

Guideline Name	Immune Globulins - PA, NF

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	9/5/2000
P&T Revision Date:	07/17/2019 ; 09/18/2019 ; 08/15/2019 ; 10/16/2019 ; 11/14/2019 ; 12/18/2019 ; 04/15/2020 ; 05/14/2020 ; 04/21/2021 ; 09/15/2021 ; 12/15/2021 ; 01/19/2022 ; 02/17/2022 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Bivigam and Octagam 5% (immune globulin [Human])
Primary Immunodeficiency Disorders Indicated for the treatment of primary immunodeficiency disorders associated with defects in humoral immunity. These include, but are not limited to: congenital agammaglobulinemia, X-linked agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.
Drug Name: Flebogamma 5% (immune globulin [Human])
Primary Immunodeficiency Disorders Indicated in adults and pediatric patients 2 years of age and older for the treatment of primary immunodeficiency (PI), including the humoral immune defects in common variable immunodeficiency, x-linked agammaglobulinemia, severe combined immunodeficiency, and Wiskott-Aldrich syndrome.
Drug Name: Flebogamma 10% (immune globulin [Human])
Primary Immunodeficiency Disorders Indicated as replacement therapy in primary immunodeficiency (PI) including the humoral immune defects in common variable immunodeficiency, xlinked agammaglobulinemia, severe combined immunodeficiency, and

Wiskott-Aldrich syndrome.

Chronic Primary Immune Thrombocytopenia (ITP) Indicated for the treatment of patients 2 years of age and older with chronic primary ITP to raise platelet count.

Drug Name: Gamastan (immune globulin [Human])

Measles (Rubeola) Indicated to prevent or modify measles in a susceptible person exposed fewer than 6 days previously. A susceptible person is one who has not been vaccinated and has not had measles previously. Gamastan may be especially indicated for susceptible household contacts of measles patients, particularly contacts under 1 year of age, for whom the risk of complications is highest. Gamastan is also indicated for pregnant women without evidence of immunity. Gamastan and measles vaccine should not be given at the same time. If a child is older than 12 months and has received Gamastan, he should be given measles vaccine about 5 months later when the measles antibody titer will have disappeared. If a susceptible child exposed to measles is immunocompromised, give Gamastan immediately.

Rubella Indicated to modify rubella in exposed women who will not consider a therapeutic abortion. Some studies suggest that the use of Gamastan in exposed, susceptible women can lessen the likelihood of infection and fetal damage; therefore, Gamastan may benefit those women who will not consider a therapeutic abortion. Do not give Gamastan for routine prophylaxis of rubella in early pregnancy to an unexposed woman.

Hepatitis A Indicated for prophylaxis following exposure to hepatitis A. The prophylactic value of Gamastan is greatest when given before or soon after exposure to hepatitis A. Gamastan is not indicated in persons with clinical manifestations of hepatitis A or in those exposed more than 2 weeks previously.

Varicella Indicated to modify varicella. Passive immunization against varicella in immunosuppressed patients is best accomplished by use of Varicella Zoster Immune globulin (Human) [VZIG]. If VZIG is unavailable, Gamastan, promptly given, may also modify varicella.

Drug Name: Carimune NF (immune globulin [Human])

Idiopathic Thrombocytopenic Purpura (ITP) (1) Acute ITP: A controlled study was performed in children in which Carimune was compared with steroids for the treatment of acute (defined as less than 6 months duration) ITP. In this study sequential platelet levels of 30,000, 100,000, and 150,000/microliter were all achieved faster with Carimune than with steroids and without any of the side effects associated with steroids. However, it should be noted that many cases of acute ITP in childhood resolve spontaneously within weeks to months. Carimune has been used with good results in the treatment of acute ITP in adult patients. In a study involving 10 adults with ITP of less than 16 weeks duration, Carimune therapy raised the platelet count to the normal range after a 5 day course. This effect lasted a mean of over 173 days, ranging from 30 to 372 days. (2) Chronic ITP: Children and adults with chronic (defined as greater than 6 months duration) ITP have also shown an increase (sometimes temporary) in platelet counts upon administration of Carimune. Therefore, in situations that require a rapid rise in platelet count, for example prior to surgery or to control excessive bleeding, use of Carimune should be considered. In children with chronic ITP, Carimune therapy resulted in a mean rise in platelet count of 312,000/microliter with a duration of increase ranging from 2 to 6 months. Carimune therapy may be considered as a

means to defer or avoid splenectomy. In adults, Carimune therapy has been shown to be effective in maintaining the platelet count in an acceptable range with or without periodic booster therapy. The mean rise in platelet count was 93,000/microliter and the average duration of the increase was 20-24 days. However, it should be noted that not all patients will respond. Even in those patients who do respond, this treatment should not be considered to be curative.

Primary Immunodeficiency Disorders Indicated for the maintenance treatment of patients with primary immunodeficiencies (PID), e.g., common variable immunodeficiency, X-linked agammaglobulinemia, severe combined immunodeficiency. Carimune NF is preferable to intramuscular Immune Globulin (Human) preparations in treating patients who require an immediate and large increase in the intravascular immunoglobulin level, in patients with limited muscle mass, and in patients with bleeding tendencies for whom intramuscular injections are contraindicated. The infusions must be repeated at regular intervals.

Drug Name: Privigen (immune globulin [Human])

Chronic Immune Thrombocytopenic Purpura (ITP) Indicated for the treatment of patients age 15 years and older with chronic ITP to raise platelet counts.

Primary Immunodeficiency Disorders Indicated as replacement therapy for primary humoral immunodeficiency (PI). This includes, but is not limited to, the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Indicated for the treatment of adults with chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability and impairment. Limitation of Use: Privigen maintenance therapy in CIDP has not been studied for periods longer than 6 months. After responding during an initial treatment period, not all patients require indefinite maintenance therapy with Privigen in order to remain free of CIDP symptoms. Individualize the duration of any treatment beyond 6 months based upon the patient's response and demonstrated need for continued therapy.

Drug Name: Gammagard S/D (immune globulin [Human])

Kawasaki Disease Indicated for the prevention of coronary artery aneurysms associated with Kawasaki syndrome in pediatric patients.

B-cell Chronic Lymphocytic Leukemia (CLL) Indicated for prevention of bacterial infections in hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell Chronic Lymphocytic Leukemia (CLL).

Idiopathic Thrombocytopenic Purpura (ITP) Indicated for the treatment of adult chronic idiopathic thrombocytopenic purpura to increase platelet count and to prevent and/or to control bleeding.

Primary Immunodeficiency Disorders Indicated for the treatment of primary immunodeficiency (PI) associated with defects in humoral immunity, in adults and children two years and older. This includes, but is not limited to, congenital agammaglobulinemia, common

variable immunodeficiency, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Drug Name: Gammaked and Gamunex-C (immune globulin [Human])

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Indicated for the treatment of CIDP in adults to improve neuromuscular disability and impairment and for maintenance therapy to prevent relapse.

Idiopathic Thrombocytopenic Purpura (ITP) Indicated for the treatment of adults and children with idiopathic thrombocytopenic purpura to raise platelet counts to prevent bleeding or to allow a patient with ITP to undergo surgery.

Primary Immunodeficiency Disorders Indicated for treatment of primary humoral immunodeficiency in patients 2 years of age and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Drug Name: Immune globulin products (IVIG)

Off Label Uses: Bone Marrow Transplant (BMT) [6, 21-24] Has been used to decrease the incidence of infections and graft versus host disease (GVHD) in patients 20 years of age and older who underwent bone marrow transplantation.

Dermatomyositis [6, 25-29] In patients with treatment-resistant dermatomyositis, IVIG therapy resulted in improvements in muscle strength and neuromuscular symptoms.

Multifocal Motor Neuropathy (MMN) [6, 30, 34] In placebo-controlled trials, IVIG has been shown to improve strength and reduce disability and conduction block in patients with MMN.

Pediatric HIV [6, 35-37, 75] Used to decrease the frequency of serious and minor bacterial infections; the frequency of hospitalization; and to increase the time free of serious bacterial infections in patients with HIV.

Guillain-Barre Syndrome [6, 38-40] Considered to be equally effective as plasma exchange for the treatment of Guillain-Barre Syndrome.

Lambert-Eaton Myasthenic Syndrome [6, 41] Shown to produce short-term improvement in strength in patients with Lambert-Eaton Myasthenic Syndrome.

Myasthenia Gravis [6, 72, 74] A clinical study comparing IVIG with plasma exchange did not show a significant difference between the two treatments in patients with myasthenia gravis exacerbation. Several open studies support beneficial effects of IVIG in treating myasthenia gravis.

Relapsing Remitting Multiple Sclerosis [6, 50, 52] Published studies indicate that IVIG may reduce the frequency of acute exacerbations and provide symptomatic relief in patients with relapsing-remitting forms of multiple sclerosis.

Stiff-Person Syndrome [6, 83, 84] The efficacy of IVIG for the treatment of stiff-person

syndrome was demonstrated in a randomized, double-blind, placebo-controlled, crossover trial.

Polymyositis [6, 64] Found to be effective in reversing chronic polymyositis previously unresponsive to immunosuppressive therapy.

Drug Name: Gammagard liquid (immune globulin [Human])

Primary Immunodeficiency Disorders Indicated as replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age or older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Multifocal Motor Neuropathy (MMN) Indicated as a maintenance therapy to improve muscle strength and disability in adult patients with Multifocal Motor Neuropathy (MMN).

Drug Name: Gammaplex (immune globulin [Human])

Primary Immunodeficiency Disorders Indicated for replacement therapy in primary humoral immunodeficiency (PI) in adults and pediatric patients two years of age and older. This includes, but is not limited to, the humoral immune defect in common variable immunodeficiency, X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Chronic Immune Thrombocytopenic Purpura (ITP) Indicated for the treatment of adults with chronic immune thrombocytopenic purpura (ITP) to raise platelet counts.

Drug Name: Octagam 10% (immune globulin [Human])

Chronic Immune Thrombocytopenic Purpura Indicated in chronic immune thrombocytopenic purpura to rapidly raise platelet counts to control or prevent bleeding in adults.

Dermatomyositis Indicated for the treatment of dermatomyositis in adults.

Drug Name: Cytogam (human cytomegalovirus immune globulin liquid)

Cytomegalovirus Indicated for the prophylaxis of cytomegalovirus disease associated with transplantation of kidney, lung, liver, pancreas and heart. In transplants of these organs other than kidney from CMV seropositive donors into seronegative recipients, prophylactic CMV-IGIV should be considered in combination with ganciclovir.

Drug Name: Varizig (varicella zoster immune globulin [Human] solution)

Post-exposure prophylaxis of varicella Indicated for post-exposure prophylaxis of varicella in high risk individuals. High risk groups include: immunocompromised children and adults, newborns of mothers with varicella shortly before or after delivery, premature infants, neonates and infants less than one year of age, adults without evidence of immunity,

pregnant women. Limitations of Use: There is no convincing evidence that Varizig reduces the incidence of chickenpox infection after exposure to VZV. There is no convincing evidence that established infections with VZV can be modified by Varizig administration. There is no indication for the prophylactic use of Varizig in immunodeficient children or adults when there is a past history of varicella, unless the patient is undergoing bone marrow transplantation.

Drug Name: Hizentra (immune globulin [Human] liquid)

Primary Immunodeficiency Disorders Indicated as replacement therapy for primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older. This includes, but is not limited to, the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Indicated for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy to prevent relapse of neuromuscular disability and impairment. Limitations of Use: Hizentra maintenance therapy in CIDP has been systematically studied for 6 months and for a further 12 months in a follow-up study. Maintenance therapy beyond these periods should be individualized based upon the patient's response and need for continued therapy.

Drug Name: Panzyga (immune globulin intravenous [Human] - ifas)

Primary Immunodeficiency Disorders Indicated for treatment of primary humoral immunodeficiency (PI) in patients 2 years of age and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Chronic Immune Thrombocytopenia (ITP) Indicated for the treatment of adult patients with ITP to raise platelet counts to control or prevent bleeding.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Indicated for the treatment of adults with chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability and impairment.

Drug Name: Cuvitru (immune globulin [Human])

Primary Immunodeficiency Disorders Indicated as replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age and older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Drug Name: Cutaquig (Immune globulin subcutaneous [Human] - hipp)

Primary Immunodeficiency Disorders Indicated as replacement therapy for primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked

agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.
Drug Name: Xembify (immune globulin subcutaneous, human - klhw)
Primary Immunodeficiency Disorders Indicated for treatment of primary humoral immunodeficiency (PI) in patients 2 years of age and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.
Drug Name: Asceniv (immune globulin intravenous, human - slra)
Primary Immunodeficiency Disorders Indicated for the treatment of primary humoral immunodeficiency (PI) in adults and adolescents (12 to 17 years of age). PI includes, but is not limited to, the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies (SCID).

2 . Criteria

Product Name: Intravenous or subcutaneous immune globulins (IVIG or SCIG)	
Diagnosis	Primary Immunodeficiency Syndrome
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For patients with a primary immunodeficiency syndrome [1, 3, 5, 6, 57, 61, 65-71, I, J]

AND

2 - Clinically significant functional deficiency of humoral immunity as evidenced by one of the following: [73]

2.1 Documented failure to produce antibodies to specific antigens

OR

2.2 History of significant recurrent infections

AND

3 - One of the following:

3.1 Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

OR

3.2 Trial and failure, contraindication, or intolerance to two of the following (applies to Cutaquig only):

- Cuvitru
- Hizentra
- Xembify

Product Name: Asceniv, Cutaquig, Panzyga	
Diagnosis	Primary Immunodeficiency Syndrome
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - For patients with a primary immunodeficiency syndrome [1, 3, 5, 6, 57, 61, 65-71, I, J]

AND

2 - Clinically significant functional deficiency of humoral immunity as evidenced by one of the following: [73]

2.1 Documented failure to produce antibodies to specific antigens

OR

2.2 History of significant recurrent infections

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following (applies to Cutaquig only):

- Cuvitru
- Hizentra
- Xembify

Product Name: Intravenous immune globulins (IVIG)	
Diagnosis	Idiopathic Thrombocytopenic Purpura (ITP)
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of idiopathic thrombocytopenic purpura (ITP) [3, 5, 62, 68-70, 88]

AND

2 - Documented platelet count of less than 50 x 10^9 / L [85]

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Asceniv, Panzyga	
Diagnosis	Idiopathic Thrombocytopenic Purpura (ITP)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of idiopathic thrombocytopenic purpura (ITP) [3, 5, 62, 68-70, 88]

AND

2 - Documented platelet count of less than 50 x 10^9 / L [85]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard

- Gammaplex
- Gamunex-C
- Privigen

Product Name: Intravenous immune globulins (IVIG)	
Diagnosis	Kawasaki Disease (KD) [5, 7-9]
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Kawasaki Disease [5]

AND

2 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Asceniv, Panzyga	
Diagnosis	Kawasaki Disease (KD) [5, 7-9]
Approval Length	1 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Kawasaki Disease [5]

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Intravenous immune globulins (IVIG)	
Diagnosis	B-cell Chronic Lymphocytic Leukemia (CLL) [5, 10-14]
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of B-cell chronic lymphocytic leukemia (CLL) [5]

AND

2 - One of the following:

2.1 Documented hypogammaglobulinemia (IgG less than 500 mg/dL) [13, 14, 78, B]

OR

2.2 History of bacterial infection(s) associated with B-cell CLL [13-15, 78, A]

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Asceniv, Panzyga	
Diagnosis	B-cell Chronic Lymphocytic Leukemia (CLL) [5, 10-14]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of B-cell chronic lymphocytic leukemia (CLL) [5]

AND

2 - One of the following:

2.1 Documented hypogammaglobulinemia (IgG less than 500 mg/dL) [13, 14, 78, B]

OR

2.2 History of bacterial infection(s) associated with B-cell CLL [13-15, 78, A]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Intravenous immune globulin (IVIG), Hizentra	
Diagnosis	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) [15-20, 55, 58, 62, C, H]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) as confirmed by all of the following [77, C]:

1.1 Progressive symptoms present for at least 2 months

AND

1.2 Symptomatic polyradiculoneuropathy as indicated by one of the following:

1.2.1 Progressive or relapsing motor impairment of more than one limb

OR

1.2.2 Progressive or relapsing sensory impairment of more than one limb

AND

1.3 Electrophysiologic findings when three of the following four criteria are present:

- Partial conduction block of 1 or more motor nerve
- Reduced conduction velocity of 2 or more motor nerves
- Prolonged distal latency of 2 or more motor nerves
- Prolonged F-wave latencies of 2 or more motor nerves or the absence of F waves

AND

2 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Intravenous immune globulin (IVIG), Hizentra	
Diagnosis	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) [15-20, 55, 58, 62, C, H]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as measured by an objective scale (e.g., Rankin, Modified Rankin, Medical Research Council [MRC] scale) [77, H, P]

AND

2 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect [P]

Product Name: Asceniv, Panzyga	
Diagnosis	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) [15-20, 55, 58, 62, C, H]
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) as confirmed by all of the following [77, C]:

1.1 Progressive symptoms present for at least 2 months

AND

1.2 Symptomatic polyradiculoneuropathy as indicated by one of the following:

1.2.1 Progressive or relapsing motor impairment of more than one limb

OR

1.2.2 Progressive or relapsing sensory impairment of more than one limb

AND

1.3 Electrophysiologic findings when three of the following four criteria are present:

- Partial conduction block of 1 or more motor nerve
- Reduced conduction velocity of 2 or more motor nerves
- Prolonged distal latency of 2 or more motor nerves
- Prolonged F-wave latencies of 2 or more motor nerves or the absence of F waves

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Gamastan	
Diagnosis	Hepatitis A

Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For prophylaxis of Hepatitis A before or soon after exposure [57, 93]

AND

2 - Patient does not have clinical manifestations of hepatitis A [57, 93]

AND

3 - Patient does not have exposure to hepatitis A for more than 2 weeks previously [57, 93]

Product Name: Gamastan	
Diagnosis	Measles (Rubeola)
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For use in susceptible individuals exposed to measles fewer than 6 days previously [57, 93]

AND

2 - Patient is not receiving measles vaccine at the same time [57, 93]

Product Name: Gamastan	
Diagnosis	Varicella
Approval Length	14 Day(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - For passive immunization against varicella [57, 93]

AND

2 - Patient is immunosuppressed [57, 93]

AND

3 - Varicella Zoster Immune Globulin (Human) vaccine is not available

Product Name: Gamastan	
Diagnosis	Rubella
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For pregnant women who are exposed or susceptible to Rubella [57, 93]

AND

2 - Patient will not consider a therapeutic abortion [57, 93]

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Bone Marrow Transplantation (off-label) [21-24]
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Confirmed allogeneic bone marrow transplant within the last 100 days [21-23, D]

AND

2 - Documented severe hypogammaglobulinemia (IgG less than 400 mg/dL) [21, D]

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Asceniv, Panzyga	
Diagnosis	Bone Marrow Transplantation (off-label) [21-24]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Confirmed allogeneic bone marrow transplant within the last 100 days [21-23, D]

AND

2 - Documented severe hypogammaglobulinemia (IgG less than 400 mg/dL) [21, D]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	HIV (off-label) [35-37, 75, 79, 80]
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HIV disease [35, 75, K]

AND

2 - Patient is less than or equal to 13 years of age [75, 80]

AND

3 - One of the following:

3.1 Documented hypogammaglobulinemia (IgG less than 400 mg/dL) [75, L]

OR

3.2 Functional antibody deficiency as demonstrated by one of the following: [79]

- Poor specific antibody titers
- Recurrent bacterial infections

AND

4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Asceniv, Panzyga	
Diagnosis	HIV (off-label) [35-37, 75, 79, 80]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of HIV disease [35, 75, K]

AND

2 - Patient is less than or equal to 13 years of age [75, 80]

AND

3 - One of the following:

3.1 Documented hypogammaglobulinemia (IgG less than 400 mg/dL) [75, L]

OR

3.2 Functional antibody deficiency as demonstrated by one of the following: [79]

- Poor specific antibody titers

- Recurrent bacterial infections

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Multifocal Motor Neuropathy (off-label) [30-34]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multifocal motor neuropathy (MMN) as confirmed by all of the following [76, 86, 87, N]:

1.1 Weakness with slowly progressive or stepwise progressive course over at least one month

AND

1.2 Asymmetric involvement of two or more nerves

AND

1.3 Absence of both of the following:

1.3.1 Motor neuron signs

AND

1.3.2 Bulbar signs

AND

2 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Multifocal Motor Neuropathy (off-label) [30-34]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale] [76, 87]

AND

2 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

Product Name: Asceniv, Panzyga	
Diagnosis	Multifocal Motor Neuropathy (off-label) [30-34]
Approval Length	12 month(s)

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of multifocal motor neuropathy (MMN) as confirmed by all of the following [76, 86, 87, N]:

1.1 Weakness with slowly progressive or stepwise progressive course over at least one month

AND

1.2 Asymmetric involvement of two or more nerves

AND

1.3 Absence of both of the following:

1.3.1 Motor neuron signs

AND

1.3.2 Bulbar signs

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Relapsing-Remitting Multiple Sclerosis (off-label) [50-52]

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsing remitting multiple sclerosis (RRMS)) [6, 50, 52, 75, G]

AND

2 - Documentation of an MS exacerbation or progression (worsening) of the patient's clinical status from the visit prior to the one prompting the decision to initiate immune globulin therapy [6, 50, 52, 75, G, M, O]

AND

3 - Trial and failure, contraindication, or intolerance to two of the following agents: [52, G, M, O]

- Aubagio (teriflunomide)*
- Avonex (interferon beta-1a)*
- Betaseron (interferon beta-1b)*
- Copaxone/Glatopa (glatiramer acetate)*
- Extavia (interferon beta-1b)*
- Gilenya (Fingolimod)*
- Lemtrada (alemtuzumab)*
- Plegridy (peginterferon beta-1a)*
- Rebif (interferon beta-1a)*
- Tecfidera (dimethyl fumarate)*
- Tysabri (natalizumab)*

AND

4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C

• Privigen	
Notes	*This agent may require prior authorization.

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Relapsing-Remitting Multiple Sclerosis (off-label) [50-52]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The prescriber maintains and provides chart documentation of the patient's evaluation, including both of the following [6, 50, 52, 75, O]:

1.1 Findings of interval examination including neurological deficits incurred

AND

1.2 Assessment of disability (e.g., Expanded Disability Status Score [EDSS], Functional Systems Score [FSS], Multiple Sclerosis Functional Composie [MSFC], Disease Steps [DS])

AND

2 - Stable or improved disability score (e.g., EDSS, FSS, MSFC, DS) [6, 50, 52, 75]

AND

3 - Documentation of decreased number of relapses since starting immune globulin therapy [6, 50, 52, 75]

AND

4 - Diagnosis continues to be the relapsing-remitting form of MS (RRMS)

AND

5 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

Product Name: Asceniv, Panzyga	
Diagnosis	Relapsing-Remitting Multiple Sclerosis (off-label) [50-52]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of relapsing remitting multiple sclerosis (RRMS)) [6, 50, 52, 75, G]

AND

2 - Documentation of an MS exacerbation or progression (worsening) of the patient's clinical status from the visit prior to the one prompting the decision to initiate immune globulin therapy [6, 50, 52, 75, G, M, O]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following agents: [52, G, M, O]

- Aubagio (teriflunomide)*
- Avonex (interferon beta-1a)*
- Betaseron (interferon beta-1b)*
- Copaxone/Glatopa (glatiramer acetate)*
- Generic dimethyl fumarate
- Gilenya (Fingolimod)*
- Lemtrada (alemtuzumab)*
- Tysabri (natalizumab)*

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Notes	*This agent may require prior authorization.

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Myasthenia Gravis Exacerbation (off-label) [45-49]
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis [45, 72, 74, F, R]

AND

2 - Evidence of myasthenic exacerbation, defined by one of the following symptoms in the last month: [45, 72, 74, F, R]

2.1 Difficulty swallowing

OR

2.2 Acute respiratory failure

OR

2.3 Major functional disability responsible for the discontinuation of physical activity

AND

3 - Concomitant immunomodulator therapy (e.g., azathioprine, mycophenolate mofetil, cyclosporine), unless contraindicated, will be used for long-term management of myasthenia gravis [45, 72, 74, F, R]

AND

4 - Prescribed by or in consultation with a neurologist

AND

5 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Asceniv, Panzyga	
Diagnosis	Myasthenia Gravis Exacerbation (off-label) [45-49]
Approval Length	3 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis [45, 72, 74, F, R]

AND

2 - Evidence of myasthenic exacerbation, defined by one of the following symptoms in the last month: [45, 72, 74, F, R]

2.1 Difficulty swallowing

OR

2.2 Acute respiratory failure

OR

2.3 Major functional disability responsible for the discontinuation of physical activity

AND

3 - Concomitant immunomodulator therapy (e.g., azathioprine, mycophenolate mofetil, cyclosporine), unless contraindicated, will be used for long-term management of myasthenia gravis [45, 72, 74, F, R]

AND

4 - Prescribed by or in consultation with a neurologist

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Stiff Person Syndrome (off-label) [53]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of stiff-person syndrome [55, 83, 84]

AND

2 - Trial and failure, contraindication or intolerance to GABAergic medication (e.g., baclofen, benzodiazepines) [55, 83, 84]

AND

3 - Trial and failure, contraindication or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids) [55, 83, 84]

AND

4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Stiff Person Syndrome (off-label) [53]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

Product Name: Asceniv, Panzyga	
Diagnosis	Stiff Person Syndrome (off-label) [53]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of stiff-person syndrome [55, 83, 84]

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication or intolerance to GABAergic medication (e.g., baclofen, benzodiazepines) [55, 83, 84]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids) [55, 83, 84]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Dermatomyositis and Polymyositis (off-label) [6, 25-29, 64]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses [29]:

- Dermatomyositis
- Polymyositis

AND

2 - Trial and failure, contraindication, or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids, cyclophosphamide, methotrexate) [29, Q]

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Dermatomyositis and Polymyositis (off-label) [6, 25-29, 64]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

Product Name: Asceniv, Panzyga	
Diagnosis	Dermatomyositis and Polymyositis (off-label) [6, 25-29, 64]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following diagnoses [29]:

- Dermatomyositis
- Polymyositis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids, cyclophosphamide, methotrexate) [29, Q]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Guillain-Barre Syndrome (off-label) [38-40]
Approval Length	3 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Guillain-Barre Syndrome

AND

2 - Patients with severe disease requiring aid to walk [40, E]

AND

3 - Onset of neuropathic symptoms within the last four weeks [40, E]

AND

4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Guillain-Barre Syndrome (off-label) [38-40]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

Product Name: Asceniv, Panzyga	
Diagnosis	Guillain-Barre Syndrome (off-label) [38-40]
Approval Length	3 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Guillain-Barre Syndrome

AND

2 - Patients with severe disease requiring aid to walk [40, E]

AND

3 - Onset of neuropathic symptoms within the last four weeks [40, E]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Lambert-Eaton Myasthenic Syndrome (off-label) [41]
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Lambert-Eaton Myasthenic Syndrome (LEMS) [41]

AND

2 - History of failure, contraindication, or intolerance to immunomodulator monotherapy (e.g., azathioprine, corticosteroids) [81, 82]

AND

3 - Concomitant immunomodulator therapy (eg, azathioprine, corticosteroids), unless contraindicated, will be used for long-term management of LEMS [81, 82]

AND

4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Lambert-Eaton Myasthenic Syndrome (off-label) [41]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

Product Name: Asceniv, Panzyga	
Diagnosis	Lambert-Eaton Myasthenic Syndrome (off-label) [41]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Lambert-Eaton Myasthenic Syndrome (LEMS) [41]

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming history of failure, contraindication, or intolerance to immunomodulator monotherapy (e.g., azathioprine, corticosteroids) [81, 82]

AND

3 - Concomitant immunomodulator therapy (e.g., azathioprine, corticosteroids), unless contraindicated, will be used for long-term management of LEMS [81, 82]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Cytogam	
Diagnosis	Prophylaxis for CMV Infection
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Patient requires prophylaxis for CMV infection following kidney transplantation

AND

1.1.2 Patient is CMV- seronegative and organ donor is CMV-seropositive

OR

1.2 All of the following:

1.2.1 Patient requires prophylaxis for CMV infection following liver, heart, lung, or pancreas transplantation

AND

1.2.2 Patient is CMV- seronegative and organ donor is CMV-seropositive

AND

1.2.3 Used in combination with ganciclovir or valganciclovir unless the patient has a hypersensitivity to, is intolerant of, or therapy is deemed inappropriate

Product Name: Varizig	
Diagnosis	Varicella

Approval Length	1 Dose
Guideline Type	Prior Authorization

Approval Criteria

1 - For passive immunization or post exposure-prophylaxis of varicella

AND

2 - Patient is considered a high risk individual (e.g., immune compromised, pregnant woman, newborn of mother with varicella, premature infant, and infant less than 1 year old)

AND

3 - Prescribed immune globulin is being used intramuscularly

3 . Endnotes

A. Guidelines from the British Committee for Standards in Haematology [11] and the National Comprehensive Cancer Network [16] state that IVIG therapy may be beneficial in patients with recurrent infections. Clinical studies show that IVIG reduces the number of bacterial infections, but not viral or fungal infections. [24]
B. Based on inclusion criteria from Molica et al. [14]
C. According to published data, there appears to be no difference in efficacy among IVIG, plasma exchange, and corticosteroids. [15, 17, 20]
D. A controlled trial indicated that treatment with IVIG beyond three months was associated with a delayed recovery of humoral immunity, and the rate of infections after two years of treatment was increased significantly in IVIG recipients. [25] Centers for Disease Control and Prevention, Infectious Disease Society of America, and American Society of Blood and Marrow Transplantation guidelines recommended routine IVIG use to prevent bacterial infections among BMT recipients with unrelated marrow grafts who experience severe hypogammaglobulinemia (e.g., IgG < 400 mg/dl) within the first 100 days after transplant. [21]
E. The American Academy of Neurology recommends that IVIG is for patients with GBS who require aid to walk within 2 weeks from the onset of neuropathic symptoms. [40]
F. The effectiveness of IVIG for moderate-to-severe but stable myasthenia gravis, or for moderate exacerbations of myasthenia gravis have not been demonstrated in adequately controlled trials. [48] IVIG may be as effective as plasma exchange for patients with acute exacerbations of myasthenia gravis. [45] The indications for the use of IVIG are the same as those for plasma exchange: to produce rapid improvement to

help the patient through a difficult period of myasthenic weakness. It has the advantages of not requiring special equipment or large-bore vascular access. [59] The usual dose of immune globulin is 400 mg per kilogram per day for five successive days. The improvement rate after immune globulin treatment, calculated from eight published reports, was 73 percent, but this figure is likely to be biased by selective reporting of positive uncontrolled trials. In patients who respond, improvement begins within four to five days. The effect is temporary but may be sustained for weeks to months, allowing intermittent long-term therapy in patients with otherwise refractory disease.

G. Guidelines from the American Academy of Neurology [42] state that interferon Beta or glatirimer are appropriate treatments for patients who have relapsing-remitting multiple sclerosis. The guidelines state that it is only possible that IVIG reduces the attack rate in RRMS, and that current evidence suggests IVIG is of little benefit with regard to slowing disease progression.
H. Treatment for CIDP includes corticosteroids such as prednisone, which may be prescribed alone or in combination with immunosuppressant drugs. [58] Plasmapheresis and intravenous immunoglobulin (IVIG) therapy are effective. IVIG may be used even as a first-line therapy. Physiotherapy may improve muscle strength, function and mobility, and minimize the shrinkage of muscles and tendons and distortions of the joints.
I. Subcutaneous formulations of immune globulin are available for the treatment of patients with primary immune deficiency. Subcutaneous infusions may be an alternative for patients with adverse effects to intravenous infusions of immune globulin or with poor venous access. Other advantages include decreased cost of administration, independence from scheduled home nursing visits, better maintenance of intravenous immune globulin trough levels, and a serum IgG profile (smaller variation in the peak and trough IgG concentrations compared to intravenous administration) that is similar to that in a normal population. Disadvantages include more frequent infusions and local reactions. [6]
J. There are good data to show that all immune globulins (IVIG/SCIG) are effective for primary immunodeficiency. There are no data for SCIG for indications other than PI. Efficacy is a class effect for all immune globulins products. It is appropriate to combine all IVIG/SCIG products as they are used interchangeably for PI; can combine all IVIG for other indications. Gamastan S/D (IMIG) has unique indications and should be available on the formulary. [74]
K. IVIG has been used in children with symptomatic human immunodeficiency virus (HIV) infection who are immunosuppressed in association with acquired immunodeficiency syndrome (AIDS) or AIDS-related complex (ARC) in an attempt to control or prevent infections and improve immunologic parameters. Results of studies in adults and children with symptomatic HIV infection indicate that IVIG, used in dosages similar to those used for replacement therapy in patients with primary immunodeficiencies, reduces the incidence of recurrent bacterial infections and sepsis, including upper respiratory tract infections. [75]
L. The ACIP, American Academy of Pediatrics (AAP), Centers for Disease Control (CDC), National Institutes of Health (NIH), HIV Medicine Association of the Infectious Diseases Society of America (IDSA), Pediatric Infectious Diseases Society, and other experts state that HIV-infected infants and children who have hypogammaglobulinemia (IgG less than 400 mg/dL) should receive IVIG (400 mg/kg once every 2-4 weeks) to prevent serious bacterial infections. [75]
M. Per expert consultant regarding MS: IVIG is only used in acute, severe MS. IVIG is used for bad relapses of MS with significant neurological dysfunction when a patient is breaking through their regular maintenance medications. It takes about 3 months to see

if there is improvement in MS and one cannot say a patient has failed a medication if they have a breakthrough episode of MS within this 3 month period [86].

N. Per expert consultant regarding multifocal motor neuropathy: the European Federation of Neurological Societies (EFNS) guidelines [88] as outlined on page 344 and in the table are fairly reasonable: 1. Weakness with slowly progressive or stepwise progressive course 2. Asymmetric involvement of two or more nerves 3. Absence of upper motor neuron signs and bulbar signs [87].
O. Per expert consultant regarding MS: there are no data to support the initial length of IVIG treatment in MS. I would suggest 3 months and then reevaluate. An appropriate length of time for reauthorization of IVIG is 12 months. Patients who receive IVIG for RRMS should be in acute exacerbation, should have tried steroids, have documentation of inability to tolerate other disease modifying drugs, as well as show progression of disease. IVIG should be used 2nd or 3rd line if other injectable disease modifying drugs are not tolerated. Guidelines do not support IVIG as first line treatment for MS [87].
P. Per expert consultant regarding CIDP: It is important to reevaluate a patient after initial treatment. Some patients may need changes in dosing intervals due to wearing off of a dose within 2-3 weeks. Treatment can be lifelong for some patient [87].
Q. Per expert consultant regarding dermatomyositis: It is reasonable to ask a patient to try steroids prior to treatment with IVIG. [87]
R. Per expert consultant regarding MG: IVIG should be used in patients with moderate to severe myasthenia gravis with acute exacerbation. Most MDs favor plasma exchange for maintenance therapy in MG patients. Myasthenic exacerbation = myasthenic crisis. [87]

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5 . Revision History

Date	Notes
4/5/2023	Annual review: Removed obsolete/unavailable product GPI. Updated Gamastan's authorization duration and background.

Prior Authorization Guideline

Guideline Name	Increlex (mecasermin [rDNA origin])

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	4/4/2006
P&T Revision Date:	11/14/2019 ; 11/12/2020 ; 11/18/2021 ; 11/17/2022

1 . Indications

Drug Name: Increlex (mecasermin [rDNA origin]) injection
Severe Primary IGF-1 deficiency (Primary IGFD) Indicated for the treatment of growth failure in pediatric patients 2 years of age and older with severe primary IGF-1 deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH. Severe Primary IGFD is defined by: height standard deviation score less than or equal to -3.0, basal IGF-1 standard deviation score less than or equal to -3.0, and normal or elevated GH. Limitations of use: Increlex is not a substitute to GH for approved GH indications. Increlex is not indicated for use in patients with secondary forms of IGF-1 deficiency, such as GH deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacological doses of anti-inflammatory corticosteroids.

2 . Criteria

Product Name: Increlex	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following: [A]

1.1 All of the following:

1.1.1 Diagnosis of severe primary IGF-1 deficiency [3]

AND

1.1.2 Height standard deviation score less than or equal to -3.0

AND

1.1.3 Basal IGF-1 standard deviation score less than or equal to -3.0

AND

1.1.4 Normal or elevated growth hormone

AND

1.1.5 Prescribed by or in consultation with a pediatric endocrinologist

OR

1.2 Both of the following:

1.2.1 Diagnosis of growth hormone (GH) gene deletion in patients who have developed neutralizing antibodies to GH

AND **1.2.2** Prescribed by or in consultation with a pediatric endocrinologist	
Notes	NOTE: Documentation of previous height, current height and goal exp ected adult height will be required for renewal. Increlex is not a substit ute for GH for approved GH indications.

Product Name: Increlex	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Growth increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [2, B]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height is not obtained
- Documentation of expected adult height goal

Notes	NOTE: Increlex is not a substitute for GH for approved GH indications.

3 . Endnotes

A. Growth Hormone Deficiency (GHD) and severe Primary IGF-1 Deficiency (IGFD) are two distinct hormone disorders. Patients with severe Primary IGFD are not GH deficient, and

therefore, exogenous GH treatment cannot be expected to resolve the patient's growth deficiency. [1]

B. Typically near-adult height is defined as bone age of 16 years or more for males and 14 years or more for females and a growth rate less than 2 cm/year for 1 year. [2]

4 . References

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5 . Revision History

Date	Notes
11/2/2022	2022 Annual Review

Prior Authorization Guideline

Guideline Name	Infliximab – PA, NF

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	12/15/2009
P&T Revision Date:	07/15/2020 ; 08/13/2020 ; 12/16/2020 ; 05/20/2021 ; 08/19/2021 ; 02/17/2022 ; 08/18/2022 ; 10/19/2022

1 . Indications

Drug Name: Remicade (infliximab), Infliximab, Avsola (infliximab-axxq), Inflectra (infliximab-dyyb), Renflexis (Infliximab-abda)
Rheumatoid Arthritis (RA) Indicated in combination with methotrexate, for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis. **Psoriatic Arthritis (PsA)** Indicated for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis. **Plaque Psoriasis (PsO)** Indicated for the treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate. Therapy should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician. **Ankylosing Spondylitis (AS)** Indicated for reducing signs and symptoms in patients with active ankylosing spondylitis. **Crohn's Disease (CD)** Indicated for reducing signs and symptoms and inducing and

maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. Also indicated for reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing Crohn's disease.

Pediatric Crohn's Disease Indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy.

Ulcerative Colitis (UC) Indicated for reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.

Pediatric Ulcerative Colitis Indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.

Off Label Uses: **Sarcoidosis** Has been used for the treatment of refractory sarcoidosis. [5-7]

2 . Criteria

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active RA

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide
- sulfasalazine

AND

4 - Used in combination with methotrexate

AND

5 - Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of moderately to severely active RA

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide
- sulfasalazine

AND

4 - Used in combination with methotrexate

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and

failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only) • Avsola • Inflectra

Notes	*Includes attestation that a total of two infliximab products have alread y been tried in the past, and the patient should not be made to try a thi rd infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active PsA

AND

2 - One of the following [4]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

AND

4 - Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of active PsA

AND

2 - One of the following [4]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic severe (i.e., extensive and/or disabling) plaque psoriasis

AND

2 - One of the following [5]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [6]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to infliximab therapy as evidenced by ONE of the following [1, 5]

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of chronic severe (i.e., extensive and/or disabling) plaque psoriasis

AND

2 - One of the following [5]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [6]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [7]

AND

4 - Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following [1, 7]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)

- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [7]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Crohn's Disease (CD) or Fistulizing Crohn's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Moderately to severely active Crohn's disease
- Fistulizing Crohn's disease

AND

2 - One of the following [8, 9]:

- Frequent diarrhea and abdominal pain
- At least 10% weight loss
- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values (e.g., C-reactive protein [CRP])
- CD Activity Index (CDAI) greater than 220

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies [8, 9]:

- 6-mercaptopurine
- Azathioprine
- Corticosteroids (e.g., prednisone)
- Methotrexate

AND

5 - Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Crohn's Disease (CD) or Fistulizing Crohn's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 8, 9]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Crohn's Disease (CD) or Fistulizing Crohn's Disease
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following diagnoses:

- Moderately to severely active Crohn's disease
- Fistulizing Crohn's disease

AND

2 - One of the following [8, 9]:

- Frequent diarrhea and abdominal pain
- At least 10% weight loss
- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values (e.g., C-reactive protein [CRP])
- CD Activity Index (CDAI) greater than 220

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one of the following conventional therapies [8, 9]:

- 6-mercaptopurine
- Azathioprine
- Corticosteroids (e.g., prednisone)
- Methotrexate

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [10, 11]:

- Greater than 6 stools per day
- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers
- Abnormal lab values (e.g., hemoglobin, ESR, CRP)
- Dependent on, or refractory to, corticosteroids

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies [10, 11]:

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine

- Corticosteroids (e.g., prednisone)

AND

5 - Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes	*Includes attestation that a total of two infliximab products have alread y been tried in the past, and the patient should not be made to try a thi rd infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 10, 11]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [10, 11]:

- Greater than 6 stools per day
- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers
- Abnormal lab values (e.g., hemoglobin, ESR, CRP)
- Dependent on, or refractory to, corticosteroids

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one of the following conventional therapies [10, 11]:

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine
- Corticosteroids (e.g., prednisone)

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Sarcoidosis [Off-label] [12-15]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of sarcoidosis

AND

2 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Dermatologist
- Ophthalmologist

AND

3 - Trial and failure, contraindication, or intolerance to one corticosteroid (e.g., prednisone)

AND

4 - Trial and failure, contraindication, or intolerance to one immunosuppressant (e.g., methotrexate, cyclophosphamide, or azathioprine)

AND

5 - Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Sarcoidosis [Off-label] [12-15]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to infliximab therapy

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Sarcoidosis [Off-label] [12-15]
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of sarcoidosis

AND

2 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Dermatologist
- Ophthalmologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one corticosteroid (e.g., prednisone)

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one immunosuppressant (e.g., methotrexate, cyclophosphamide, or azathioprine)

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

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4 . Revision History

Date	Notes
10/23/2022	Further clinical detail and criteria added

Prior Authorization Guideline

Guideline Name	Inhaled Corticosteroids

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	2/18/2015
P&T Revision Date:	03/18/2020 ; 10/21/2020 ; 03/17/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Alvesco (ciclesonide) Inhalation Aerosol
Asthma Indicated for the maintenance treatment of asthma as prophylactic therapy in adult and adolescent patients 12 years of age and older. Important Limitations of Use: Alvesco is NOT indicated for the relief of acute bronchospasm or for children under 12 years of age.
Drug Name: ArmonAir Digihaler (fluticasone propionate) Inhalation Powder
Asthma Indicated for the maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older. Limitations of Use: ArmonAir Digihaler is not indicated for the relief of acute bronchospasm.
Drug Name: Asmanex HFA (mometasone furoate) Inhalation Aerosol
Asthma Indicated for the maintenance treatment of asthma as prophylactic therapy in patients 5 years of age and older. Important Limitations of Use: Asmanex HFA is NOT indicated for the relief of acute bronchospasm.
Drug Name: Asmanex (mometasone furoate) Inhalation Powder

Asthma Indicated for the maintenance treatment of asthma as prophylactic therapy in patients 4 years of age and older. Limitations of Use: Asmanex Twisthaler is NOT indicated for the relief of acute bronchospasm or in children less than 4 years of age.

2 . Criteria

Product Name: Armonair Digihaler*, Alvesco*, Asmanex HFA*, Asmanex Twisthaler*	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication **AND** **2** - Trial and failure, contraindication, or intolerance to two of the following preferred brands: • Arnuity Ellipta • Flovent Diskus or Flovent HFA • Pulmicort Flexhaler • QVAR Redihaler	
Notes	*Product may be excluded depending on the plan.

3 . References

1. Alvesco [prescribing information]. Zug 6300, Switzerland: Covis Pharma; December 2022.
2. ArmonAir Digihaler [prescribing information]. Parsippany, NJ: Teva Respiratory, LLC; September 2022.
3. Asmanex [prescribing information]. Jersey City, NJ: Organon LLC; June 2021.
4. Asmanex HFA [prescribing information]. Jersey City, NJ: Organon LLC; June 2021.

4 . Revision History

Date	Notes
2/22/2023	2023 UM Annual Review. Removed QVAR as ST1 alt option since it i s now obsolete. Updated references

Prior Authorization Guideline

Guideline Name	Inlyta (axitinib)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	8/21/2012
P&T Revision Date:	07/17/2019 ; 07/15/2020 ; 07/21/2021 ; 05/19/2022 ; 08/18/2022 ; 5/18/2023

1 . Indications

Drug Name: Inlyta (axitinib)
Advanced Renal Cell Carcinoma Indicated in combination with avelumab or pembrolizumab, for the first-line treatment of patients with advanced renal cell carcinoma (RCC). It is also indicated as a single agent, for the treatment of advanced RCC after failure of one prior systemic therapy.

2 . Criteria

Product Name: Inlyta	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of renal cell carcinoma

AND

2 - One of the following: [2]

- Disease has relapsed
- Diagnosis of stage IV disease

AND

3 - One of the following:

3.1 Used as first-line treatment in combination with one of the following for clear cell renal cell carcinoma**: [2]

- avelumab*
- pembrolizumab*

OR

3.2 Used after failure of one prior systemic therapy (e.g., chemotherapy) for clear cell renal cell carcinoma** [2]

OR

3.3 One of the following:

3.3.1 Both of the following: [2]

- Used in the treatment of non-clear cell renal cell carcinoma
- Trial and failure, contraindication or intolerance to generic sunitinib

OR

3.3.2 For continuation of prior therapy

AND

4 - Prescribed by or in consultation with an oncologist

Notes	*This product may require prior authorization. ***Criterion is part of FDA-approved label

Product Name: Inlyta	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Inlyta Prescribing Information. Pfizer Labs. New York, NY. September 2022.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Kidney Cancer. v.4.2023. Available at https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed May 3, 2023.

4 . Revision History

Date	Notes
5/4/2023	Annual review: Updated criteria, operational notes, references.

Prior Authorization Guideline

Guideline Name	Insomnia Agents

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	2/18/2015
P&T Revision Date:	09/18/2019 ; 09/16/2020 ; 09/15/2021 ; 09/21/2022 ; 10/19/2022

1 . Indications

Drug Name: Edluar (zolpidem tartrate)
Insomnia Indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation. The clinical trials performed with zolpidem tartrate in support of efficacy were 4-5 weeks in duration with the final formal assessments of sleep latency performed at the end of treatment.
Drug Name: Zolpimist (zolpidem tartrate)
Insomnia Indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation. Zolpidem tartrate has been shown to decrease sleep latency for up to 35 days in controlled clinical studies. The clinical trials performed in support of efficacy were 4-5 weeks in duration with the final formal assessments of sleep latency performed at the end of treatment.
Drug Name: Ambien (zolpidem tartrate)
Insomnia Indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation.
Drug Name: Ambien CR (zolpidem tartrate)

Insomnia Indicated for the short-term treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.
Drug Name: Quviviq (daridorexant)
Insomnia Indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance in adults.
Drug Name: Belsomra (suvorexant)
Insomnia Indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.
Drug Name: Dayvigo (lemborexant)
Insomnia Indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

2 . Criteria

Product Name: Ambien, Ambien CR, Edluar, Zolpimist	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), or intolerance to one of the following:

- zolpidem
- zolpidem ER

Product Name: Quviviq

Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - ONE of the following:

2.1 If the patient is less than 65 years of age, BOTH of the following:

2.1.1 Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to ONE of the following:

- Belsomra*
- Dayvigo*

AND

2.1.2 Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to TWO of the following:

- eszopiclone
- zaleplon
- zolpidem
- zolpidem ER
- triazolam
- temazepam
- generic ramelteon
- doxepin

OR

2.2 If the patient is 65 years of age and older, trial and failure (of a minimum 30-day supply), contraindication, or intolerance to TWO of the following:

- generic ramelteon

• Belsomra* • Dayvigo* • doxepin	
Notes	*NOTE: Step Therapy (ST) requirements may apply for brand Belsomra and brand Dayvigo

Product Name: Belsomra, Dayvigo	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to one of the following:

- doxepin
- eszopiclone
- temazepam
- zaleplon
- zolpidem
- zolpidem ER

3 . References

1. Edluar Prescribing Information. Meda Pharmaceuticals Inc. Somerset, NJ. September 2021.
2. Zolpimist Prescribing Information. Aytu Bioscience, Inc. Englewood, CO. August 2019.
3. Ambien Prescribing Information. Sanofi-Aventis U.S. LLC. Bridgewater, NJ. February 2022.
4. Ambien CR Prescribing Information. Sanofi-Aventis U.S. LLC. Bridgewater, NJ. February 2022.
5. Quviviq Prescribing Information. Idorsia Pharmaceuticals US Inc. Radnor, PA. April 2022.
6. Belsomra Prescribing Information. Merck Sharp & Dohme LLC. Rahway, NJ. May 2022.

7. Dayvigo Prescribing Information. Eisai, Inc. Nutley, NJ. January 2023.
8. The 2019 American Geriatrics Society Beers Criteria Update Expert Panel. American Geriatrics Society 2019 Updated AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc 00:1-21, 2019. Available at https://www.uclahealth.org/geriatrics/workfiles/education/clinical-skills/handouts/Education-Updated-Beers-List-2019.pdf. Accessed May 9, 2022.
9. Sateia MJ, Buysse DJ, Krystal AD, Neubauer DN, Heald JL. Clinical practice guideline for the pharmacologic treatment of chronic insomnia in adults: An American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2017;13(2):307-349. Available at https://jcsm.aasm.org/doi/10.5664/jcsm.6470. Accessed May 9, 2022.
10. UpToDate. Overview of the Treatment of Insomnia in Adults. Available at https://www.uptodate.com/contents/overview-of-the-treatment-of-insomnia-in-adults?search=insomnia&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1. Accessed March 28, 2023.

4 . Revision History

Date	Notes
4/5/2023	update guideline

Prior Authorization Guideline

Guideline Name	Insulin Delivery Systems

Guideline Note:

Effective Date:	8/1/2022
P&T Approval Date:	6/23/2009
P&T Revision Date:	09/15/2021 ; 6/15/2022

Note:

This guideline applies to plans that only provide coverage for insulin vials. The intent of this policy is to serve as guidance for clients who would like to allow for exceptions reviews for excluded insulin delivery systems.

1 . Criteria

Product Name: Insulin dosers, cartridges, or pen devices	
Guideline Type	Administrative

Approval Criteria

1 - Will be approved, except when excluded as a plan benefit, based on one of the following criteria:

1.1 The patient has visual impairment (unable to use insulin vial and syringe)

OR

1.2 The patient has physical impairment (unable to use insulin vial and syringe)

2 . Revision History

Date	Notes
6/17/2022	Annual review: no criteria changes. Added "cartridge" as a search term.

Prior Authorization Guideline

Guideline Name	Interstitial Lung Disease (ILD) Agents

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	11/4/2014
P&T Revision Date:	11/14/2019 ; 05/14/2020 ; 12/16/2020 ; 11/18/2021 ; 06/15/2022 ; 09/21/2022 ; 11/17/2022 ; 3/15/2023

1 . Indications

Drug Name: Esbriet (pirfenidone)
Idiopathic Pulmonary Fibrosis Indicated for the treatment of idiopathic pulmonary fibrosis (IPF).
Drug Name: Ofev (nintedanib)
Idiopathic Pulmonary Fibrosis Indicated for the treatment of idiopathic pulmonary fibrosis (IPF). **Systemic Sclerosis-associated Interstitial Lung Disease** Indicated for slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD). **Chronic Fibrosing Interstitial Lung Diseases (ILDs) with a Progressive Phenotype** Indicated for the treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype.

2 . Criteria

Product Name: Brand Esbriet, Generic pirfenidone, Ofev	
Diagnosis	Idiopathic Pulmonary Fibrosis (IPF)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of idiopathic pulmonary fibrosis (IPF) as documented by both of the following: [3]

1.1 Exclusion of other known causes of interstitial lung disease (ILD) (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity)

AND

1.2 One of the following:

1.2.1 In patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF

OR

1.2.2 In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF

AND

2 - Prescribed by or in consultation with a pulmonologist

Product Name: Ofev	
Diagnosis	Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) as documented by the following: [5-6]

1.1 Exclusion of other known causes of interstitial lung disease (ILD) (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity)

AND

1.2 One of the following:

1.2.1 In patients not subjected to surgical lung biopsy, the presence of idiopathic interstitial pneumonia (e.g., fibrotic nonspecific interstitial pneumonia [NSIP], usual interstitial pneumonia [UIP] and centrilobular fibrosis) pattern on high-resolution computed tomography (HRCT) revealing SSc-ILD or probable SSc-ILD

OR

1.2.2 In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD

AND

2 - Prescribed by or in consultation with a pulmonologist

Product Name: Ofev	
Diagnosis	Chronic Fibrosing Interstitial Lung Diseases (ILDs) with a Progressive Phenotype
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic fibrosing interstitial lung disease

AND

2 - Patient has a high-resolution computed tomography (HRCT) showing at least 10% of lung volume with fibrotic features

AND

3 - Disease has a progressive phenotype as observed by one of the following:

- Decline of forced vital capacity (FVC)
- Worsening of respiratory symptoms
- Increased extent of fibrosis seen on imaging

AND

4 - Prescribed by or in consultation with a pulmonologist

Product Name: Brand Esbriet, Generic pirfenidone	
Diagnosis	Idiopathic Pulmonary Fibrosis (IPF)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Ofev

Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

3 . References

1. Esbriet prescribing information. Genentech, Inc. South San Francisco, CA. February 2022.
2. Ofev prescribing information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. January 2022.
3. Raghu G, Collard HR, Egan JJ, et al. Official ATS/ERS/JRS/ALAT statement: idiopathic pulmonary fibrosis: evidence-based guidelines for diagnosis and management. Am J of Respir Crit Care Med. 2011;183:788-824.
4. Raghu G, Rochwerg B, Zhang Y, et al. An Official ATS/ERS/JRS/ALAT clinical practice guideline: treatment of idiopathic pulmonary fibrosis, an update of the 2011 clinical practice guideline. Am J Respir Crit Care Med. 2015;192(2):e3-e19.
5. Fischer A, Swigris JJ, Groshong SD, et al. Clinically significant interstitial lung disease in limited scleroderma: histopathology, clinical features, and survival. Chest 2008; 134:601.
6. UptoDate [internet database]. Waltham, MA. UpToDate, Inc. Clinical manifestations, evaluation, and diagnosis of interstitial lung disease in systemic sclerosis (scleroderma). Available by subscription at: https://www.uptodate.com. Accessed November 18, 2020.
7. Pirfenidone Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, New Jersey. May 2022.

4 . Revision History

Date	Notes
1/31/2023	Added generic Esbriet (pirfenidone) 267mg capsule to guideline

Prior Authorization Guideline

Guideline Name	Intrarosa (prasterone)

Guideline Note:

Effective Date:	8/1/2022
P&T Approval Date:	7/21/2021
P&T Revision Date:	6/15/2022

1 . Indications

Drug Name: Intrarosa (prasterone)
Moderate to Severe Dyspareunia Indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.

2 . Criteria

Product Name: Intrarosa	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria	

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to one of the following:

- Premarin vaginal cream
- Osphena

3 . References

1. Intrarosa prescribing information. AMAG Pharmaceuticals, Inc. Waltham, MA. February 2018.

4 . Revision History

Date	Notes
6/2/2022	Updated criteria.

Prior Authorization Guideline

Guideline Name	Jakafi (ruxolitinib)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	2/21/2012
P&T Revision Date:	08/15/2019 ; 03/18/2020 ; 03/17/2021 ; 11/18/2021 ; 03/16/2022 ; 05/19/2022 ; 3/15/2023

1 . Indications

Drug Name: Jakafi (ruxolitinib)
Myelofibrosis Indicated for treatment of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis in adults. **Polycythemia Vera** Indicated for treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea. **Acute Graft Versus Host Disease** Indicated for treatment of steroid-refractory acute graft-versus-host disease (GVHD) in adult and pediatric patients 12 years and older. **Chronic Graft Versus Host Disease** Indicated for treatment of chronic graft-versus-host disease (cGVHD) after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.

2 . Criteria

Product Name: Jakafi	
Diagnosis	Myelofibrosis
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Primary myelofibrosis
- Post-polycythemia vera myelofibrosis
- Post-essential thrombocythemia myelofibrosis

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Jakafi	
Diagnosis	Polycythemia Vera
Approval Length	8 Months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of polycythemia vera [1]

AND

2 - Trial and failure, contraindication, or intolerance to hydroxyurea [1]

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Jakafi	
Diagnosis	Myelofibrosis, Polycythemia Vera
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Jakafi therapy (e.g., spleen volume reduction, symptom improvement, hematocrit control)

Notes	If the member does not meet the medical necessity reauthorization criteria requirements, a denial should be issued and a 2-month authorization should be issued one time for Jakafi gradual therapy discontinuation.

Product Name: Jakafi	
Diagnosis	Acute Graft Versus Host Disease
Approval Length	6 Month(s) [C]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute graft-versus-host disease

AND

2 - Disease is steroid-refractory

AND

3 - Patient is 12 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist
- Physician experienced in the management of transplant patients

Product Name: Jakafi	
Diagnosis	Chronic Graft Versus Host Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic graft-versus-host disease

AND

2 - Patient is 12 years of age or older

AND

3 - Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.)

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

- Physician experienced in the management of transplant patients

Product Name: Jakafi	
Diagnosis	Chronic Graft Versus Host Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. Jakafi should be discontinued after 6 months if there is no spleen size reduction or symptom improvement since initiation of therapy. [1]
B. The initial authorization duration of 8 months is based on clinical trials (primary endpoint of hematocrit control and spleen volume reduction was evaluated at 32 weeks). [1]
C. Authorization duration of 6 months is based median time from response to death or need for new therapy for acute GVHD in clinical trials (173 days). Additionally, tapering of Jakafi may be considered after 6 months of treatment in patients with response who have discontinued therapeutic doses of corticosteroids. [1]

4 . References

1. Jakafi Prescribing Information. Incyte Corp. Wilmington, DE. January 2023.

5 . Revision History

Date	Notes
3/2/2023	2023 Annual Review

Prior Authorization Guideline

Guideline Name	Jevtana (cabazitaxel)

Guideline Note:

Effective Date:	5/1/2022
P&T Approval Date:	2/15/2011
P&T Revision Date:	03/17/2021 ; 3/16/2022

1 . Indications

Drug Name: Jevtana (cabazitaxel)
Prostate Cancer Indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen.

2 . Criteria

Product Name: Jevtana	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of metastatic castration-resistant prostate cancer

AND

1.2 Used in combination with prednisone

AND

1.3 Patient has been previously treated with a docetaxel-containing regimen

AND

1.4 Prescribed by or in consultation with an oncologist

Product Name: Jevtana	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease

3 . References

1. Jevtana Prescribing Information. Sanofi-Aventis U.S. LLC, Bridgewater, NJ. February 2021.

4 . Revision History

Date	Notes
3/8/2022	Annual Review

Prior Authorization Guideline

Guideline Name	Kadcyla (ado-trastuzumab emtansine)

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	5/21/2013
P&T Revision Date:	11/14/2019 ; 11/12/2020 ; 12/15/2021 ; 11/17/2022

1 . Indications

Drug Name: Kadcyla (ado-trastuzumab emtansine)
Early Breast Cancer Indicated for the adjuvant treatment of patients with HER2-positive early breast cancer who have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment. **Metastatic Breast Cancer** Indicated for the treatment of patients with HER2-positive, metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either: received prior therapy for metastatic disease, or developed disease recurrence during or within six months of completing adjuvant therapy.

2 . Criteria

Product Name: Kadcyla	
Diagnosis	Early Breast Cancer
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of early breast cancer

AND

2 - Patient has human epidermal growth factor receptor 2 (HER2)-positive disease

AND

3 - Patient has residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Kadcyla	
Diagnosis	Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic breast cancer

AND

2 - Patient has human epidermal growth factor receptor 2 (HER2)-positive disease [2, 3]

AND

3 - Patient has been previously treated with trastuzumab and a taxane

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Kadcyla	
Diagnosis	Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Kadcyla Prescribing Information. Genentech Inc. South San Francisco, CA. September 2020.
2. National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium [internet database]. National Comprehensive Cancer Network, Inc. 2021. Updated periodically. Available by subscription at: https://www.nccn.org/professionals/drug_compendium/content/. Accessed November 1, 2021.
3. Verma S, Miles D, Gianni L, et al. Trastuzumab emtansine for HER2-positive advanced breast cancer. N Engl J Med. 2012; 367:1783-91.

4 . Revision History

Date	Notes

11/1/2022	2022 Annual Review - no changes

Prior Authorization Guideline

Guideline Name	Kalydeco (ivacaftor)

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	2/21/2012
P&T Revision Date:	04/15/2020 ; 11/12/2020 ; 02/18/2021 ; 02/17/2022 ; 2/16/2023

1 . Indications

Drug Name: Kalydeco (ivacaftor)
Cystic fibrosis Indicated for the treatment of cystic fibrosis (CF) in patients age 4 months and older who have one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use.

2 . Criteria

Product Name: Kalydeco	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Patient has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data* as detected by an FDA-cleared cystic fibrosis mutation test or a test performed at a Clinical Laboratory Improvement Amendments (CLIA)-approved facility

AND

3 - Patient is 4 months of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Specialist affiliated with a CF care center
- Pulmonologist

Notes	*Please consult Background section for table of CFTR gene mutations responsive to Kalydeco.

Product Name: Kalydeco	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response (i.e., improvement in lung function [percent

predicted forced expiratory volume in one second {PPFEV1}], decreased number of pulmonary exacerbations) to therapy [A]

3 . Background

Clinical Practice Guidelines

CFTR Gene Mutations that are Responsive to Kalydeco [1]

*Intent of table is to provide a quick reference; PA team members should still review at point of request for clinical appropriateness as off label support continuously evolves. [Last Reviewed: 1/6/23]

List of *CFTR* Gene Mutations that Produce CFTR Protein and are Responsive to KALYDE				
*711+3A→G *	*F311del*	*I148T*	*R75Q*	*S589N*
*2789+5G→A *	*F311L*	*I175V*	*R117C *	*S737F*
*3272-26A→G *	*F508C*	*I807M*	*R117G*	*S945L *
*3849+10kbC→T *	*F508C;S1251N † *	*I1027T*	*R117H *	*S977F *
A120T	*F1052V*	*I1139V*	*R117L*	*S1159F*
A234D	*F1074L*	*K1060T*	*R117P*	*S1159P*
A349V	*G178E*	*L206W *	*R170H*	*S1251N *
*A455E *	*G178R *	*L320V*	*R347H *	*S1255P *
A1067T	*G194R*	*L967S*	*R347L*	*T338I*
D110E	*G314E*	*L997F*	*R352Q *	*T1053I*
D110H	*G551D *	*L1480P*	*R553Q*	*V232D*
D192G	*G551S *	*M152V*	*R668C*	*V562I*
*D579G *	*G576A*	*M952I*	*R792G*	*V754M*
D924N	*G970D*	*M952T*	*R933G*	*V1293G*
*D1152H *	*G1069R*	*P67L *	*R1070Q*	*W1282R*
D1270N	*G1244E *	*Q237E*	*R1070W *	*Y1014C*
E56K	*G1249R*	*Q237H*	*R1162L*	*Y1032C*

E193K	*G1349D **	*Q359R*	*R1283M*
E822K	*H939R*	*Q1291R*	*S549N **
*E831X **	*H1375P*	*R74W*	*S549R **

** Clinical data exist for these mutations.*

† Complex/compound mutations where a single allele of the CFTR gene has multiple mutations these exist independent of the presence of mutations on the other allele.

4 . Endnotes

A. The primary efficacy endpoint in both Kalydeco pivotal trials was improvement in lung function as determined by the mean absolute change from baseline in percent predicted pre-dose FEV1 through 24 weeks of treatment. [2]

5 . References

1. Kalydeco Prescribing Information. Vertex Pharmaceuticals Incorporated. Boston, MA. December 2020.
2. Ramsey BW, Davies J, McElvaney G, et al. A CFTR potentiator in patients with cystic fibrosis and the G551D mutation. N Engl J Med. 2011;365:1663-1672.

6 . Revision History

Date	Notes
1/6/2023	Annual review: No criteria changes.

Prior Authorization Guideline

Guideline Name	Kanuma (sebelipase alfa)

Guideline Note:

Effective Date:	9/1/2022
P&T Approval Date:	2/25/2016
P&T Revision Date:	07/15/2020 ; 07/21/2021 ; 7/20/2022

1 . Indications

Drug Name: Kanuma (sebelipase alfa)
Lysosomal Acid Lipase (LAL) deficiency Indicated for the treatment of patients with a diagnosis of Lysosomal Acid Lipase (LAL) deficiency.

2 . Criteria

Product Name: Kanuma	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of lysosomal acid lipase deficiency (LAL-D, Wolman Disease, Cholesteryl ester storage disease) [B]

AND

2 - Diagnosis was confirmed by one of the following: [A]

2.1 Enzymatic blood test (e.g., dried blood spot test) demonstrating a deficiency of LAL enzyme activity

OR

2.2 Genetic testing for mutations in the lipase A, lysosomal acid type (LIPA) gene

AND

3 - Prescribed by or in consultation with one of the following:

- A specialist experienced in the treatment of inborn errors of metabolism
- Gastroenterologist
- Lipidologist

Product Name: Kanuma	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduction in LDL, triglycerides, AST or ALT, increase in HDL, reduction in liver fat content)

AND

2 - Prescribed by or in consultation with one of the following:

- A specialist experienced in the treatment of inborn errors of metabolism
- Gastroenterologist
- Lipidologist

3 . Endnotes

A. Due to similar clinical presentations, LAL-D is often misdiagnosed as familial defective apolipoprotein B (ApoB) deficiency, heterozygous familial hypercholesterolemia (HeFH), familial combined hyperlipidemia (FCH), or polygenic hypercholesterolaemia [3]. A diagnosis of LAL-D can be confirmed by identification of a LIPA mutation or a deficient LAL enzyme in peripheral blood leukocytes, fibroblasts, or dried blood spots. A biopsy and/or radiographic findings may help support a LAL-D diagnosis, however these are not considered diagnostic. [2,3]
B. LAL deficiency is sub-classified as Wolman disease in infants and cholesteryl ester storage disease (CESD) in children and adults. [4]

4 . References

1. Kanuma prescribing information, Alexion Pharmaceuticals. Cheshire, CT. December 2015.
2. Burton BK, Balwani M, Feillet F, et al. A Phase 3 Trial of Sebelipase Alfa in Lysosomal Acid Lipase Deficiency. N Engl J Med. 2015;373(11):1010-20.
3. Reiner, Guardamagna, Nair, et al. Lysosomal acid lipase deficiency - an under-recognized cause of dyslipidaemia and liver dysfunction. Atherosclerosis. 2014;235(1): 21-30.
4. Strebinger G, Müller E, Feldman A, Aigner E. Lysosomal acid lipase deficiency - early diagnosis is the key. Hepat Med. 2019 May 23;11:79-88.

5 . Revision History

Date	Notes
7/1/2022	Annual Review - criteria updated to have initial and reauth criteria an d respective approval lengths updated; specialist requirement option s expanded

Prior Authorization Guideline

Guideline Name	Keveyis (dichlorphenamide)

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	11/18/2015
P&T Revision Date:	08/13/2020 ; 08/19/2021 ; 08/18/2022 ; 01/18/2023 ; 3/15/2023

1 . Indications

Drug Name: Keveyis (dichlorphenamide)
Primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants Indicated for the treatment of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants.

2 . Criteria

Product Name: Brand Keveyis, Generic dichlorphenamide	
Approval Length	3 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Primary hyperkalemic periodic paralysis
- Primary hypokalemic periodic paralysis
- Paramyotonia Congenita with periodic paralysis [2]
- Andersen-Tawil syndrome [3]

AND

2 - One of the following [3]:

2.1 Patient has positive genetic panel for periodic paralysis

OR

2.2 One of the following tests demonstrated positive results for periodic paralysis:

- EMG/nerve conduction studies
- Long exercise test
- Muscle biopsy
- Muscle MRI

AND

3 - Patient has distinct, regular episodes of weakness at least once a week [4]

AND

4 - Trial and inadequate response, contraindication or intolerance to acetazolamide [off-label] [5]

AND

5 - Provider attests that other known causes of potassium fluctuations have been excluded (e.g., thyrotoxic periodic paralysis, drugs that cause potassium abnormalities, etc)

AND

6 - One of the following:

6.1 If new to therapy, dose will be initiated at 50mg twice daily

OR

6.2 Medication is being prescribed as continuation of therapy

AND

7 - Prescribed by or in consultation with a neurologist

Product Name: Brand Keveyis, Generic dichlorphenamide	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by a decrease in weekly attack frequency from baseline [4]

3 . Endnotes

A. Prescribers should evaluate the patient's response to Keveyis after 2 months of treatment to decide whether treatment should be continued [1]. An additional month is added to the initial authorization duration to allow patient follow-up with the provider.

4 . References

1. Keveyis Prescribing Information. Stonebridge Biopharma; Trevose, PA. November 2019
2. Tawil R, McDermott MP, Brown R Jr, et al. Randomized trials of dichlorphenamide in the periodic paralyses. Working Group on Periodic Paralysis. Ann Neurol. 2000;47(1):46-53.
3. Ciafaloni E, Jackson C, Kincaid J, et al. Primary Periodic Paralysis: The Diagnostic Journey.; 2019. Accessed January 4, 2023. https://keveyis.com/wp-content/uploads/keveyis-ppp-diagnostic-journey.pdf
4. Sansone VA, Burge J, McDermott MP, et al. Randomized, placebo-controlled trials of dichlorphenamide in periodic paralysis. Neurology. 2016;86(15):1408-1416. doi:10.1212/wnl.0000000000002416
5. Statland JM, Fontaine B, Hanna MG, et al. Review of the Diagnosis and Treatment of Periodic Paralysis. Muscle & Nerve. 2017;57(4):522-530. doi:10.1002/mus.26009

5 . Revision History

Date	Notes
2/10/2023	Added generic Keveyis (dichlorphenamide) tablets to guideline

Prior Authorization Guideline

Guideline Name	Kineret (anakinra)

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	1/28/2002
P&T Revision Date:	09/18/2019 ; 10/16/2019 ; 03/18/2020 ; 09/16/2020 ; 02/18/2021 ; 02/17/2022 ; 10/19/2022 ; 12/14/2022 ; 2/16/2023

1 . Indications

Drug Name: Kineret (anakinra)
Rheumatoid Arthritis (RA) Indicated for the reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active rheumatoid arthritis (RA), in patients 18 years of age or older who have failed 1 or more disease modifying antirheumatic drugs (DMARDs). Kineret can be used alone or in combination with DMARDs other than tumor necrosis factor (TNF) blocking agents. **Cryopyrin-Associated Periodic Syndromes (CAPS): Neonatal-Onset Multisystem Inflammatory Disease (NOMID) [A]** Indicated for the treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID). **Deficiency of Interleukin-1 Receptor Antagonist (DIRA)** Indicated for the treatment of Deficiency of Interleukin-1 Receptor Antagonist (DIRA). **Off Label Uses: Systemic Juvenile Idiopathic Arthritis (SJIA)** Has been used for the treatment of systemic juvenile idiopathic arthritis. [7]

2 . Criteria

Product Name: Kineret	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide
- sulfasalazine

AND

4 - One of the following:

4.1 All of the following:

4.1.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab) or Amjevita (adalimumab-atto)
- Rinvoq (upadacitinib)

- Simponi (golimumab)
- Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER)

AND

4.1.2 Trial and failure, contraindication, or intolerance to BOTH of the following:

- Actemra (tocilizumab)
- Orencia (abatacept)

OR

4.2 For continuation of prior Kineret therapy, defined as no more than a 45-day gap in therapy

Notes	*Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Kineret	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Kineret	
Diagnosis	Neonatal-Onset Multisystem Inflammatory Disease (NOMID) [A]
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neonatal-onset multisystem inflammatory disease (NOMID)

AND

2 - Diagnosis of NOMID has been confirmed by one of the following: [5-6, B]

2.1 NLRP-3 (nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3-gene (also known as Cold-Induced Auto-inflammatory Syndrome-1 [CIAS1]) mutation

OR

2.2 Both of the following:

2.2.1 Two of the following clinical symptoms:

- Urticaria-like rash
- Cold/stress triggered episodes
- Sensorineural hearing loss
- Musculoskeletal symptoms (e.g., arthralgia, arthritis, myalgia)
- Chronic aseptic meningitis
- Skeletal abnormalities (e.g., epiphyseal overgrowth, frontal bossing)

AND

2.2.2 Elevated acute phase reactants (e.g., erythrocyte sedimentation rate [ESR], C-reactive protein [CRP], serum amyloid A [SAA])

AND

3 - Prescribed by or in consultation with one of the following

- Allergist/Immunologist
- Rheumatologist

- Pediatrician

Product Name: Kineret	
Diagnosis	Neonatal-Onset Multisystem Inflammatory Disease (NOMID) [A]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Kineret	
Diagnosis	Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA)

Product Name: Kineret	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA) (Off-Label)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active systemic juvenile idiopathic arthritis [7]

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [7]:

- Minimum duration of a 3-month trial and failure of methotrexate
- Minimum duration of a 1-month trial of a nonsteroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, naproxen)
- Minimum duration of a 2-week trial of a systemic glucocorticoid (e.g., prednisone)

Product Name: Kineret	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA) (Off-Label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [7]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in clinical features or symptoms (e.g., pain, fever, inflammation, rash, lymphadenopathy, serositis) from baseline

3 . Endnotes

A. Three clinically overlapping, interleukin-1-associated, autoinflammatory disorders are known collectively as the cryopyrin-associated periodic syndromes (CAPS) or cryopyrinopathies: familial cold autoinflammatory syndrome (FCAS), Muckle-Wells

syndrome (MWS), and neonatal onset multisystem inflammatory disorder (NOMID, also known as chronic infantile neurological cutaneous and articular [CINCA] syndrome). [4]

B. In addition to clinical symptoms, a diagnosis should be made using a combination of procedures including laboratory assessments, skin biopsy, and genetic testing. [5] Diagnostic criteria developed by a multidisciplinary team of international experts in the care of children and adults with CAPS found that the best diagnosis criteria model included: raised inflammatory markers (CRP/SAA) plus two or more of six CAPS-typical signs/symptoms including (1) urticaria-like rash, (2) cold-triggered episodes, (3) sensorineural hearing loss, (4) musculoskeletal symptoms (arthralgia/arthritis/myalgia), (5) chronic aseptic meningitis, and (6) skeletal abnormalities (epiphyseal overgrowth/frontal bossing). This proposed model had a sensitivity of 81% and a specificity of 94%. It performed equally well for all CAPS subtypes and in subgroups with and without evidence of NLRP3 mutation ($p < 0.001$). [4, 6]

4 . References

1. Kineret Prescribing Information. Swedish Orphan Biovitrum. Stockholm, Sweden. December 2020.
2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. Arthritis Rheumatol. 2021;73(7):1108-23.
3. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.
4. Nigrovic PA. Cryopyrin-associated periodic syndromes and related disorders. UpToDate. Updated June 6, 2017. http:www.uptodate.com. Accessed March 19, 2019.
5. Yu JR and Leslie KS. Cryopyrin-associated periodic syndrome: an update on diagnosis and treatment response. Curr Allergy Asthma Rep. 2011;11(1):12-20
6. Kuemmerle-Deschner JB, Ozen S, Tyrrell PN, et al. Diagnostic criteria for cryopyrin-associated periodic syndrome (CAPS). Ann Rheum Dis. 2017 Jun;76(6):942-947.
7. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. Arthritis Rheumatol. 2022;74(4):553-569.

5 . Revision History

Date	Notes
2/1/2023	Annual review - no criteria changes

Prior Authorization Guideline

Guideline Name	Korlym (mifepristone)

Guideline Note:

Effective Date:	11/1/2022
P&T Approval Date:	4/10/2012
P&T Revision Date:	09/18/2019 ; 09/16/2020 ; 09/15/2021 ; 9/21/2022

1 . Indications

Drug Name: Korlym (mifepristone)
Hyperglycemia in Patients with Endogenous Cushing's Syndrome and Type 2 Diabetes Mellitus Indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. Limitations of use: Korlym should not be used in the treatment of patients with type 2 diabetes unless it is secondary to Cushing's syndrome.

2 . Criteria

Product Name: Korlym	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endogenous Cushing's syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids) [A]

AND

2 - One of the following:

- Diagnosis of type 2 diabetes mellitus
- Diagnosis of glucose intolerance

AND

3 - Patient has hyperglycemia that is secondary to hypercortisolism

AND

4 - One of the following:

- Patient has failed surgery
- Patient is not a candidate for surgery

AND

5 - Prescribed by or in consultation with an endocrinologist

AND

6 - Patient is not pregnant [1]

Product Name: Korlym	
Approval Length	6 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of one of the following:

- Patient has improved glucose tolerance while on therapy
- Patient has stable glucose tolerance while on therapy

3 . Endnotes

A. Korlym should not be used in the treatment of patients with type 2 diabetes unless it is secondary to Cushing's syndrome. [1]

4 . References

1. Korlym prescribing information. Corcept Therapeutics Inc. Menlo Park, CA. November 2019.

5 . Revision History

Date	Notes
9/14/2022	Annual Review

Prior Authorization Guideline

Guideline Name	Koselugo (selumetinib)

Guideline Note:

Effective Date:	8/1/2022
P&T Approval Date:	6/17/2020
P&T Revision Date:	06/16/2021 ; 6/15/2022

1 . Indications

Drug Name: Koselugo (selumetinib)
Neurofibromatosis Type 1 Indicated for the treatment of pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN)

2 . Criteria

Product Name: Koselugo	
Diagnosis	Neurofibromatosis Type 1
Approval Length	6 Month(s) [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neurofibromatosis type 1

AND

2 - Patient has plexiform neurofibromas that are both of the following:

- Inoperable [B]
- Causing significant morbidity (e.g., disfigurement, motor dysfunction, pain, airway dysfunction, visual impairment)

AND

3 - One of the following:

3.1 Patient is less than 18 years of age

OR

3.2 Both of the following:

- Patient is 18 years of age or older
- Patient is continuing therapy [C]

AND

4 - Patient is able to swallow a capsule whole

AND

5 - Prescribed by or in consultation with one of the following:

- Oncologist
- Neurologist

Product Name: Koselugo	
Diagnosis	Neurofibromatosis Type 1
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of disease progression while on therapy

3 . Endnotes

A. The initial authorization duration of 6 months is to allow for assessment of adverse reactions (e.g., cardiomyopathy) without interruption of therapy [1,2].
B. Inoperable plexiform neurofibromas are defined as those that could not be completely removed without risk for substantial morbidity due to encasement of, or close proximity to, vital structures, invasiveness, or high vascularity of the PN [1].
C. It is the recommendation of the consultant that the medication should not be discontinued due to patient's age [2].

4 . References

1. Koselugo Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. December 2021.
2. Per clinical consult with oncologist, May 27, 2020.

5 . Revision History

Date	Notes
6/8/2022	Annual Review

Prior Authorization Guideline

Guideline Name	Kymriah (tisagenlecleucel) - PA, NF

Guideline Note:

Effective Date:	2/1/2023
P&T Approval Date:	11/16/2017
P&T Revision Date:	07/15/2020 ; 07/21/2021 ; 07/20/2022 ; 12/14/2022

1 . Indications

Drug Name: Kymriah (tisagenlecleucel)
Acute lymphoblastic leukemia (ALL) Indicated for the treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse. **Diffuse Large B-Cell Lymphoma (DLBCL)** Indicated for adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma. Limitation of Use: Kymriah is not indicated for treatment of patients with primary central nervous system lymphoma. **Follicular Lymphoma (FL)** Indicated for adult patients with relapsed or refractory (r/r) follicular lymphoma (FL) after two or more lines of systemic therapy. Note: This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

2 . Criteria

Product Name: Kymriah	
Diagnosis	Acute lymphoblastic leukemia (ALL)
Approval Length	1 Time Authorization in Lifetime
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of B-cell precursor ALL

AND

2 - Patient is 25 years of age or younger

AND

3 - Disease is one of the following: [2]

- Refractory
- In second or later relapse

AND

4 - Patient has not previously received CAR-T Cell Therapy for ALL

AND

5 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Kymriah	
Diagnosis	Acute lymphoblastic leukemia (ALL)
Approval Length	1 Time Authorization in Lifetime
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of B-cell precursor ALL

AND

2 - Patient is 25 years of age or younger

AND

3 - Disease is one of the following: [2]

- Refractory
- In second or later relapse

AND

4 - Patient has not previously received CAR-T Cell Therapy for ALL

AND

5 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Kymriah	
Diagnosis	Diffuse large B-cell lymphoma (DLBCL)
Approval Length	1 Time Authorization in Lifetime
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Diffuse large B-cell lymphoma (DLBCL)

- High grade B-cell lymphoma
- DLBCL arising from follicular lymphoma

AND

2 - Disease is relapsed or refractory after two or more lines of systemic therapy (e.g., rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, dexamethasone, cisplatin, cytarabine) [3]

AND

3 - Patient has not previously received CAR-T Cell Therapy for DLBCL

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Kymriah	
Diagnosis	Diffuse large B-cell lymphoma (DLBCL)
Approval Length	1 Time Authorization in Lifetime
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following diagnoses:

- Diffuse large B-cell lymphoma (DLBCL)
- High grade B-cell lymphoma
- DLBCL arising from follicular lymphoma

AND

2 - Submission of medical records (e.g., chart notes) documenting disease is relapsed or refractory after two or more lines of systemic therapy (e.g., rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, dexamethasone, cisplatin, cytarabine) [3]

AND

3 - Patient has not previously received CAR-T Cell Therapy for DLBCL

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Kymriah	
Diagnosis	Follicular Lymphoma (FL)
Approval Length	1 Time Authorization in Lifetime
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of follicular lymphoma (FL)

AND

2 - Disease is relapsed or refractory after two or more lines of systemic therapy (e.g., rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, dexamethasone, cisplatin, cytarabine) [3]

AND

3 - Patient has not previously received CAR-T Cell Therapy for FL

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Kymriah	
Diagnosis	Follicular Lymphoma (FL)
Approval Length	1 Time Authorization in Lifetime
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of follicular lymphoma (FL)

AND

2 - Submission of medical records (e.g., chart notes) documenting disease is relapsed or refractory after two or more lines of systemic therapy (e.g., rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, dexamethasone, cisplatin, cytarabine) [3]

AND

3 - Patient has not previously received CAR-T Cell Therapy for FL

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

3 . References

1. Kymriah Prescribing Information. Novartis Pharmaceuticals. East Hanover, NJ. May 2022.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Acute Lymphoblastic Leukemia v.1.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed July 5, 2022.
3. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. B-Cell lymphomas. v.4.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed July 5, 2022.

4 . Revision History

Date	Notes
11/30/2022	Addition of NF criteria

Prior Authorization Guideline

Guideline Name	Kyprolis (carfilzomib)

Guideline Note:

Effective Date:	12/1/2022
P&T Approval Date:	11/13/2012
P&T Revision Date:	10/18/2019 ; 10/21/2020 ; 10/20/2021 ; 02/17/2022 ; 08/18/2022 ; 10/19/2022

1 . Indications

Drug Name: Kyprolis (carfilzomib)
Multiple myeloma - combination therapy Indicated in combination with dexamethasone or with lenalidomide plus dexamethasone or daratumumab plus dexamethasone or daratumumab and hyaluronidase-fihj plus dexamethasone, or isatuximab plus dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy. **Multiple myeloma - monotherapy** Indicated as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.

2 . Criteria

Product Name: Kyprolis	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma (MM)

AND

2 - Disease is relapsed or refractory

AND

3 - Patient has received at least one prior therapy for MM

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Kyprolis	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Kyprolis Prescribing Information. Onyx Pharmaceuticals, Inc. Thousand Oaks, CA. June 2022.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Multiple Myeloma v5.2022. Available by subscription at:

https://www.nccn.org/professionals/physician_gls/pdf/myeloma_blocks.pdf. Accessed July 20, 2022.

4 . Revision History

Date	Notes
10/21/2022	Annual Review - no criteria updates

Prior Authorization Guideline

Guideline Name	Lenvima (lenvatinib)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	4/14/2015
P&T Revision Date:	11/14/2019 ; 11/12/2020 ; 11/12/2020 ; 09/15/2021 ; 11/18/2021 ; 08/18/2022 ; 11/17/2022 ; 5/18/2023

1 . Indications

Drug Name: Lenvima (lenvatinib)
Differentiated Thyroid Carcinoma Indicated for the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer (DTC). **Renal Cell Carcinoma** 1) Indicated for use in combination with everolimus for the treatment of adult patients with advanced renal cell carcinoma (RCC) following one prior anti-angiogenic therapy. 2) Indicated as first-line treatment of adult patients with advanced RCC in combination with pembrolizumab. **Hepatocellular Carcinoma** Indicated for the treatment of patients with unresectable hepatocellular carcinoma (HCC). **Endometrial Carcinoma** In combination with pembrolizumab, is indicated for the treatment of patients with advanced endometrial carcinoma (EC) that is mismatch repair proficient (pMMR), as determined by an FDA-approved test, or not microsatellite instability-high (MSI-H), who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation

2 . Criteria

Product Name: Lenvima	
Diagnosis	Differentiated thyroid cancer (DTC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of differentiated thyroid cancer (DTC) [A]

AND

2 - One of the following:

- Locally recurrent disease
- Metastatic disease

AND

3 - One of the following: [2]

- Patient has symptomatic disease
- Patient has progressive disease

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Lenvima	
Diagnosis	Renal Cell Carcinoma (RCC)

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of renal cell carcinoma

AND

2 - One of the following: [4]

- Disease has relapsed
- Diagnosis of stage IV disease

AND

3 - One of the following:

3.1 Both of the following*: [4]

- Treatment follows one prior anti-angiogenic therapy [e.g., Inlyta (axitinib), Votrient (pazopanib), Nexavar (sorafenib), Sutent (sunitinib)]
- Used in combination with Afinitor (everolimus) for clear cell renal cell carcinoma [B]

OR

3.2 Both of the following*: [4]

- Used as first-line treatment for clear cell renal cell carcinoma
- Used in combination with Keytruda (pembrolizumab)

OR

3.3 One of the following:

3.3.1 Both of the following: [4]

- Used in the treatment of non-clear cell renal cell carcinoma
- Trial and failure, contraindication or intolerance to generic sunitinib

OR

3.3.2 For continuation of prior therapy

AND

4 - Prescribed by or in consultation with an oncologist

Notes	*Criterion is part of FDA-approved label.

Product Name: Lenvima	
Diagnosis	Hepatocellular Carcinoma (HCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hepatocellular carcinoma

AND

2 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hepatologist
- Gastroenterologist

Product Name: Lenvima	
Diagnosis	Endometrial Carcinoma

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)

AND

2 - Patient has disease progression following systemic therapy

AND

3 - Used in combination with Keytruda (pembrolizumab) therapy

AND

4 - Patient is not a candidate for curative surgery or radiation

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Lenvima	
Diagnosis	All indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. Differentiated thyroid carcinoma includes papillary carcinoma, follicular carcinoma, Hurthle cell carcinoma, and poorly differentiated carcinoma. [2]
B. NCCN recognizes use for subsequent therapy in combination with everolimus for relapse or for surgically unresectable stage IV disease with predominant clear cell histology that progressed on prior antiangiogenic therapy. [2]

4 . References

1. Lenvima Prescribing Information. Eisai Inc. Nutley, NJ. November 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed October 2, 2019.
3. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Hepatobiliary Cancers. v3.2018. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf. Accessed September 5, 2018.
4. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Kidney Cancer. V1.2023. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed July 20, 2022.

5 . Revision History

Date	Notes
5/4/2023	Annual review: Updated criteria and references.

Prior Authorization Guideline

Guideline Name	Leukotriene Modifiers

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	8/21/1998
P&T Revision Date:	03/18/2020 ; 03/17/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Zileuton extended-release
Asthma Indicated for the prophylaxis and chronic treatment of asthma in adults and children 12 years of age and older. Zileuton extended-release tablet is not indicated for use in the reversal of bronchospasm in acute asthma attacks. Therapy with zileuton extended-release tablet can be continued during acute exacerbations of asthma.

2 . Criteria

Product Name: Generic zileuton ER	
Diagnosis	Asthma
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure, intolerance, or contraindication to at least one of the following generics:

- montelukast
- zafirlukast

3 . References

1. Zileuton Extended-Release [prescribing information]. Baltimore, MD: Lupin Pharmaceuticals, Inc; August 2020

4 . Revision History

Date	Notes
2/22/2023	2023 UM Annual Review. No changes

Prior Authorization Guideline

Guideline Name	Long Acting Insulins

Guideline Note:

Effective Date:	3/1/2023
P&T Approval Date:	7/21/2021
P&T Revision Date:	06/15/2022 ; 2/16/2023

1 . Indications

Drug Name: Levemir (insulin detemir)
Diabetes Mellitus Indicated to improve glycemic control in adult and pediatric patients with diabetes mellitus. Limitations of Use: Levemir is not recommended for the treatment of diabetic ketoacidosis.
Drug Name: Tresiba (insulin degludec)
Diabetes Mellitus Indicated to improve glycemic control in patients 1 year of age and older with diabetes mellitus. Limitations of Use: Not recommended for the treatment of diabetic ketoacidosis.

2 . Criteria

Product Name: Levemir, Tresiba	
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of diabetes mellitus

AND

2 - Trial and failure of a minimum 30 days supply, contraindication, or intolerance to one of the following:

- Lantus
- Toujeo

3 . References

1. Levemir Prescribing Information. Novo Nordisk Inc. Plainsboro, New Jersey. March 2020.
2. Tresiba Prescribing Information. Novo Nordisk Inc. Plainsboro, New Jersey. November 2019.

4 . Revision History

Date	Notes
2/9/2023	Added new Levemir Flexpen formulation to guideline. No changes to criteria.

Prior Authorization Guideline

Guideline Name	Long-Acting Bronchodilator Combinations

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	3/20/2019
P&T Revision Date:	03/18/2020 ; 03/17/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Bevespi Aerosphere (glycopyrrolate and formoterol fumarate)
Chronic Obstructive Pulmonary Disease (COPD) Indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Limitations of use: Bevespi Aerosphere is not indicated for the relief of acute bronchospasm or for the treatment of asthma.

2 . Criteria

Product Name: Bevespi	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria	

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure, contraindication, or intolerance to any one of the following generics or preferred brands:

- Advair HFA
- Breo Ellipta
- fluticasone/salmeterol
- Serevent
- Symbicort
- Wixela Inhub

AND

3 - Trial and failure, contraindication, or intolerance to Spiriva

3 . References

1. Bevespi Aerosphere [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2020.

4 . Revision History

Date	Notes
2/22/2023	2023 UM Annual Review. No changes

Prior Authorization Guideline

Guideline Name	Lonsurf (trifluridine and tipiracil)

Guideline Note:

Effective Date:	11/1/2022
P&T Approval Date:	11/18/2015
P&T Revision Date:	09/16/2020 ; 09/15/2021 ; 9/21/2022

1 . Indications

Drug Name: Lonsurf (trifluridine and tipiracil)
Metastatic Colorectal Cancer (mCRC) Indicated for the treatment of patients with metastatic colorectal cancer (mCRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and, if RAS wild type, an anti-EGFR therapy. **Metastatic Gastric Cancer** Indicated for the treatment of adult patients with metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy.

2 . Criteria

Product Name: Lonsurf	
Diagnosis	Metastatic Colorectal Cancer

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic colorectal cancer (mCRC)

AND

2 - Trial and failure, intolerance or contraindication to fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI)

AND

3 - Trial and failure, intolerance or contraindication to an anti-VEGF therapy (e.g., Avastin [bevacizumab], Zaltrap [ziv-aflibercept])

AND

4 - One of the following:

4.1 Patient has RAS mutant tumors

OR

4.2 Both of the following:

4.2.1 Patient has RAS wild-type tumors

AND

4.2.2 Trial and failure, intolerance or contraindication to an anti-EGFR therapy (e.g., Vectibix [panitumumab], Erbitux [cetuximab])

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Lonsurf	
Diagnosis	Metastatic Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Lonsurf	
Diagnosis	Gastric/Gastroesophageal Junction Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of Metastatic Gastric Cancer

OR

1.2 Diagnosis of gastroesophageal junction adenocarcinoma

AND

2 - Trial and failure, contraindication or intolerance to two of the following:

- Fluoropyrimidine-based chemotherapy
- Platinum-based chemotherapy
- Taxane or irinotecan-based chemotherapy
- HER2/neu-targeted therapy (if appropriate)

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Lonsurf	
Diagnosis	Gastric/Gastroesophageal Junction Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Lonsurf Prescribing Information. Taiho Oncology, Inc. Princeton, NJ. January 2020.
2. National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium [internet database]. National Comprehensive Cancer Network, Inc.; 2019. Updated periodically. Available by subscription at: www.nccn.org. Accessed March 19, 2019.

4 . Revision History

Date	Notes

9/8/2022	Annual Review - No criteria changes

Prior Authorization Guideline

Guideline Name	Low Molecular Weight Heparin and Arixtra QL override

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	3/21/2018
P&T Revision Date:	06/17/2020 ; 06/16/2021 ; 07/21/2021 ; 06/15/2022 ; 12/14/2022 ; 4/19/2023

1 . Criteria

Product Name: Brand Lovenox, Generic enoxaparin, Enoxiluv, Fragmin, Brand Arixtra, Generic fondaparinux	
Diagnosis	Additional 35 day supply
Approval Length	35 Day(s)
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

- Superficial vein thrombosis > 5 cm in length
- A second surgery requiring venous thromboembolism (VTE) prophylaxis

- Bridging therapy for acute deep vein thrombosis (DVT) or pulmonary embolism (PE)

Product Name: Brand Lovenox, Generic enoxaparin, Enoxiluv, Fragmin	
Diagnosis	Greater than 35 days
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 Pregnancy when anticoagulation is required

OR

1.2 Ovarian hyperstimulation syndrome

OR

1.3 Cancer patient requiring treatment of DVT or PE

OR

1.4 Cancer patient with additional risk factors for VTE requiring prophylaxis of DVT or PE

OR

1.5 Trail and failure, contraindication or intolerance to warfarin for any of the following indications:

- Prophylaxis and/or treatment of DVT and PE
- Prophylaxis and/or treatment of thromboembolic complications associated with atrial fibrillation, left ventricular thrombus and/or dysfunction with or without congestive heart failure (CHF), and/or mechanical cardiac valve replacement

- Prophylaxis of ischemic complications of unstable angina and non-Q-wave myocardial infarction (MI)
- Treatment of ST-segment elevation myocardial infarction (STEMI) managed medically or with subsequent percutaneous coronary intervention (PCI)
- Child requiring anticoagulation

Product Name: Brand Arixtra, Generic fondaparinux	
Diagnosis	Greater than 35 days
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Pregnancy when anticoagulation is required

AND

1.1.2 Patient has had a severe allergic reaction to heparin

OR

1.2 Trial and failure, contraindication or intolerance to warfarin for any of the following indications:

- Prophylaxis and/or treatment of DVT and PE
- Prophylaxis and/or treatment of thromboembolic complications associated with atrial fibrillation, left ventricular thrombus and/or dysfunction with or without congestive heart failure (CHF), and/or mechanical cardiac valve replacement
- Prevention of thromboembolic events in patients with recurrent MI

2 . References

1. Arixtra Prescribing Information. Mylan Institutional LLC. Rockford, IL. August 2020.
2. Fragmin Prescribing Information. Pfizer Inc. New York, New York. August 2022.
3. Lovenox Prescribing Information. sanofi-aventis U.S. LLC. Bridgewater, NJ. May 2020.
4. Lexi-Comp Online [internet database]. Hudson, OH. Lexi-Comp, Inc. Updated periodically. Available by subscription at: http://online.lexi.com/. Accessed November 16, 2022.
5. Enoxiluv Kit Prescribing Information. Sandoz Inc., Princeton, NJ. February 2023.

3 . Revision History

Date	Notes
4/21/2023	Added new product, Enoxiluv Kit, to guideline.

Prior Authorization Guideline

Guideline Name	Lumizyme (alglucosidase alfa)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	12/5/2006
P&T Revision Date:	06/17/2020 ; 05/20/2021 ; 11/18/2021 ; 05/19/2022 ; 5/18/2023

1 . Indications

Drug Name: Lumizyme (alglucosidase alfa)
Pompe Disease Indicated for patients with Pompe disease [acid alpha-glucosidase (GAA) deficiency].

2 . Criteria

Product Name: Lumizyme	
Diagnosis	Infantile Onset Pompe Disease (IOPD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of infantile-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) as confirmed by one of the following: [3]

1.1 Absence or deficiency (less than 1% of the lab specific normal mean) of GAA enzyme activity in lymphocytes, fibroblasts, or muscle tissues as confirmed by an enzymatic assay

OR

1.2 Molecular genetic testing confirms mutations in the GAA gene

AND

2 - Presence of clinical signs and symptoms of the disease (e.g., cardiomegaly, hypotonia, etc.)

AND

3 - Patient is less than or equal to 12 months of age

Product Name: Lumizyme	
Diagnosis	Infantile Onset Pompe Disease (IOPD)
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Lumizyme	
Diagnosis	Late Onset Pompe Disease (LOPD)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) as confirmed by one of the following: [3, 5]

1.1 Absence or deficiency (less than 40% of the lab specific normal mean) of GAA enzyme activity in lymphocytes, fibroblasts, or muscle tissues as confirmed by an enzymatic assay

OR

1.2 Molecular genetic testing confirms mutations in the GAA gene

AND

2 - Presence of clinical signs and symptoms of the disease (e.g., respiratory distress, skeletal muscle weakness, etc.) [A]

AND

3 - Patient is 1 year of age or older

Product Name: Lumizyme	
Diagnosis	Late Onset Pompe Disease (LOPD)
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

3 . Endnotes

A. Consensus recommendation based on current clinical guidelines indicate that treatment should be started in patients with late onset Pompe disease when they become symptomatic and/or show signs of disease progression [3, 5].

4 . References

1. Lumizyme Prescribing Information. Genzyme Corporation. Cambridge, MA. May 2022.
2. Kronn DF, Day-Salvatore D, Hwu WL, et al. Management of Confirmed Newborn-Screened Patients With Pompe Disease Across the Disease Spectrum.
3. Kishani PS, Steiner RD, Bali, D. ACMG Practice Guideline. Pompe disease diagnosis and management guideline. Genet Med. 2006;8(5):267-88.
4. Diagnosing Pompe Disease (also known as Acid Maltase Deficiency). Available at: https://www.pompe.com/-/media/EMS/Conditions/RareDiseases/Brands/pompe-us/hcp/PDF/SAUSPD18042050bk1vFinal10.pdf?la=en-US and https://www.pompe.com/-/media/EMS/Conditions/RareDiseases/Brands/pompe-us/hcp/PDF/SAUSPD18042050bj1vFinal10.pdf?la=en-US. Accessed May 12, 2020.
5. Barba-Romero MA, Barrot E, Bautista-Lorite J, et al. Clinical guidelines for late-onset Pompe disease. Rev Neurol 2012; 54 (8): 497-507.

5 . Revision History

Date	Notes
5/5/2023	Annual review: No criteria changes. Updated reauthorization criteria approval length to 24 months for both indications. Updated reference s.

Prior Authorization Guideline

Guideline Name	Lynparza (olaparib)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	2/18/2015
P&T Revision Date:	03/18/2020 ; 07/15/2020 ; 03/17/2021 ; 03/16/2022 ; 05/19/2022 ; 10/19/2022 ; 3/15/2023

1 . Indications

Drug Name: Lynparza (olaparib)
First-line maintenance treatment of BRCA-mutated advanced ovarian cancer Indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAmor sBRCAm) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza. **Maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer** Indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy. **First-line maintenance treatment of HRD-positive advanced ovarian cancer in combination with bevacizumab** Indicated in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either: a deleterious or suspected deleterious BRCA mutation, and/or genomic instability. Select patients for therapy based on an FDA-approved

companion diagnostic for Lynparza.

Germline BRCA-mutated HER2-negative high risk early breast cancer Indicated for the adjuvant treatment of adult patients with deleterious or suspected deleterious gBRCA-mutated, HER2-negative high risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

Germline BRCA-mutated HER2-negative metastatic breast cancer Indicated for the treatment of adult patients with deleterious or suspected deleterious gBRCA-mutated, HER2-negative metastatic breast cancer, who have been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

First-line maintenance treatment of germline BRCA-mutated metastatic pancreatic adenocarcinoma Indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

HRR gene-mutated metastatic castration-resistant prostate cancer Indicated for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

2 . Criteria

Product Name: Lynparza	
Diagnosis	First-line maintenance treatment of BRCA-mutated advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Advanced epithelial ovarian cancer
- Advanced fallopian tube cancer
- Advanced primary peritoneal cancer

AND

2 - Presence of deleterious or suspected deleterious BRCA-mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Patient has had a complete or partial response to first-line platinum-based chemotherapy (e.g., carboplatin, cisplatin)

AND

4 - Lynparza will be used as first-line maintenance treatment

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Lynparza	
Diagnosis	First-line maintenance treatment of HRD-positive advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer in combination with bevacizumab
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Advanced epithelial ovarian cancer
- Advanced fallopian tube cancer
- Advanced primary peritoneal cancer

AND

2 - Cancer is associated with homologous recombination deficiency (HRD)-positive status (defined by either: a deleterious or suspected deleterious BRCA mutation, and/or genomic instability) as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Patient has had a complete or partial response to first-line platinum-based chemotherapy (e.g., carboplatin, cisplatin)

AND

4 - Used in combination with bevacizumab (e.g., Avastin, Mvasi)

AND

5 - Lynparza will be used as first-line maintenance treatment

AND

6 - Prescribed by or in consultation with an oncologist

Product Name: Lynparza	
Diagnosis	Maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Recurrent epithelial ovarian cancer
- Recurrent fallopian tube cancer
- Recurrent primary peritoneal cancer

AND

2 - Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin)

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Lynparza	
Diagnosis	Germline BRCA-mutated HER2-negative high risk early breast cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of high risk early breast cancer

AND

2 - Presence of a deleterious or suspected deleterious germline BRCA-mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [A - D]

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

4 - Patient has been previously treated with neoadjuvant or adjuvant chemotherapy (e.g., anthracycline, taxane)

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Lynparza	
Diagnosis	Germline BRCA-mutated HER2-negative metastatic breast cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic breast cancer [C]

AND

2 - Presence of a deleterious or suspected deleterious germline BRCA-mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [A - D]

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

4 - Patient has been previously treated with chemotherapy (e.g., anthracycline, taxane) in the neoadjuvant, adjuvant, or metastatic setting [C]

AND

5 - One of the following

5.1 Both of the following [C]:

5.1.1 Disease is hormone receptor (HR)-positive

AND

5.1.2 One of the following:

- Patient has been treated with prior endocrine therapy
- Patient is considered an inappropriate candidate for endocrine therapy

OR

5.2 Disease is hormone receptor (HR)-negative

AND

6 - Prescribed by or in consultation with an oncologist

Product Name: Lynparza	
Diagnosis	Germline BRCA-mutated metastatic pancreatic adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic pancreatic adenocarcinoma

AND

2 - Presence of a deleterious or suspected deleterious germline BRCA-mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Disease has not progressed while receiving at least 16 weeks of a first-line platinum-based chemotherapy regimen (e.g., FOLFIRINOX, FOLFOX, etc.)

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Lynparza	
Diagnosis	HRR gene-mutated metastatic castration-resistant prostate cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic castration-resistant prostate cancer

AND

2 - Presence of deleterious or suspected deleterious homologous recombination repair (HRR)

gene mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [E]

AND

3 - Disease has progressed following prior treatment with one of the following:

- Enzalutamide (Xtandi)
- Abiraterone (e.g., Zytiga, Yonsa)

AND

4 - Prescribed by or in consultation with one of the following:

- Oncologist
- Urologist

Product Name: Lynparza	
Diagnosis	All Indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. Lynparza (olaparib) tablets were approved for use in patients with a germline BRCA mutation and human epidermal growth factor receptor type 2 (HER2) negative metastatic breast cancer based on results from the OlympiAD clinical trial. OlympiAD (N= 305) was a randomized, open-label, phase 3 trial in which Lynparza (olaparib) monotherapy was compared with standard therapy (one of three pre-specified chemotherapy regimens). Enrolled patients were required to have received neoadjuvant,

adjuvant treatment or treatment for metastatic disease with an anthracycline (unless it was contraindicated) and a taxane. Also, patients with hormone receptor positive breast cancer had received at least one endocrine therapy, unless the patient was not an appropriate candidate for therapy. The assigned treatment was continued until disease progression or unacceptable toxicity. The primary end point was progression-free survival, which was defined as the time from randomization to objective radiologic disease progression or death from any cause. Study results reported that the median progression-free survival was significantly longer in the olaparib group than in the standard-therapy group (7.0 months vs. 4.2 months; hazard ratio for disease progression or death, 0.58; 95% confidence interval [CI], 0.43 to 0.80; P<0.001) [4].

B. In OlympiAD, the BRCA mutation was detected by central testing with BRACAnalysis (Myriad Genetics) in 297 patients and by local testing in 167 patients (with confirmation by central testing with BRACAnalysis in all but 5 of those patients) [4].
C. For patients with metastatic castration-resistant prostate cancer (mCRPC), examples of homologous recombination repair (HRR) gene mutations include: BRCA1, BRCA2, ATM, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, RAD51B, RAD51C, RAD51D, RAD54L. [1, 3]

4 . References

1. Lynparza Tablets prescribing information. AstraZeneca Pharmaceuticals LP, Inc. Wilmington, DE. December 2022.
2. Lynparza FDA Medical Review. http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/206162Orig1s000MedR.pdf. Accessed on June 12, 2015.
3. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 9, 2021.
4. Robson M, Im SA, Senkus E, et al. Olaparib for Metastatic Breast Cancer in Patients with a Germline BRCA Mutation. N Engl J Med. 2017 Aug 10;377(6):523-533
5. U.S. Food and Drug Administration [website]: List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Available at https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm301431.htm Accessed 3/7/2018

5 . Revision History

Date	Notes
3/2/2023	2023 Annual Review - updated references

Prior Authorization Guideline

Guideline Name	Mavyret (glecaprevir/pibrentasvir)

Guideline Note:

Effective Date:	7/1/2022

1 . Indications

Drug Name: Mavyret (glecaprevir/pibrentasvir)
Chronic Hepatitis C (CHC) Indicated for the treatment of adult and pediatric patients 3 years and older with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A). Indicated for the treatment of adult and pediatric patients 3 years and older with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor (PI), but not both.

2 . Criteria

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; Treatment-Naïve; without Decompensated Cirrhosis
Approval Length	8 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient is treatment-naive

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, or 4; Treatment-Naive; Coinfection with HIV; with Compensated Cirrhosis*
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, or 4

AND

2 - Patient is coinfected with human immunodeficiency virus (HIV) [2]

AND

2 - Patient is treatment-naive for chronic hepatitis C

AND

3 - Patient has compensated cirrhosis (e.g., Child-Pugh Class A) [2]

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Notes	*Patients with chronic hepatitis C Genotype 1, 2, 3, or 4 who are treatment-naive, coinfected with HIV, and do NOT have cirrhosis can follow the standard 8-week treatment regimen for patients without HIV infection

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 5, or 6; Treatment-Naive; Coinfection with HIV; without Decompensated Cirrhosis

Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 5 or 6

AND

2 - Patient is coinfected with human immunodeficiency virus (HIV) [2]

AND

3 - Patient is treatment-naive for chronic hepatitis C

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C) [2]

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)

Diagnosis	Chronic Hepatitis C - Genotype 1; Treatment-Experienced (Prior failure to an NS3/4A Protease Inhibitor); without Decompensated Cirrhosis
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1

AND

2 - Patient has experienced failure with a previous treatment regimen that included a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)]

AND

3 - Patient has had no previous treatment experience with a treatment regimen that included an NS5A inhibitor (e.g., Daklinza [daclatasvir])

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1; Treatment-Experienced (Prior failure to an NS5A Inhibitor); without Decompensated Cirrhosis
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1

AND

2 - Patient has experienced failure with a previous treatment regimen that included an NS5A inhibitor (e.g., Daklinza [daclatasvir])

AND

3 - Patient has had no previous treatment experience with a treatment regimen that included a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)]

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist

- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 3; Treatment-Experienced (Interferon- or Sovaldi-based Regimen); without Decompensated Cirrhosis
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 3

AND

2 - Patient has experienced treatment failure with a previous treatment regimen that included interferon, peginterferon, ribavirin, and/or Sovaldi (sofosbuvir)

AND

3 - Patient has had no previous treatment experience with a treatment regimen that included a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)] or an NS5A inhibitor (e.g., Daklinza [daclatasvir])

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 4, 5, or 6; Treatment-Experienced (Interferon-based Regimen); without Cirrhosis
Approval Length	8 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with a previous interferon-based treatment regimen

AND

3 - Patient has had no previous treatment experience with a treatment regimen that included a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)] or an NS5A inhibitor (e.g., Daklinza [daclatasvir])

AND

4 - Patient is without cirrhosis

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 4, 5, or 6; Treatment-Experienced (Interferon-based Regimen); with Compensated Cirrhosis
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with a previous interferon-based treatment regimen

AND

3 - Patient has had no previous treatment experience with a treatment regimen that included a

HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)] or an NS5A inhibitor (e.g., Daklinza [daclatasvir])

AND

4 - Patient has compensated cirrhosis (e.g., Child-Pugh Class A)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 4, 5, or 6; Treatment-Experienced (Sovaldi-based regimen); without Decompensated Cirrhosis
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with a previous treatment regimen that included Sovaldi (sofosbuvir)

AND

3 - Patient has had no previous treatment experience with an HCV NS3/4A protease inhibitor inclusive combination direct acting antiviral regimen (e.g., Zepatier [elbasvir/grazoprevir])

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; Treatment-Experienced (Prior failure of Mavyret); without Decompensated Cirrhosis
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with Mavyret (glecaprevir/pibrentasvir) [2]

AND

3 - Used in combination with Sovaldi (sofosbuvir) and ribavirin [2]

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; Treatment-Experienced (Prior failure of Vosevi); without Decompensated Cirrhosis
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with Vosevi (sofosbuvir/velpatasvir/voxilaprevir) [2]

AND

3 - Used in combination with Sovaldi (sofosbuvir) and ribavirin [2]

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)

Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; HCV-Uninfected Recipients of a Liver Transplant from HCV-Viremic Donors; without Decompensated Cirrhosis
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

- Patient was not infected with HCV prior to receiving a liver transplant
- Patient received a liver transplant from a donor with a diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

3 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

4 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6 Post-Liver or Kidney Transplant; without Decompensated Cirrhosis
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient has had a liver or kidney transplant

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

3 . References

1. Mavyret Prescribing Information. Abbvie Inc. North Chicago, IL. September 2021.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. September 2021. http://www.hcvguidelines.org/full-report-view. Accessed May 16, 2022.

4 . Revision History

Date	Notes
6/22/2022	Updated guideline effective date to 7/1/22 to align with UM optimizati on updates. No other updates made to guideline.

Prior Authorization Guideline

Guideline Name	Mekinist (trametinib)

Guideline Note:

Effective Date:	10/1/2022
P&T Approval Date:	7/9/2013
P&T Revision Date:	03/18/2020 ; 03/17/2021 ; 03/16/2022 ; 8/18/2022

1 . Indications

Drug Name: Mekinist (trametinib)
BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma Indicated as a single agent for the treatment of BRAF-inhibitor treatment-naïve patients or in combination with dabrafenib for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test. **BRAF V600E mutation-positive metastatic non-small cell lung cancer** Indicated in combination with dabrafenib for the treatment of patients with metastatic non-small cell lung cancer with BRAF V600E mutation as detected by an FDA-approved test. **Adjuvant treatment for BRAF V600E or V600K mutation-positive melanoma** Indicated for adjuvant treatment in combination with dabrafenib for patients with melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test, and involvement of lymph node (s), following complete resection. **Anaplastic thyroid cancer (ATC) with BRAF V600E mutation** Indicated for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional options. **BRAF V600E mutation-positive unresectable or metastatic solid tumors** Indicated, in combination with dabrafenib, for the treatment of adult and pediatric patients 6 years of age

and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options.

2 . Criteria

Product Name: Mekinist	
Diagnosis	Unresectable or metastatic melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses: [2]

- Unresectable melanoma
- Metastatic melanoma

AND

2 - Cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Mekinist	
Diagnosis	Unresectable or metastatic melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Mekinist	
Diagnosis	Non-small cell lung cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer

AND

2 - Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

AND

3 - Medication is used in combination with Tafinlar (dabrafenib)

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Mekinist	
Diagnosis	Non-small cell lung cancer
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Mekinist	
Diagnosis	Adjuvant treatment for melanoma
Approval Length	12 Month [A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of melanoma

AND

2 - Cancer is BRAF V600E mutation or V600K mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Involvement of lymph nodes following complete resection [2]

AND

4 - Used as adjunctive therapy

AND

5 - Medication is used in combination with Tafinlar (dabrafenib)

AND

6 - Prescribed by or in consultation with an oncologist

Product Name: Mekinist	
Diagnosis	Anaplastic thyroid cancer (ATC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC) [4]

AND

2 - Cancer is BRAF V600E mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Cancer may not be treated with standard locoregional treatment options

AND

4 - Medication is used in combination with Tafinlar (dabrafenib)

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Mekinist	
Diagnosis	Anaplastic thyroid cancer (ATC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Mekinist	
Diagnosis	Unresectable or metastatic solid tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of solid tumors

AND

2 - Patient is 6 years of age or older

AND

3 - Disease is one of the following:

- unresectable
- metastatic

AND

4 - Patient has progressed on or following prior treatment and have no satisfactory alternative treatment options

AND

5 - Cancer is BRAF V600E mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

6 - Medication is used in combination with Tafinlar (dabrafenib)

AND

7 - Prescribed by or in consultation with an oncologist

Product Name: Mekinist	
Diagnosis	Unresectable or metastatic solid tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. The recommended dosage of MEKINIST is 2 mg orally taken once daily in combination with dabrafenib until disease recurrence or unacceptable toxicity for up to 1 year for the adjuvant treatment of melanoma [1].

4 . References

1. Mekinist Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. June 2022.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Melanoma v.2.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed February 15, 2022.
3. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Non-Small Cell Lung Cancer v.1.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed February 15, 2022.
4. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Thyroid Carcinoma v.3.2021. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed February 15, 2021.

5 . Revision History

Date	Notes
8/4/2022	Added new solid tumor indication. Updated background and references.

Prior Authorization Guideline

Guideline Name	Mepsevii (vestronidase alfa-vjbk)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	2/15/2018
P&T Revision Date:	06/17/2020 ; 05/20/2021 ; 04/20/2022 ; 5/18/2023

1 . Indications

Drug Name: Mepsevii (vestronidase alfa-vjbk)
Mucopolysaccharidosis (MPS VII, Sly Syndrome) Indicated for the treatment of Mucopolysaccharidosis (MPS VII, Sly Syndrome) in pediatric and adult patients. Limitations of use: The effect of Mepsevii on the central nervous system manifestations of MPS VII has not been determined.

2 . Criteria

Product Name: Mepsevii	
Diagnosis	Mucopolysaccharidosis (MPS VII, Sly Syndrome)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Mucopolysaccharidosis VII (MPS VII, Sly syndrome)

Product Name: Mepsevii	
Diagnosis	Mucopolysaccharidosis (MPS VII, Sly Syndrome)
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

3 . References

1. Mepsevii Prescribing Information. Ultragenyx Pharmaceutical Inc. Novato CA. December 2020.

4 . Revision History

Date	Notes
5/3/2023	Annual review: Initial authorization approval duration updated to 12 months. New reauthorization section added.

Prior Authorization Guideline

Guideline Name	Migraine Quantity Limit

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	5/19/2016
P&T Revision Date:	03/18/2020 ; 03/17/2021 ; 03/16/2022 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Amerge (naratriptan), Frova (frovatriptan), Imitrex (sumatriptan) tablets and nasal spray, Onzetra (sumatriptan), Relpax (eletriptan), Tosymra (sumatriptan), Zembrace SymTouch (sumatriptan), Zomig (zolmitriptan) tablets, Zomig-ZMT (zolmitriptan)
Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Safety and effectiveness of respective triptan therapy have not been established for cluster headache (not applicable to Zembrace SymTouch). Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine attack treated with therapy, reconsider the diagnosis of migraine before therapy is administered to treat any subsequent attacks. Therapy is not indicated for the prevention of migraine attacks.
Drug Name: Axert (almotriptan)
Migraine Headaches Indicated for the acute treatment of migraine attacks in adults with a history of migraine with or without aura. Indicated for the acute treatment of migraine headache pain in adolescents age 12 to 17 years with a history of migraine attacks with or without aura usually lasting 4 hours or more (when untreated). Important Limitations: Only use where a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with Axert, the diagnosis of migraine should be reconsidered before Axert is administered to treat any subsequent attacks. In adolescents age 12 to 17

years, efficacy of Axert on migraine-associated symptoms (nausea, photophobia, and phonophobia) was not established. Axert is not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. Safety and effectiveness of Axert have not been established for cluster headache which is present in an older, predominantly male population.

Drug Name: Maxalt (rizatriptan), Maxalt-MLT (rizatriptan)

Migraine headaches Indicated for the acute treatment of migraine with or without aura in adults and in pediatric patients 6 to 17 years old. Limitations of Use: Maxalt should only be used where a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with Maxalt, the diagnosis of migraine should be reconsidered before Maxalt is administered to treat any subsequent attacks. Maxalt is not indicated for use in the management of hemiplegic or basilar migraine. Maxalt is not indicated for the prevention of migraine attacks. Safety and effectiveness of Maxalt have not been established for cluster headache.

Drug Name: Migranal (dihydroergotamine mesylate)

Migraine Headaches Indicated for the acute treatment of migraine headaches with or without aura. Not intended for the prophylactic therapy of migraine or for the management of hemiplegic or basilar migraine.

Drug Name: Treximet (sumatriptan/naproxen)

Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age or older. Limitations of Use: Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine attack treated with Treximet, reconsider the diagnosis of migraine before Treximet is administered to treat any subsequent attacks. Treximet is not indicated for the prevention of migraine attacks. Safety and effectiveness of Treximet have not been established for cluster headache.

Drug Name: Zomig (zolmitriptan) nasal spray

Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older. Limitations of Use: Only use Zomig if a clear diagnosis of migraine has been established. If a patient has no response to Zomig treatment for the first migraine attack, reconsider the diagnosis of migraine before Zomig is administered to treat any subsequent attacks. Zomig is not indicated for the prevention of migraine attacks. Safety and effectiveness of Zomig have not been established for cluster headache. Not recommended in patients with moderate or severe hepatic impairment.

Drug Name: D.H.E. 45 (dihydroergotamine mesylate) injection

Migraine Headache Indicated for the acute treatment of migraine headaches with or without aura.

Cluster Headaches Indicated for acute treatment of cluster headache episodes.

Drug Name: Imitrex (sumatriptan) injection

Migraine Headache Indicated in adults for the acute treatment of migraine, with or without aura. Limitations of Use: Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine headache attack treated with Imitrex injection, reconsider the diagnosis before Imitrex injection is administered to treat any subsequent attacks. Imitrex injection is not indicated for the prevention of migraine headache attacks.

Cluster Headaches Indicated in adults for the acute treatment of cluster headache. Limitations of Use: Use only if a clear diagnosis of cluster headache has been established. If a patient has no response to the first cluster headache attack treated with Imitrex injection, reconsider the diagnosis before Imitrex injection is administered to treat any subsequent attacks. Imitrex injection is not indicated for the prevention of cluster headache attacks.

Drug Name: Trudhesa (dihydroergotamine mesylate)

Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Not indicated for the preventive treatment of migraine or for the management of hemiplegic or basilar migraine

Drug Name: Nurtec ODT (rimegepant sulfate)

Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults.

Preventive Treatment of Episodic Migraine Indicated for the preventive treatment of episodic migraine in adults.

Drug Name: Ubrelvy (ubrogepant)

Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Not indicated for the preventive treatment of migraine.

2 . Criteria

Product Name: Brand Amerge, Generic naratriptan, Brand Axert, Generic almotriptan, Brand Frova, Generic frovatriptan, Brand Imitrex, Generic sumatriptan, Brand Maxalt, Generic rizatriptan, Onzetra, Brand Relpax, Generic eletriptan, Sumavel DosePro, Tosymra, Brand Treximet, Generic sumatriptan/naproxen, Zembrace SymTouch, Brand Zomig, Generic zolmitriptan, or Brand Zolmitriptan nasal spray

Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Patient is experiencing 2 or more headaches per month [10-12]

AND

3 - Patient will not be treating 15 or more headache days per month

AND

4 - Currently receiving prophylactic therapy with at least one of the following: [A, 10, 25]

- An antidepressant (i.e., Elavil [amitriptyline] or Effexor [venlafaxine])
- An anticonvulsant (i.e., Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate])
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol)
- An angiotensin receptor blocker (i.e., Atacand [candesartan])
- An angiotensin-converting enzyme (ACE) inhibitor (i.e., lisinopril)

AND

5 - Prescribed by or in consultation with one of the following:

- Neurologist
- Pain specialist
- Headache specialist [B]

AND

6 - Not used in combination with another triptan-containing product

AND

7 - One of the following: [C]

7.1 Higher dose or quantity is supported in the Dosage and Administration section of the manufacturer's prescribing information

OR

7.2 Higher dose or quantity is supported by one of the following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System

Product Name: Brand D.H.E. 45, Generic dihydroergotamine mesylate injection, Brand Migranal, Generic dihydroergotamine mesylate nasal spray, Nurtec ODT, Trudhesa, or Ubrelvy	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - One of the following: [C]

2.1 Higher dose or quantity is supported in the Dosage and Administration section of the manufacturer's prescribing information

OR

2.2 Higher dose or quantity is supported by one of the following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System

3 . Endnotes

A. The American Academy of Neurology and American Headache Society support the use of the following medications for the prevention of episodic migraine in adult patients (with level A or B evidence): antidepressants [i.e., Elavil (amitriptyline), Effexor (venlafaxine)], antiepileptics [i.e., Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], beta-blockers [i.e., atenolol, propranolol, nadolol, timolol, metoprolol], and candesartan. [10, 25]
B. Headache specialists are physicians certified by the United Council for Neurologic Subspecialties (UCNS). [24]
C. Published biomedical literature may be used as evidence to support safety and additional efficacy at higher than maximum doses for the diagnosis provided.

4 . References

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3. Frova Prescribing Information. Endo Pharmaceuticals Inc. Malvern, PA. August 2018.
4. Imitrex Tablets Prescribing Information. GlaxoSmithKline. Research Triangle Park, NC. December 2020.
5. Imitrex Nasal Spray Prescribing Information. GlaxoSmithKline. Research Triangle Park, NC. December 2017.
6. Imitrex Injection Prescribing Information. GlaxoSmithKline. Research Triangle Park, NC. December 2021.
7. Maxalt/Maxalt MLT Prescribing Information. Organon LLC. Jersey City, NJ. June 2021.
8. Migranal Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. September 2022.
9. Relpax Prescribing Information. Roerig. New York, NY. March 2020.
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20. Tosymra Prescribing Information. Promius Pharma, LLC. Princeton, NJ. January 2019.
21. Trudhesa Prescribing Information. Impel NeuroPharma Inc. Seattle, WA. September 2021.
22. Nurtec ODT Prescribing Information. Biohaven Pharmaceuticals, Inc. New Haven, CT. April 2022.
23. Ubrelvy Prescribing Information. Allergan USA, Inc. Madison, NJ. March 2021.
24. United Council for Neurologic Subspecialties website. www.ucns.org. Accessed February 13, 2023.
25. AHS Consensus Statement. Update on integrating new migraine treatments into clinical practice. Headache. 2021 Jul;61(7):1021-1039.

5 . Revision History

Date	Notes
4/5/2023	Annual review: Added Nurtec ODT and Ubrelvy and updated criteria and background.

Prior Authorization Guideline

Guideline Name	Mitoxantrone

Guideline Note:

Effective Date:	7/1/2022
P&T Approval Date:	5/18/2001
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 5/19/2022

1 . Indications

Drug Name: Mitoxantrone
Multiple Sclerosis Indicated for reducing neurologic disability and/or the frequency of clinical relapses in patients with secondary (chronic) progressive, progressive relapsing, or worsening relapsing-remitting multiple sclerosis (i.e., patients whose neurologic status is significantly abnormal between relapses). It is not indicated in the treatment of patients with primary progressive multiple sclerosis. **Prostate Cancer** Indicated, in combination with corticosteroids, as initial chemotherapy for the treatment of patients with pain related to advanced hormone-refractory prostate cancer. **Acute Non-Lymphocytic Leukemia (ANLL)** Indicated, in combination with other approved drug(s), in the initial therapy of ANLL in adults. This category includes myelogenous, promyelocytic, monocytic, and erythroid acute leukemias.

2 . Criteria

Product Name: Generic mitoxantrone	
Diagnosis	Multiple Sclerosis
Approval Length	6 Months [5-6, A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

1.1 Secondary progressive multiple sclerosis: gradually worsening disability with or without superimposed relapses [2]

OR

1.2 Progressive relapsing multiple sclerosis: progression of disability from the onset with superimposed relapses [2]

OR

1.3 Worsening relapsing-remitting multiple sclerosis: neurological status remains significantly abnormal in between multiple sclerosis relapses [3]

AND

2 - Trial and failure, contraindication, or intolerance to two of the following disease-modifying therapies for MS: [B, 3, 11]

- Aubagio (teriflunomide)
- Lemtrada (alemtuzumab)
- Mavenclad (cladribine)
- Plegridy (peginterferon beta-1a)
- Tysabri (natalizumab)
- Any one of the interferon beta-1a injections (e.g., Avonex)
- Any one of the interferon beta-1b injections (e.g., Betaseron)
- Any one of the glatiramer acetate injections (e.g., Copaxone, Glatopa, generic glatiramer acetate)
- Any one of the oral fumarates (e.g., generic dimethyl fumarate)

- Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (e.g., Gilenya, Mayzent, Zeposia)
- Any one of the B-cell targeted therapies (e.g., Kesimpta)

AND

3 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

4 - Neutrophil count greater than or equal to 1,500 cell/mm^3

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Generic mitoxantrone	
Diagnosis	Multiple Sclerosis
Approval Length	6 Months [5-6, A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

3 - A lifetime cumulative dose less than 140 mg/m^2 [1]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Generic mitoxantrone	
Diagnosis	Prostate Cancer
Approval Length	6 Months [5-6, A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced hormone-refractory (castration-resistant) prostate cancer

AND

2 - Used in combination with corticosteroids (e.g., prednisone, methylprednisolone) [7, 8, 10]

AND

3 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

4 - Neutrophil count greater than or equal to 1,500 cell/mm^3

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Generic mitoxantrone

Diagnosis	Prostate Cancer
Approval Length	6 Months [5-6, A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

3 - A lifetime cumulative dose less than 140mg/m^2 [1]

Product Name: Generic mitoxantrone	
Diagnosis	Acute Non-Lymphocytic Leukemia (ANLL)
Approval Length	6 Months [5-6, A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute non-lymphocytic leukemia (ANLL) (e.g., myelogenous, promyelocytic, monocytic, and erythroid)

AND

2 - Used in combination with other medications used for the treatment of ANLL [9, 10]

AND

3 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Generic mitoxantrone	
Diagnosis	Acute Non-Lymphocytic Leukemia (ANLL)
Approval Length	6 Months [5-6, A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

3 - A lifetime cumulative dose less than 140mg/m^2 [1]

3 . Endnotes

A. All patients should be carefully assessed for cardiac signs and symptoms by history and physical examination prior to start of Novantrone therapy. Left ventricular ejection fraction (LVEF) should be evaluated prior to administration of the initial dose of mitoxantrone and all subsequent doses. Mitoxantrone is recommended to be dosed

once every three months. Additional doses of mitoxantrone should not be administered to multiple sclerosis patients who have experienced either a drop in LVEF to below 50% or a clinically significant reduction in LVEF during mitoxantrone therapy. [1]

B. Per 2018 American Academy of Neurology (AAN) Multiple Sclerosis (MS) guideline, mitoxantrone should not be prescribed to people with MS due to the high frequency of severe adverse effects unless the potential benefit greatly outweighs the risk. Another MS agent that has relatively more side effects include Lemtrada and its prescribing information recommends reserving use after two prior lines of therapies have been tried. Due to this, a requirement of two prior agents for Mitoxantrone would be more appropriate to align with other MS agents that have more risks than benefit. [11]

4 . References

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5 . Revision History

Date	Notes
5/4/2022	Annual Review, no changes.

Prior Authorization Guideline

Guideline Name	Mozobil (plerixafor injection)

Guideline Note:

Effective Date:	10/1/2022
P&T Approval Date:	5/19/2009
P&T Revision Date:	08/15/2019 ; 08/13/2020 ; 08/19/2021 ; 8/18/2022

1 . Indications

Drug Name: Mozobil (plerixafor injection)
Hematopoietic Stem Cell Mobilization Indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) or multiple myeloma (MM).

2 . Criteria

Product Name: Mozobil	
Approval Length	1 course of therapy (up to four days of therapy). [A]
Guideline Type	Prior Authorization
Approval Criteria	

1 - One of the following:

- Patients with non-Hodgkin's lymphoma (NHL) who will be undergoing autologous hematopoietic stem cell (HSC) transplantation
- Patients with multiple myeloma (MM) who will be undergoing autologous HSC transplantation

AND

2 - Used in combination with granulocyte-colony stimulating factor (G-CSF) [e.g., Neupogen (filgrastim), Zarxio (filgrastim)]

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

3 . Endnotes

A. The duration of treatment for Mozobil in both the pivotal studies and compassionate use data was limited to one course of therapy. [2-4]

4 . References

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5 . Revision History

Date	Notes
8/3/2022	Annual review, no criteria changes.

Prior Authorization Guideline

Guideline Name	Multiple Sclerosis (MS) Agents - PA, NF

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	6/16/2021
P&T Revision Date:	08/19/2021 ; 12/15/2021 ; 12/15/2021 ; 05/19/2022 ; 12/14/2022

1 . Indications

Drug Name: Aubagio (teriflunomide)
Relapsing forms of multiple sclerosis (MS) Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Avonex (interferon beta-1a)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Bafiertam (monomethyl fumarate)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Betaseron (interferon beta-1b)

Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Drug Name: Copaxone (glatiramer acetate), Glatopa (glatiramer acetate)

Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Drug Name: Extavia (interferon beta-1b)

Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Drug Name: Kesimpta (ofatumumab)

Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Drug Name: Lemtrada (alemtuzumab)

Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of Lemtrada should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS. Limitations of Use: Lemtrada is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.

Drug Name: Mavenclad (cladribine)

Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, use of Mavenclad is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternate drug indicated for the treatment of MS. Limitations of Use: Mavenclad is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.

Drug Name: Mayzent (siponimod)

Relapsing forms of MS Indicated for the treatment of relapsing forms of MS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Drug Name: Ocrevus (ocrelizumab)

Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. **Primary Progressive Forms of Multiple Sclerosis (PPMS)** Indicated for the treatment of primary progressive MS, in adults.
Drug Name: Plegridy (peginterferon beta-1a)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Ponvory (ponesimod)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Rebif (interferon beta-1a)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Vumerity (diroximel fumarate)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

2 . Criteria

Product Name: Aubagio, Avonex, Bafiertam, Betaseron, Brand Copaxone, Generic glatiramer acetate, Glatopa, Kesimpta*, Mayzent, Vumerity	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A-D]

AND

2 - Prescribed by or in consultation with a neurologist

Notes	*For Kesimpta, there is a QL Override (For new starts only): Please e nter 2 PAs as follows with the same start date: First PA: Approve 3 syr inges or pens per 28 days for the first month (Loading dose has a MD D of 0.05); Second PA: Approve 1 syringe or pen per 28 days (no ove rrides needed) for 12 months. (Kesimpta is hard-coded with a quantity of 1 syringe or pen per 28 days; 0.4 mL per 20 mg pen or syringe. Ma intenance dose has a MDD of 0.02)

Product Name: Aubagio, Kesimpta, Vumerity	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A-D]

AND

2 - Prescribed by or in consultation with a neurologist

Product Name: Extavia, Plegridy, Ponvory, Rebif	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 For continuation of therapy

OR

2.2 Failure after a trial of at least 4 weeks, contraindication, or intolerance to at least two of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Bafiertam (monomethyl fumarate)
- Copaxone/Glatopa (glatiramer acetate)
- Kesimpta (ofatumumab)
- Dimethyl fumarate

AND

3 - Prescribed by or in consultation with a neurologist

Product Name: Extavia, Plegridy, Ponvory, Rebif	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

OR

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming failure after a trial of at least 4 weeks, contraindication, or intolerance to at least two of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Bafiertam (monomethyl fumarate)
- Copaxone/Glatopa (glatiramer acetate)
- Dimethyl fumarate

AND

3 - Prescribed by or in consultation with a neurologist

Product Name: Aubagio, Avonex, Bafiertam, Betaseron, Brand Copaxone, Extavia, Generic glatiramer acetate, Glatopa, Kesimpta, Mayzent, Plegridy, Ponvory, Rebif, Vumerity	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Prescribed by or in consultation with a neurologist

Product Name: Lemtrada	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient has not been previously treated with alemtuzumab

AND

2.1.2 Failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Kesimpta (ofatumumab)
- Tysabri (natalizumab)
- Any one of the glatiramer acetate injections (e.g., Copaxone, Glatopa, generic glatiramer acetate)
- Any one of the oral fumarates (e.g., generic dimethyl fumarate)
- Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (e.g., Gilenya, Mayzent)

OR

2.2 Both of the following: [E]

2.2.1 Patient has previously received treatment with alemtuzumab

AND

2.2.2 At least 12 months have or will have elapsed since the most recent treatment course with alemtuzumab

AND

3 - Not used in combination with another disease-modifying therapy for MS

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Lemtrada	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient has not been previously treated with alemtuzumab

AND

2.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Tysabri (natalizumab)
- Any one of the glatiramer acetate injections (e.g., Copaxone, Glatopa, generic glatiramer acetate)
- Any one of the oral fumarates (e.g., generic dimethyl fumarate)
- Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (e.g., Gilenya, Mayzent)

OR

2.2 Both of the following: [E]

2.2.1 Patient has previously received treatment with alemtuzumab

AND

2.2.2 At least 12 months have or will have elapsed since the most recent treatment course with alemtuzumab

AND

3 - Not used in combination with another disease-modifying therapy for MS

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Mavenclad	
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a relapsing form of MS (e.g., relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient has not been previously treated with cladribine

AND

2.1.2 Failure after a trial of at least 4 weeks, contraindication, or intolerance to one of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Kesimpta (ofatumumab)
- Tysabri (natalizumab)
- Any one of the glatiramer acetate injections (e.g., Copaxone, Glatopa, generic glatiramer acetate)
- Any one of the oral fumarates (e.g., generic dimethyl fumarate)
- Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (e.g., Gilenya, Mayzent)

OR

2.2 Both of the following:

2.2.1 Patient has previously received treatment with cladribine

AND

2.2.2 Patient has not already received the FDA-recommended lifetime limit of 2 treatment courses (or 4 treatment cycles total) of cladribine

AND

3 - Not used in combination with another disease-modifying therapy for MS

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Mavenclad	
Approval Length	1 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of a relapsing form of MS (e.g., relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient has not been previously treated with cladribine

AND

2.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming failure after a trial of at least 4 weeks, contraindication, or intolerance to one of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Tysabri (natalizumab)

- Any one of the glatiramer acetate injections (e.g., Copaxone, Glatopa, generic glatiramer acetate)
- Any one of the oral fumarates (e.g., generic dimethyl fumarate)
- Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (e.g., Gilenya, Mayzent)

OR

2.2 Both of the following:

2.2.1 Patient has previously received treatment with cladribine

AND

2.2.2 Patient has not already received the FDA-recommended lifetime limit of 2 treatment courses (or 4 treatment cycles total) of cladribine

AND

3 - Not used in combination with another disease-modifying therapy for MS

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Ocrevus	
Diagnosis	Relapsing Forms of MS
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome,

relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Failure after a trial of at least 4 weeks, contraindication, or intolerance to one of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Kesimpta (ofatumumab)
- Tysabri (natalizumab)
- Any one of the glatiramer acetate injections (e.g., Copaxone, Glatopa, generic glatiramer acetate)
- Any one of the oral fumarates (e.g., generic dimethyl fumarate)
- Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (e.g., Gilenya, Mayzent)

OR

2.2 For continuation of prior therapy

AND

3 - Not used in combination with another disease-modifying therapy for MS

AND

4 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [16]

AND

5 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

6 - Prescribed by or in consultation with a neurologist

Product Name: Ocrevus	
Diagnosis	Relapsing Forms of MS
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS

AND

3 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [16]

AND

4 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Ocrevus	
Diagnosis	Relapsing Forms of MS
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) confirming failure after a trial of at least 4 weeks, contraindication, or intolerance to one of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Tysabri (natalizumab)
- Any one of the glatiramer acetate injections (e.g., Copaxone, Glatopa, generic glatiramer acetate)
- Any one of the oral fumarates (e.g., generic dimethyl fumarate)
- Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (e.g., Gilenya, Mayzent)

OR

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

3 - Not used in combination with another disease-modifying therapy for MS

AND

4 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [16]

AND

5 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

6 - Prescribed by or in consultation with a neurologist

Product Name: Ocrevus	
Diagnosis	Primary Progressive Multiple Sclerosis (PPMS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Primary Progressive Multiple Sclerosis (PPMS)

AND

2 - Not used in combination with another disease-modifying therapy for MS

AND

3 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [16]

AND

4 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Ocrevus	
Diagnosis	Primary Progressive Multiple Sclerosis (PPMS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS

AND

3 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [16]

AND

4 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Ocrevus	
Diagnosis	Primary Progressive Multiple Sclerosis (PPMS)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Primary Progressive Multiple Sclerosis (PPMS)

AND

2 - Not used in combination with another disease-modifying therapy for MS

AND

3 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [16]

AND

4 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

5 - Prescribed by or in consultation with a neurologist

3 . Endnotes

A. According to the National MS Society, of the four disease courses that have been identified in MS, relapsing-remitting MS (RRMS) is characterized primarily by relapses, and secondary-progressive MS (SPMS) has both relapsing and progressive characteristics. These two constitute “relapsing forms of MS” if they describe a disease course that is characterized by the occurrence of relapses. [7] The effectiveness of interferon beta in SPMS patients without relapses is uncertain. [6]
B. Initiation of treatment with an interferon beta medication or glatiramer acetate should be considered as soon as possible following a definite diagnosis of MS with active, relapsing disease, and may also be considered for selected patients with a first attack who are at high risk of MS. [6]
C. Based on several years of experience with glatiramer acetate and interferon beta 1a and 1b, it is the consensus of researchers and clinicians with expertise in MS that these agents are likely to reduce future disease activity and improve quality of life for many individuals with relapsing forms of MS, including those with secondary progressive disease who continue to have relapses. For those who are appropriate candidates for one of these drugs, treatment must be sustained for years. Cessation of treatment may result in a resumption of pre-treatment disease activity. [6]
D. MS specialists will use Copaxone in relapsing forms of disease, including SPMS with relapses. While there have been no trials of Copaxone in SPMS (so we have no evidenced-based data upon which to make decisions or recommendations), it's clear that where there are relapses, the injectable therapies are partially effective – they reduce relapses and new lesions on MRI. In SPMS, the trials suggest that the interferons work better in earlier, more inflammatory (i.e. those with relapses prior to the trial and with gadolinium-enhancing lesions, which is the MRI equivalent of active inflammation). Since Copaxone and the interferons appear to have rather similar efficacy in the head-to-head trials, most assume that Copaxone has a similar efficacy in SPMS: where there are relapses or active inflammation on MRI, it will likely have some benefit. Thus, most MS specialists will use Copaxone in patients with SPMS who have persistent relapses. [8]
E. According to Prescribing Information, the recommended dosage of Lemtrada is 12 mg/day administered by intravenous infusion for 2 treatment courses (first treatment course: 12 mg/day on 5 consecutive days; second treatment course: 12 mg/day on 3 consecutive days administered 12 months after the first treatment course). Following the second treatment course, subsequent treatment courses of 12 mg per day on 3 consecutive days (36 mg total dose) may be administered, as needed, at least 12 months after the last dose of any prior treatment courses. [13]
F. Not to exceed the FDA-recommended dosage of 2 treatment courses (with the second course administered 43 weeks following the last dose of the first course). According to Prescribing Information, the recommended cumulative dosage of Mavenclad is 3.5 mg per kg body weight administered orally and divided into 2 yearly treatment courses (1.75 mg per kg per treatment course). Each treatment course is divided into 2 treatment cycles with the second cycle of each course administered 23 to 27 days after the last dose of the first cycle. Following the administration of 2 treatment courses, do not administer additional Mavenclad treatment during the next 2 years. Treatment during these 2 years may further increase the risk of malignancy. The safety and efficacy of

reinitiating Mavenclad more than 2 years after completing 2 treatment courses has not been studied. [19]

4 . References

1. Avonex Prescribing Information. Biogen Inc. Cambridge, MA. March 2020.
2. Betaseron Prescribing Information. Bayer. Whippany, NJ. October 2020.
3. Copaxone Prescribing Information. Teva Pharmaceuticals. North Wales, PA. July 2020.
4. Extavia Prescribing Information. Novartis. East Hanover, NJ. October 2020.
5. Rebif Prescribing Information. Serono Inc. Rockland, MA. October 2020.
6. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline: Disease-modifying therapies for adults with multiple sclerosis. Neurology 2018;90:777-788.
7. National Multiple Sclerosis Society. Types of MS. Available at: https://www.nationalmssociety.org/What-is-MS/Types-of-MS. Accessed March 29, 2019.
8. Per clinical consultation with MS specialist, December 29, 2010.
9. Plegridy Prescribing Information. Biogen Idec Inc. Cambridge, MA. January 2021.
10. Aubagio Prescribing Information. Genzyme Corporation. Cambridge, MA. November 2020.
11. Lemtrada Prescribing Information. Genzyme Corporation. Cambridge, MA. September 2020.
12. Glatopa Prescribing Information. Sandoz Inc. Princeton, NJ. January 2020.
13. Hawker K, O'Connor P, Freedman MS, et al. Rituximab in patients with primary progressive multiple sclerosis: results of a randomized double-blind placebo-controlled multicenter trial. Ann Neurol. 2009; Oct;66(4):460-71.
14. Ocrevus Prescribing Information. Genentech, Inc. San Francisco, CA. December 2020.
15. Mayzent Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. January 2021.
16. Mavenclad Prescribing Information. EMD Serono, Inc. Rockland, MA. April 2019.
17. Vumerity Prescribing Information. Biogen Inc. Cambridge, MA. January 2021.
18. Bafiertam Prescribing Information. Banner Life Sciences. High Point, NC. April 2020.
19. Kesimpta Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. August 2020.
20. Hauser S, Bar-Or A, Cohen J et al. Ofatumumab versus Teriflunomide in Multiple Sclerosis. New England Journal of Medicine. 2020;383(6):546-557.
21. Ponvory Prescribing Information. Janssen Pharmaceuticals Inc. Titusville, NJ. March 2021.

5 . Revision History

Date	Notes
11/30/2022	Removed Gilenya

Prior Authorization Guideline

Guideline Name	Myalept (metreleptin for injection)

Guideline Note:

Effective Date:	10/1/2022
P&T Approval Date:	5/21/2014
P&T Revision Date:	08/13/2020 ; 08/19/2021 ; 8/18/2022

Note:

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1 . Indications

Drug Name: Myalept (metreleptin for injection)
Congenital or acquired generalized lipodystrophy Indicated as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy

2 . Criteria

Product Name: Myalept	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of congenital or acquired generalized lipodystrophy

AND

2 - Patient is refractory to current standards of care for lipid and diabetic management

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Documentation demonstrates that patient has at least one of the following metabolic abnormalities: [2]

- Insulin resistance (defined as requiring more than 200 units per day)
- Hypertriglyceridemia
- Diabetes

Product Name: Myalept	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy, such as one of the following:

- Sustained reduction in hemoglobin A1c level from baseline

- Sustained reduction in triglyceride levels from baseline

3 . References

1. Myalept Prescribing Information. Amryt Pharmaceuticals DAC. Dublin, Ireland. February 2022.
2. Handelsman Y, Oral EA, Bloomgarden ZT, et al. The clinical approach to the detection of lipodystrophy – an AACE consensus statement. Endocrine Practice 2013;19(1):107-116.
3. Araujo-Vilar, D., Santini, F. Diagnosis and Treatment of Lipodystrophy: A Step-by-Step Approach. Journal of Endocrinological Investigation volume 42, pages61–73 (2019). Available at https://link.springer.com/article/10.1007/s40618-018-0887-z. Accessed July 13, 2022.

4 . Revision History

Date	Notes
7/13/2022	2022 Annual Review

Prior Authorization Guideline

Guideline Name	Naglazyme (galsulfase injection)

Guideline Note:

Effective Date:	8/1/2022
P&T Approval Date:	8/1/2006
P&T Revision Date:	06/17/2020 ; 06/16/2021 ; 6/15/2022

1 . Indications

Drug Name: Naglazyme (galsulfase injection)
Mucopolysaccharidosis (MPS VI) Indicated for patients with Mucopolysaccharidosis VI (MPS VI). Naglazyme has been shown to improve walking and stair-climbing capacity.

2 . Criteria

Product Name: Naglazyme	
Approval Length	60 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Mucopolysaccharidosis VI (MPS VI, Maroteaux-Lamy Syndrome)	

3 . References

1. Naglazyme Prescribing Information. BioMarin Pharmaceuticals Inc. April 2020.

4 . Revision History

Date	Notes
6/1/2022	Annual Review, no criteria changes.

Prior Authorization Guideline

Guideline Name	Nexavar (sorafenib)

Guideline Note:

Effective Date:	8/1/2022
P&T Approval Date:	4/4/2006
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 05/19/2022 ; 07/20/2022

1 . Indications

Drug Name: Nexavar (sorafenib)
Renal Cell Carcinoma Indicated for the treatment of patients with advanced renal cell carcinoma (RCC). **Hepatocellular Carcinoma** Indicated for the treatment of patients with unresectable hepatocellular carcinoma (HCC). **Differentiated Thyroid Carcinoma** Indicated for the treatment of patients with locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment.

2 . Criteria

Product Name: Brand Nexavar, generic sorafenib	
Diagnosis	Renal cell carcinoma

Approval Length	12 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of renal cell carcinoma

AND

2 - Prescribed by or in consultation with one of the following:

- Oncologist
- Nephrologist

AND

3 - Trial and failure or intolerance to generic sorafenib (Applies to Brand Nexavar only)

Product Name: Brand Nexavar, generic sorafenib	
Diagnosis	Renal cell carcinoma
Approval Length	12 Months [B]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Brand Nexavar, generic sorafenib	
Diagnosis	Hepatocellular carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hepatocellular carcinoma

AND

2 - One of the following: [3,5]

2.1 Patient has metastatic disease

OR

2.2 Patient has extensive liver tumor burden

OR

2.3 Patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only)

OR

2.4 Disease is unresectable

AND

3 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hepatologist
- Gastroenterologist

AND

4 - Trial and failure or intolerance to generic sorafenib (Applies to Brand Nexavar only)

Product Name: Brand Nexavar, generic sorafenib	
Diagnosis	Hepatocellular carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Brand Nexavar, generic sorafenib	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of differentiated thyroid carcinoma (i.e., follicular, Hurthle, or papillary carcinoma) [C]

AND

1.1.2 One of the following [6]:

- Locally recurrent disease
- Metastatic disease
- Unresectable disease

AND

1.1.3 One of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

1.1.4 Disease is refractory to radioactive iodine (RAI) treatment

OR

1.2 All of the following: [5]

1.2.1 Diagnosis of disseminated medullary thyroid carcinoma

AND

1.2.2 One of the following:

- Disease is progressive
- Disease is symptomatic with distant metastases

AND

1.2.3 Trial and failure, contraindication, or intolerance to one of the following:

- Caprelsa (vandetanib)
- Cometriq (cabozantinib)

AND

2 - Prescribed by or in consultation with an oncologist

AND

3 - Trial and failure or intolerance to generic sorafenib (Applies to Brand Nexavar only)

Product Name: Brand Nexavar, generic sorafenib	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. Treatment should continue until the patient is no longer clinically benefiting from therapy or until unacceptable toxicity occurs. Mean progression-free survival in Study 1 as described in the Nexavar prescribing information indicates a median progression-free survival of 167 days in Nexavar-treated patients with renal cell carcinoma. [1]
B. Differentiated thyroid carcinoma includes papillary carcinoma, follicular carcinoma, Hurthle cell carcinoma, and poorly differentiated carcinoma. [4-5]

4 . References

1. Nexavar Prescribing Information. Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ. July 2020.
2. Brose MS, Nutting CM, Sherman SI, et al. Rationale and design of DECISION: a doubleblind, randomized, placebo-controlled phase III trial evaluating the efficacy and safety of sorafenib in patients with locally advanced or metastatic radioactive iodine (RAI)-refractory, differentiated thyroid cancer. BMC Cancer. 2011;349.
3. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium [internet database]. https://www.nccn.org. Accessed April 3, 2021.
4. National Comprehensive Cancer network (NCCN) Clinical Practice Guidelines in Oncology. Kidney Cancer. V.2.2020. NCCN Website. https://www.nccn.org/professionals/physician_gls/default.aspx. Accessed April 3, 2020.

5. National Comprehensive Cancer network (NCCN) Clinical Practice Guidelines in Oncology. Hepatobiliary Cancers. V.2.2021. NCCN Website. https://www.nccn.org/professionals/physician_gls/default.aspx. Accessed April 3, 2021
6. National Comprehensive Cancer network (NCCN) Clinical Practice Guidelines in Oncology. Thyroid Carcinoma. V.1.2021. NCCN Website. https://www.nccn.org/professionals/physician_gls/default.aspx. Accessed April 3, 2021
7. Sorafenib Prescribing Information. Dr. Reddys Laboratories Inc. Princeton, NJ. June 2022.

5 . Revision History

Date	Notes
7/22/2022	Updated indications section. No changes to criteria.

Prior Authorization Guideline

Guideline Name	Nexletol (bempedoic acid) and Nexlizet (bempedoic acid-ezetimibe)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	5/14/2020
P&T Revision Date:	05/20/2021 ; 05/19/2022 ; 5/18/2023

1 . Indications

Drug Name: Nexletol (bempedoic acid), Nexlizet (bempedoic acid-ezetimibe)
HeFH or ASCVD Indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or established atherosclerotic cardiovascular disease (ASCVD) who require additional lowering of LDL-C. Limitations of Use: The effect of bempedoic acid on cardiovascular morbidity and mortality has not been determined.

2 . Criteria

Product Name: Nexletol, Nexlizet	
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

1.1 Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following: [1-2, B]

1.1.1 Both of the following: [4]

1.1.1.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age) [4]

AND

1.1.1.2 One of the following: [4]

- Family history of myocardial infarction in first-degree relative less than 60 years of age
- Family history of myocardial infarction in second-degree relative less than 50 years of age
- Family history of LDL-C greater than 190 mg/dL in first- or second-degree relative
- Family history of familial hypercholesterolemia in first- or second-degree relative [11]
- Family history of tendinous xanthomata and/or arcus cornealis in first- or second-degree relative

OR

1.1.2 Both of the following:

1.1.2.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age) [4]

AND

1.1.2.2 One of the following:

- Functional mutation in the LDL receptor, ApoB, or PCSK9 gene [3-4]
- Tendinous xanthomata [3-4]
- Arcus cornealis before age 45 [3]

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD) as confirmed by one of the following: [1, 2, 5]

- Acute coronary syndromes
- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization (e.g., percutaneous coronary intervention [PCI] or coronary artery bypass graft [CABG] surgery)
- Stroke
- Transient ischemic attack
- Peripheral arterial disease presumed to be of atherosclerotic origin

AND

2 - One of the following: [1, 2, 5]

2.1 Patient has been receiving at least 12 consecutive weeks of one HIGH-INTENSITY statin therapy [i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg] and will continue to receive a HIGH-INTENSITY statin at maximally tolerated dose

OR

2.2 Both of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms: [C]

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

2.2.2 One of the following:

2.2.2.1 Patient has been receiving at least 12 consecutive weeks of one MODERATE-INTENSITY statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 20-40 mg, pravastatin 40-80 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin

40 mg twice daily, or Livalo (pitavastatin) 2-4 mg] and will continue to receive a MODERATE-INTENSITY statin at maximally tolerated dose

OR

2.2.2.2 Patient has been receiving at least 12 consecutive weeks of one LOW-INTENSITY statin therapy [i.e., simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, Livalo (pitavastatin) 1 mg] and will continue to receive a LOW-INTENSITY statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low-, moderate-, or high-intensity statins as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms: [C]

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times ULN)

OR

2.4 Patient has a labeled contraindication to all statins

OR

2.5 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN [5]

AND

3 - One of the following LDL-C values while on maximally tolerated statin therapy within the last 120 days: [6-9]

- LDL-C greater than or equal to 70 mg/dL with ASCVD
- LDL-C greater than or equal to 100 mg/dL without ASCVD

AND

4 - One of the following: [D]

4.1 Patient has been receiving at least 12 consecutive weeks of generic ezetimibe therapy as adjunct to maximally tolerated statin therapy [A]

OR

4.2 Patient has a history of contraindication or intolerance to ezetimibe

Product Name: Nexletol, Nexlizet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduction in LDL-C levels)

AND

2 - One of the following:

2.1 Patient continues to receive other lipid-lowering therapy (e.g., statins, ezetimibe) at the maximally tolerated dose

OR

2.2 Patient has a documented inability to take other lipid-lowering therapy (e.g., statins, ezetimibe)

3 . Endnotes

A. Per the 2018 ACC/AHA national treatment guidelines, adherence, response to therapy, and adverse effects should be monitored within 4 -12 weeks following LDL-C lowering medication initiation or dose adjustment, repeated every 3 to 12 months as needed. [5]
B. In the Nexletol and Nexlizet pivotal trials that enrolled patients with HeFH, the diagnosis of HeFH was made either by genotyping or clinical criteria ("definite FH" using either the Simon Broome or WHO/Dutch Lipid Network criteria). [1-4]
C. In patients treated with statins, it is recommended to measure creatine kinase levels in individuals with severe statin-associated muscle symptoms. [5]
D. The effect of bempedoic acid on cardiovascular morbidity and mortality has not been determined. Outcomes trials evaluating the efficacy of bempedoic acid are currently underway. In contrast, IMPROVE-IT was a prospective randomized controlled trial evaluating the addition of ezetimibe to simvastatin 40 mg in a high-risk patient population for secondary prevention over 7 years. The addition of ezetimibe significantly reduced ASCVD events, albeit modestly (HR 0.936; 95% CI 0.887, 0.988; p = 0.016; number needed to treat [NNT] = 50). The 2017 ACC/AHA non-statin decision pathway update recommends that for patients who are maximized on statin therapy with baseline LDL-C 70-189 mg/dL, it is reasonable to consider the addition of ezetimibe. In patients with clinical ASCVD who are judged to be very high risk with LDL-C 70 mg/dL or higher, maximally tolerated LDL-C lowering therapy should include maximally tolerated statin therapy and ezetimibe. [5, 8-9]

4 . References

1. Nexletol Prescribing Information. Esperion Therapeutics, Inc. Ann Arbor, MI. February 2020.
2. Nexlizet Prescribing Information. Esperion Therapeutics, Inc. Ann Arbor, MI. November 2020.
3. WHO Familial Hypercholesterolemia Consultation Group. Familial Hypercholesterolemia (FH): report of a second WHO consultation. Geneva: World Health Organization; 1999.
4. Scientific Steering Committee on behalf of the Simon Broome Register Group. Risk of fatal coronary heart disease in familial hypercholesterolemia. BMJ. 1991;303:893-6.
5. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2019; 73:e285-e350.
6. ATP III Final Report PDF. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) Final Report. Circulation. 2002;106:3143-3421.
7. Per clinical drug consult with cardiologist. August 3, 2015.
8. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2017 Focused Update of the 2016 ACC expert consensus decision pathway on the role of non-statin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk. J Am Coll Cardiol. 2017;70:1785-1822.
9. Goldberg AC, Hopkins PN, Toth PP, et al. Familial hypercholesterolemia: screening, diagnosis, and management of pediatric and adult patients: clinical guidance from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. J Clin Lipidol. 2011;5:S1-51.

10. Cannon CP, Blazing MA, Giugliano RP, et al. Ezetimibe added to statin therapy after acute coronary syndromes. N Engl J Med. 2015;372:2387-97.
11. Per clinical drug consult with cardiologist. November 17, 2017.

5 . Revision History

Date	Notes
5/2/2023	Annual Review - criteria update

Prior Authorization Guideline

Guideline Name	Ninlaro (ixazomib citrate)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	1/27/2016
P&T Revision Date:	03/18/2020 ; 03/17/2021 ; 03/16/2022 ; 06/15/2022 ; 3/15/2023

1 . Indications

Drug Name: Ninlaro (ixazomib citrate)
Multiple Myeloma Indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy. Limitations of Use: NINLARO is not recommended for use in the maintenance setting or in newly diagnosed multiple myeloma in combination with lenalidomide and dexamethasone outside of controlled clinical trials.

2 . Criteria

Product Name: Ninlaro	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - Patient has received at least one prior therapy for multiple myeloma [e.g., Revlimid (lenalidomide), Thalomid (thalidomide), Velcade (bortezomib)]

AND

3 - Used in combination with both of the following:

- Revlimid (lenalidomide)*
- dexamethasone

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Notes	*These products may require Prior Authorization

Product Name: Ninlaro	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Ninlaro Prescribing Information. Takeda Pharmaceutical Company Limited. Cambridge, MA. November 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org. Accessed May 31, 2022.

4 . Revision History

Date	Notes
3/2/2023	2023 Annual Review - updated references

Prior Authorization Guideline

Guideline Name	Nityr and Orfadin

Guideline Note:

Effective Date:	10/1/2022
P&T Approval Date:	4/18/2018
P&T Revision Date:	11/14/2019 ; 06/17/2020 ; 03/17/2021 ; 07/21/2021 ; 8/18/2022

1 . Indications

Drug Name: Nityr (nitisinone) tablets
Hereditary Tyrosinemia Type 1 (HT-1) Indicated for the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.
Drug Name: Brand Orfadin capsules, Brand Orfadin oral suspension, Generic nitisinone capsules
Hereditary Tyrosinemia Type 1 (HT-1) Indicated for the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.

2 . Criteria

Product Name: Nityr*, Brand Orfadin, Generic nitisinone	
Diagnosis	Hereditary Tyrosinemia type 1 (HT-1)

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary tyrosinemia type 1 (HT-1)

AND

2 - Diagnosis confirmed by the presence of succinylacetone in the plasma or urine [1-3]

AND

3 - Used in combination with dietary restriction of tyrosine and phenylalanine

AND

4 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- Hepatologist
- Other specialist with experience in treating inborn errors of metabolism

Notes	*For patients who have difficulties swallowing intact tablets, including pediatric patients, the tablets can be disintegrated in water and administered using an oral syringe. If patients can swallow semi-solid foods, the tablets can also be crushed and mixed with applesauce. For preparation and administration instructions, see the full prescribing information [1].

Product Name: Nityr*, Brand Orfadin, Generic nitisinone	
Diagnosis	Hereditary Tyrosinemia type 1 (HT-1)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of a positive clinical response to therapy	
Notes	*For patients who have difficulties swallowing intact tablets, including pediatric patients, the tablets can be disintegrated in water and administered using an oral syringe. If patients can swallow semi-solid foods, the tablets can also be crushed and mixed with applesauce. For preparation and administration instructions, see the full prescribing information.

3 . References

1. Nityr prescribing information. Cycle Pharmaceuticals Ltd. Cambridge, UK. June 2021.
2. Orfadin prescribing Information. Sobi Inc. Waltham, MA. November 2021.
3. de Laet C, Dionisi-Vici C, Leonard JV, et al. Recommendations for the management of tyrosinaemia type 1. Orphanet J Rare Dis. 2013;8:8.

4 . Revision History

Date	Notes
8/3/2022	Annual review: No criteria changes. Updated references and background.

Prior Authorization Guideline

Guideline Name	Non-Formulary & Excluded Drug Exceptions Process for Drugs of Clinical Concern

Guideline Note:

Effective Date:	5/12/2023
P&T Approval Date:	
P&T Revision Date:	08/15/2019 ; 11/14/2019 ; 03/18/2020 ; 04/15/2020 ; 05/14/2020 ; 07/15/2020 ; 07/15/2020 ; 11/12/2020 ; 03/17/2021 ; 03/17/2021 ; 06/16/2021 ; 11/18/2021 ; 12/15/2021 ; 01/19/2022 ; 11/17/2022

Note:

The purpose of this guideline is to establish policies and procedures on how to handle non-formulary and excluded drugs when continuation of prior therapy is allowed. This guideline will not apply to drug exclusions that do not allow for continuation of prior therapy, drugs with step therapy edits, drugs that require quantity limit review only, or drugs that are not reviewed for prior authorization. ** Please consult client-specific resources to confirm whether benefit exclusions should be reviewed for medical necessity.**

1 . Criteria

Product Name: Aplenzin, Aptiom, Brand Atripla, Auvelity, Ayvakit, Brukinsa, Caplyta, Brand Combivir, Delstrigo, Generic efavirenz-lamivudine-tenofovir DF, Brand Emtriva capsules, Brand Epivir, Brand Epzicom, Esperoct, Fintepla, Forfivo XL, Bupropion HCL 450mg ER (XL), Brand Genvoya, Ilumya, Brand Intelence, Jivi, Brand Kaletra, Kcentra, Brand Lexiva, Lybalvi, Mononine, Brand Norvir tablets, Nubeqa, Nuplazid, Oxtellar XR, Rebinyn, Brand Retrovir, Rexulti, Brand Reyataz capsules, Savaysa, Siliq, Spritam, Stribild, Brand Sustiva, Brand

Symfi, Brand Symfi Lo, Temixys, Brand Trizivir, Trokendi XR, Brand Viramune, Brand Viramune XR, Brand Viread tablets, Xeljanz oral solution, Xembify, Brand Ziagen, Zykadia	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Both of the following:

1.1 One of the following:

1.1.1 Patient has failed or has contraindications or intolerance to at least three equivalent formulary drugs. If only one or only two equivalents are available, the patient must have failed or had contraindications or intolerance to all available equivalent formulary drugs. The clinician's judgment should be used to determine equivalent formulary drugs for the indication provided. (Refer to Table 1 for examples of equivalent formulary drugs)

OR

1.1.2 No formulary drug is appropriate to treat the patient's condition

AND

1.2 One of the following:

1.2.1 Both of the following:

1.2.1.1 Requested drug is FDA-approved for the condition being treated

AND

1.2.1.2 Additional requirements listed in the "Indications and Usage" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.)

OR

1.2.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

OR

2 - For continuation of prior therapy

2 . Background

Benefit/Coverage/Program Information

Table 1. Formulary Alternatives for Premium Exclusion Drugs of Clinical Concern

Therapeutic Category	Excluded Medication	Preferred Formulary Altern (*May require PA)
Anticonvulsants	Fintepla (fenfluramine)	• Valproic acid or cloba • Diacomit (stiripentol)* (cannabidiol)*, lamotr topiramate, zonisamic levetiracetam, Briviac (brivaracetam)*
Anticonvulsants	Trokendi XR (topiramate extended-release)	• Generic anticonvulsa lamotrigine, topiramat levetiracetam, oxcarb carbamazepine)
Anticonvulsants	Oxtellar XR (oxcarbazepine extended-release)	• Generic anticonvulsa lamotrigine, topiramat levetiracetam, oxcarb carbamazepine)
Antidepressants	Aplenzin (bupropion hydrobromide extended-release) Forfivo XL (bupropion hydrochloride extended-release)	• Generic bupropion XL
Antipsychotics, Atypical	Caplyta (lumateperone)	• Generic atypical antip (e.g., aripiprazole, ge asenapine sublingual clozapine, olanzapine paliperidone, quetiapi risperidone, ziprasido

Antivirals	Atripla (efavirenz-emtricitabine-tenofovir DF)	• Generic efavirenz-emtricitabine-tenofovir df • Symfi (efavirenz-lamivudine-tenofovir DF) • Symfi Lo (efavirenz-lamivudine-tenofovir DF) • Triumeq (abacavir-dolutegravir-lamivudine) • Juluca (dolutegravir-rilpivirine) • Cimduo (lamivudine-tenofovir DF) plus Isentress (raltegravir) • Cimduo (lamivudine-tenofovir DF) plus Tivicay (dolutegravir)
Antivirals	Temixys (lamivudine- tenofovir disoproxil fumarate)	• Cimduo (lamivudine-tenofovir disoproxil fumarate)
Antivirals	Reyataz (atazanavir sulfate) capsules	• Generic atazanavir sulfate capsules
Antivirals	Lexiva (fosamprenavir calcium)	• Generic fosamprenavir calcium
Antivirals	Norvir (ritonavir) tablets	• Generic ritonavir tablets
Antivirals	Ziagen (abacavir sulfate)	• Generic abacavir sulfate
Antivirals	Emtriva (emtricitabine) capsules	• Generic emtricitabine capsules
Antivirals	Epivir (lamivudine)	• Generic lamivudine
Antivirals	Retrovir (zidovudine)	• Generic zidovudine
Antivirals	Viread (tenofovir disoproxil fumarate) tablets	• Generic tenofovir disoproxil fumarate tablets
Antivirals	Sustiva (efavirenz)	• Generic efavirenz
Antivirals	Intelence (etravirine) 100 mg, 200 mg	• Generic etravirine
Antivirals	Viramune (nevirapine)	• Generic nevirapine
Antivirals	Viramune XR (nevirapine)	• Generic nevirapine ER
Antivirals	Epzicom (abacavir sulfate-lamivudine)	• Generic abacavir sulfate-lamivudine
Antivirals	Combivir (lamivudine-zidovudine)	• Generic lamivudine-zidovudine
Antivirals	Kaletra (lopinavir-ritonavir)	• Generic lopinavir-ritonavir
Antivirals	Trizivir (abacavir sulfate-lamivudine-zidovudine)	• Generic abacavir sulfate-lamivudine-zidovudine
Antivirals	Delstrigo (doravirine-lamivudine-tenofovir df)	• No alternative available

Antivirals	Symfi (efavirenz-lamivudine-tenofovir df), Symfi Lo (efavirenz-lamivudine-tenofovir df)	• Generic efavirenz-lamivudine-tenofovir df
Antivirals	Genvoya (elvitegravir-cobicistat-emtricitabine-tenofovir alafenamide)	• No alternative available
Antivirals	Stribild (elvitegravir-cobicistat-emtricitabine-tenofovir df)	• No alternative available
Central Nervous System	Lybalvi (olanzapine and samidorphan)	• generic aripiprazole • generic asenapine • generic clozapine • generic olanzapine • generic paliperidone • generic quetiapine IR/ER • generic risperidone • generic ziprasidone
Hemophilia Agents	Esperoct (antihemophilic factor [recombinant], glycopegylated-exei) Jivi (antihemophilic factor [recombinant], pegylated-aucl)	• Adynovate (antihemophilic factor [recombinant] pegylated) • Afstyla (antihemophilic factor [recombinant], single chain) • Eloctate (antihemophilic factor [recombinant], Fc fusion protein)
Immunological Agents	Xembify [immune globulin subcutaneous (human)- klhw]	• Cuvitru [immune globulin (human)]*
Immunomodulators	Ilumya (tildrakizumab-asmn) Siliq (brodalumab)	• Taltz (ixekizumab)* • Cimzia (certolizumab pegol)* • Humira (adalimumab)* • Skyrizi (risankizumab)* • Stelara (ustekinumab)* • Tremfya (guselkumab)*
Immunomodulators	Xeljanz (tofacitinib) oral solution	• Humira (adalimumab)*
Oncology Agents	Zykadia (ceritinib)	• Alecensa (alectinib)* • Alunbrig (brugatinib)*

3 . Revision History

Date	Notes
5/11/2023	Addition of Bupropion HCL ER (XL) (MSC M) product as a target

Prior Authorization Guideline

Guideline Name	Non-formulary Descovy and Truvada

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	10/21/2020
P&T Revision Date:	11/18/2021 ; 11/17/2022

1 . Indications

Drug Name: Descovy (emtricitabine/tenofovir alafenamide)
Treatment of HIV-1 Infection Indicated in combination with other antiretroviral agents, for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35kg. Indicated in combination with other antiretroviral agents other than protease inhibitors that require a CYP3A inhibitor for the treatment of HIV-1 infection in pediatric patients weighing at least 14 kg and less than 35 kg. **HIV-1 Pre-exposure Prophylaxis (PrEP)** Indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of human immunodeficiency virus-1 (HIV-1) infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex. Individuals must have a negative HIV-1 test immediately prior to initiating Descovy for HIV-1 PrEP. Limitations of Use: The indication does not include use of Descovy in individuals at risk of HIV-1 from receptive vaginal sex because effectiveness in this population has not been evaluated.
Drug Name: Truvada (emtricitabine/tenofovir disoproxil fumarate)
Treatment of HIV-1 Infection Indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 17 kg. **HIV-1 Pre-Exposure Prophylaxis (PrEP)** Indicated in at-risk adults and adolescents

weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test immediately prior to initiating Truvada for HIV-1 PrEP. The dosage of TRUVADA for HIV-1 PrEP is one tablet (containing 200 mg of FTC and 300 mg of TDF) once daily.

2 . Criteria

Product Name: Descovy	
Diagnosis	Treatment of HIV Infection
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Currently used for the treatment of HIV infection

Product Name: Brand Truvada	
Diagnosis	Treatment of HIV Infection
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Using for the treatment of HIV infection

AND

2 - One of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial of or intolerance to generic emtricitabine/tenofovir disoproxil fumarate (generic Truvada)

OR

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Descovy, Brand Truvada 200/300 mg	
Diagnosis	HIV Pre-exposure Prophylaxis (PrEP)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Currently used for HIV Pre-exposure Prophylaxis (PrEP)

AND

2 - Submission of medical records (e.g., chart notes) confirming patient has a history of intolerance or contraindication to generic Truvada 200/300 mg (emtricitabine/tenofovir disoproxil fumarate)

3 . References

1. Descovy Prescribing Information. Gilead Sciences, Inc. Foster City, CA. January 2022.
2. Truvada Prescribing Information. Gilead Sciences, Inc. Foster City, CA. June 2020.

4 . Revision History

Date	Notes
11/18/2022	Annual review - updated indication for Descovy, no changes to criteri a. Updated references.

Prior Authorization Guideline

Guideline Name	Non-Preferred Non-Formulary & Excluded Medications

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	11/12/2020
P&T Revision Date:	05/20/2021 ; 06/16/2021 ; 07/21/2021 ; 08/19/2021 ; 09/15/2021 ; 11/18/2021 ; 02/17/2022 ; 05/19/2022 ; 10/19/2022 ; 5/18/2023

Note:

For off-label use, do not review against the off-label administration guideline. Deny per guideline criteria.

1 . Criteria

Product Name: A Non-Preferred Non-Formulary or Excluded Medication* (Brand Absorica, Absorica LD, Alcortin A, Atopaderm, Auvi-Q, Azesco, Bensal HP, generic chlorzoxazone, Brand Diclofenac Epolamine, Brand Doryx, generic doxepin cream, Epiceram, generic fenoprofen calcium, Flector, Fluovix, Folic-K, Genicin Vita-S, Brand Inderal XL, Innopran XL, Kamdoy, Kelarx, Brand Lidocaine-tetracaine cream, Brand Naprosyn, generic naproxen-esomeprazole, Ortho DF, Brand Pennsaid, Pliaglis, Pregenna, Prodigen, Brand Prudoxin, QMIIZ ODT, Rayos, Relafen DS, Sitavig, Sprix, Tivorbex, Tolsura, Brand Vimovo, Xerese, Xhance, Yosprala, Zipsor, Brand Zonalon, Zorvolex, ZT Lido, Brand Zyclara, Zyflo)	
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting request is for an FDA-approved indication

AND

2 - Paid claims or submission of medical records (e.g., chart notes) (document drug, duration, dose and date of use) documenting history of use of ALL available formulary alternative(s)* (if request is for a combination product, member must have documentation indicating concurrent use of separate agents)

AND

3 - Both of the following:

3.1 Documentation provided stating the formulary alternative(s)* has/have not been effective

AND

3.2 Justification/rationale provided explaining how the Non-Formulary or Excluded Medication is expected to provide benefit when the formulary alternative* product(s) has/have not been shown to be effective despite having the same active ingredient and/or same mechanism of action

Notes	*See table in background section for a list of the Non-Formulary or Excluded Medications and their preferred formulary alternatives. Please double check plan formulary for coverage. For off-label use, do not review against the off-label administration guideline. Deny per guideline criteria.

2 . Background

Benefit/Coverage/Program Information
Non-Formulary or Excluded Medications and their *Formulary Alternatives

Non-Formulary or Excluded Medication	*Formulary Alternatives
Brand Absorica, Absorica LD	Amnesteem Claravis Isotretinoin Myorisan Zenatane
Alcortin-A	Hydrocortisone cream
Atopaderm	Desonide Hydrocortisone
Auvi-Q	Epipen 2-Pak/Epipen-JR 2-PK Epinephrine autoinjector
Azesco	PrePLUS prenatal vitamin
Bensal HP	Podofilox Ciclopirox
Generic chlorzoxazone	Methocarbamol Cyclobenzaprine tablet Metaxalone Orphenadrine ER Tizanidine
Generic doxepin 5% cream, Brand Prudoxin, Brand Zonalon	Betamethasone dipropionate cream Tacrolimus 0.1% ointment
Brand Doryx	Generic doxycycline delayed release Generic doxycycline monohydrate Brand Vibramycin
Epiceram	OTC topical moisturizer (e.g., Aquaphor)
Generic fenoprofen calcium, Brand Naprosyn	Celecoxib Ibuprofen (tablet/suspension) Diclofenac

	Etodolac Meloxicam
Flector, Brand Diclofenac epolamine	Celecoxib Ibuprofen Diclofenac (oral) Etodolac Meloxicam
Fluovix	Fluocinonide cream 0.1%
Folic-K, Genicin Vita-S	Generic B-Complex with C and Folic Acid
Inderal XL/Innopran XL	Propranolol extended release Nadolol Pindolol Timolol maleate tablets
Kamdoy	OTC Lidocaine
Kelarx	Scaraway (OTC)
Brand Lidocaine-tetracaine cream, Pliaglis	Lidocaine-prilocaine cream Lidocaine cream
Ortho DF	Vitamin D3 (OTC) Folic Acid
Pennsaid	Diclofenac sodium solution 1.5% Diclofenac sodium solution 2%
Pregenna	Atabex OB Tab 29-1mg
Prodigen	Visbiome
QMIIZ ODT, Relafen DS, Zipsor, Zorvolex	Diclofenac Etodolac Ketoprofen Naproxen Meloxicam

<table>
<tr><td></td><td>Nabumetone
Piroxicam
Sulindac</td></tr>
<tr><td>Rayos</td><td>Methylprednisolone
Prednisolone
Prednisone</td></tr>
<tr><td>Sitavig</td><td>Acyclovir 5% cream
Penciclovir 1% cream
Acyclovir oral
Valacyclovir oral</td></tr>
<tr><td>Sprix</td><td>Brand Ketorolac nasal spray
Geneirc ketorolac oral tablets</td></tr>
<tr><td>Tivorbex</td><td>Celecoxib
Ibuprofen (tablet/suspension)
Indomethacin
Colcrys
Diclofenac
Etodolac
Meloxicam</td></tr>
<tr><td>Tolsura</td><td>Itraconazole 100 mg capsule (higher strength)</td></tr>
<tr><td rowspan="6">Brand Vimovo, generic naproxen/esomeprazole</td><td>NSAID</td><td>ANTI-ULCER AGENT</td></tr>
<tr><td>Diclofenac</td><td>Esomeprazole</td></tr>
<tr><td>Indomethacin</td><td>Lansoprazole</td></tr>
<tr><td>Ketoprofen</td><td>Omeprazole</td></tr>
<tr><td>Naproxen</td><td>Omeprazole/Sodium bicarbonate</td></tr>
<tr><td>Meloxicam</td><td>Pantoprazole</td></tr>
</table>

	Nabumetone	Rabeprazole
	Piroxicam	
	Sulindac	
Xerese	Acyclovir 5% Cream Hydrocortisone 1% Cream	
Xhance	Generic mometasone Beconase AQ	
Yosprala	Aspirin	Omeprazole
ZTlido	Lidocaine 5% patch Gabapentin Pregabalin	
Brand Zyclara	Imiquimod 5% Fluorouracil	
Zyflo	Montelukast Zafirlukast	

3 . Revision History

Date	Notes
5/4/2023	Removed Evzio and Sil-K pad large from guideline as products are o bsolete.

Prior Authorization Guideline

Guideline Name	Non-steroidal Anti-Inflammatory Agents - PA, ST

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	11/18/2008
P&T Revision Date:	11/16/2019 ; 04/15/2020 ; 04/15/2020 ; 04/15/2020 ; 11/12/2020 ; 04/21/2021 ; 01/19/2022 ; 04/20/2022 ; 07/20/2022 ; 08/18/2022 ; 10/19/2022 ; 01/18/2023 ; 04/19/2023

1 . Indications

Drug Name: Cambia (diclofenac) powder
Migraine Indicated for the acute treatment of migraine attacks with or without aura in adults (18 years of age or older). Limitations of use: Cambia is not indicated for the prophylactic therapy of migraine. The safety and effectiveness of Cambia have not been established for cluster headache, which is present in an older, predominantly male population.
Drug Name: Celebrex (celecoxib)
Multiple Indicated for: 1) Osteoarthritis (OA) 2) Rheumatoid Arthritis (RA) 3) Juvenile Rheumatoid Arthritis (JRA) in patients 2 years of age or older 4) Ankylosing Spondylitis (AS) 5) Acute Pain 6) Primary Dysmenorrhea
Drug Name: Sprix (ketorolac tromethamine) nasal spray
Moderate to moderately severe pain Indicated in adult patients for the short term (up to 5 days) management of moderate to moderately severe pain that requires analgesia at the opioid level. Limitations of Use: Sprix is not for use in pediatric patients less than 2 years of age.

Drug Name: Tivorbex (indomethacin) capsules
Mild to moderate pain Indicated for treatment of mild to moderate acute pain in adults.
Drug Name: Pennsaid (diclofenac sodium) topical solution
Osteoarthritis (OA) Indicated for the treatment of signs and symptoms of osteoarthritis of the knee(s).
Drug Name: Indocin
Multiple Indications Indicated for the treatment for the following: moderate to severe rheumatoid arthritis including acute flare of chronic disease, moderate to severe ankylosing spondylitis, moderate to severe osteoarthritis, acute painful shoulder (bursitis and/or tendinitis) or acute gouty arthritis.
Drug Name: Vivlodex
Osteoarthritis (OA) Indicated for the treatment of osteoarthritis (OA) pain.
Drug Name: Zorvolex (diclofenac)
Pain Indicated for the treatment of mild to moderate acute pain and management of osteoarthritis (OA) pain.
Drug Name: Lofena
Primary dysmenorrhea, mild to moderate pain, osteoarthritis, and rheumatoid arthritis Indicated for treatment of primary dysmenorrhea, for relief of mild to moderate pain, for relief of the signs and symptoms of osteoarthritis, for the relief of the signs and symptoms of rheumatoid arthritis.
Drug Name: Meloxicam oral suspension 7.5mg/5mL
Multiple Indicated for: 1) Osteoarthritis (OA) 2) Rheumatoid Arthritis (RA) 3) Juvenile Rheumatoid Arthritis (JRA) in patients 2 years of age or older
Drug Name: Zipsor (diclofenac potassium)
Mild to moderate acute pain Indicated for relief of mild to moderate acute pain in adult and pediatric patients 12 years of age and older.

2 . Criteria

Product Name: Sprix nasal spray, Brand Ketorolac nasal spray

Approval Length	5 Days [A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to moderately severe pain

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to oral ketorolac* tablets

OR

2.2 Patient is unable to take medications orally

Notes	*Ketorolac is recommended only for patients less than 65 years old. [B, C]

Product Name: Brand Pennsaid topical solution, Generic diclofenac topical solution	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of osteoarthritis of the knee(s)

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to at least two prescription strength oral NSAIDs (e.g., diclofenac, diclofenac ER, ibuprofen, indomethacin, etc.)

OR

2.2 Documented swallowing disorder

OR

2.3 History of peptic ulcer disease/gastrointestinal bleed

OR

2.4 Patient is older than 65 years of age with one additional risk factor for gastrointestinal adverse events (e.g., use of anticoagulants, chronic corticosteroids)

AND

3 - Trial and failure, contraindication, or intolerance to both of the following: (applies to Brand Pennsaid only)

- generic topical diclofenac 1.5% solution
- generic topical diclofenac 2% solution

Product Name: Brand Pennsaid topical solution, Generic diclofenac topical solution	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response (e.g., improvement in pain symptoms of osteoarthritis) to therapy

Product Name: Tivorbex*, Brand Diclofenac 50mg, Brand Indomethacin 20mg, Cambia**^, Brand Celebrex, Indocin, Lofena, Vivlodex, Zorvolex, Brand diclofenac 35mg capsule, Meloxicam oral suspension 7.5mg/5mL, Brand Zipsor, generic diclofenac 25mg capsule	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - Trial and failure (of a minimum 30 day supply), contraindication, or intolerance to two of the following: • diclofenac potassium tab or diclofenac sodium • diflunisal • etodolac • fenoprofen • flurbiprofen • ibuprofen • indomethacin • ketoprofen • ketorolac • meclofenamate • meloxicam • nabumetone • naproxen • oxaprozin • piroxicam • sulindac • tolmetin • celecoxib	
Notes	*Per the American Geriatrics Society 2012 updated Beers criteria, chronic use of NSAIDs, including indomethacin, is not recommended for patients greater than or equal to 65 years old unless other alternatives are not effective and patient can take gastroprotective agent (proton pump inhibitor or misoprostol) [B] **Per the American Geriatrics Society 2012 updated Beers criteria, chronic use of NSAIDs, including diclofenac, is not recommended for patients greater than or equal to 65 years old unless other alternatives are not effective and patient can take gastroprotective agent (proton pump inhibitor or misoprostol) [B] ^Product may be excluded depending on the plan.

3 . Endnotes

A. The total duration of use of Sprix alone or sequentially with other formulations of ketorolac (IM/IV or oral) must not exceed 5 days because of the potential for increasing the frequency and severity of adverse reactions associated with the recommended doses. Treat patients for the shortest duration possible, and do not exceed 5 days of therapy with Sprix. [1]
B. This drug is included on the 2012 Beers Criteria for Potentially Inappropriate Medication Use in Older Adults greater than or equal to 65 years old. [3]
C. This drug is included on the 2013 Health Plan Employer Data and Information Set (HEDIS) list of high-risk medications in the elderly (greater than or equal to 65 years old) [4]

4 . References

1. Sprix prescribing information. Zyla Life Sciences US Inc. Wayne, PA. March 2022.
2. Pennsaid prescribing information. Horizon Therapeutics USA, Inc. Lake Forest, IL. February 2022.
3. The American Geriatrics Society 2012 Beers Criteria Update Expert Panel. American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc. 2012 Apr;60(4):616-31.
4. The National Committee for Quality Assurance (NCQA). Use of high-risk medications in the elderly (DAE). Available at www.ncqa.org. Accessed March 9, 2022.
5. Tivorbex prescribing information. Iroko Pharmaceuticals LLC, Philadelphia, PA. January 2020.
6. Cambia prescribing information. Depomed, Inc, Newark, CA. October 2019.
7. Vivlodex prescribing information. Egalet US Inc. Wayne PA. April 2021.
8. Indocin prescribing information. Iroko Pharmaceuticals, LLC. Philadelphia, PA. October 2018.
9. Zorvolex prescribing information. Zyla Life Sciences US Inc. Wayne, PA. April 2021.
10. Lofena Prescribing Information. Carwin Pharmaceutical Associates, LLC. Hazlet, NJ. July 2021.
11. Diclofenac Sodium Solution Prescribing Information. Apotex Corporation. Weston, FL. April 2022.
12. Meloxicam Oral Suspension Prescribing Information. Avondale Pharmaceuticals, LLC. Birmingham, AL. June 2022.

5 . Revision History

Date	Notes
4/26/2023	updated guideline

Prior Authorization Guideline

Guideline Name	Nplate (romiplostim)

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	4/7/2009
P&T Revision Date:	02/13/2020 ; 02/18/2021 ; 04/21/2021 ; 02/17/2022 ; 2/16/2023

1 . Indications

Drug Name: Nplate (romiplostim)
Immune Thrombocytopenia (ITP) Indicated for the treatment of thrombocytopenia in adult patients with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy and in pediatric patients 1 year of age and older with ITP for at least 6 months who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Limitations of Use: - Nplate is not indicated for the treatment of thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than ITP. - Nplate should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increases the risk for bleeding. - Nplate should not be used in an attempt to normalize platelet counts. **Hematopoietic Syndrome of Acute Radiation Syndrome** Indicated to increase survival in adults and in pediatric patients (including term neonates) acutely exposed to myelosuppressive doses of radiation.

2 . Criteria

Product Name: Nplate	
Diagnosis	Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Immune thrombocytopenia (ITP) [A]
- Relapsed/refractory ITP [4]

AND

2 - Baseline platelet count is less than 30,000/mcL [2-4]

AND

3 - Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding

AND

4 - Trial and failure, contraindication, or intolerance to one of the following: [2]

- Corticosteroids (e.g., dexamethasone, prednisone)
- Immune globulins (e.g., Gammaplex, Gammagard S/D)
- Splenectomy

AND

5 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Nplate

Diagnosis	Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding

Product Name: Nplate	
Diagnosis	Hematopoietic Syndrome of Acute Radiation Syndrome
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hematopoietic syndrome of acute radiation syndrome

AND

2 - Patient is acutely exposed to myelosuppressive doses of radiation

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

3 . Endnotes

A. ITP has previously been called idiopathic thrombocytopenic purpura, immune thrombocytopenic purpura, or autoimmune thrombocytopenic purpura (AITP). These terms have been replaced by "immune thrombocytopenia" to reflect the known autoantibody mechanism and the absence of purpura in some patients. [5]

4 . References

1. Nplate Prescribing Information. Amgen Inc. Thousand Oaks, CA. February 2022.
2. Kuter DJ, Bussel JB, Lyons RM, et al. Efficacy of romiplostim in patients with chronic immume thrombocytopenic purpura: a double-blind randomised controlled trial. Lancet. 2008; 371:395-403.
3. American Society of Hematology 2019 guidelines for immune thrombocytopenia. Available at: https://ashpublications.org/bloodadvances/article/3/23/3829/429213/American-Society-of-Hematology-2019-guidelines-for. Accessed December 9, 2022.
4. Per clinical consult with hematologist/oncologist, June 20, 2018.
5. Immune thrombocytopenia (ITP) in adults: Clinical manifestations and diagnosis. UpToDate Website. Available at: www.uptodate.com. Accessed December 9, 2022.

5 . Revision History

Date	Notes
2/1/2023	Annual review: Background updates.

Prior Authorization Guideline

Guideline Name	Nucala (mepolizumab)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	11/17/2015
P&T Revision Date:	08/15/2019 ; 11/14/2019 ; 02/13/2020 ; 12/16/2020 ; 03/17/2021 ; 09/15/2021 ; 03/16/2022 ; 07/20/2022 ; 05/19/2022 ; 5/18/2023

1 . Indications

Drug Name: Nucala (mepolizumab)
Severe Eosinophilic Asthma Indicated for the add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype. Limitations of Use: Nucala is not indicated for the relief of acute bronchospasm or status asthmaticus. **Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)** Indicated for the add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids. **Eosinophilic Granulomatosis with Polyangiitis** Indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA). **Hypereosinophilic Syndrome** Indicated for the treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for greater than or equal to 6 months without an identifiable non-hematologic secondary cause.

2 . Criteria

Product Name: Nucala	
Diagnosis	Severe Asthma
Approval Length	6 Months [G]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe asthma [1, A]

AND

2 - Asthma is an eosinophilic phenotype as defined by one of the following [1, 3, B]:

- Baseline (pre-treatment) peripheral blood eosinophil level is greater than or equal to 150 cells/microliter
- Peripheral blood eosinophil levels were greater than or equal to 300 cells/microliter within the past 12 months

AND

3 - One of the following:

3.1 Patient has had at least two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months [2-4, H]

OR

3.2 Prior asthma-related hospitalization within the past 12 months

AND

4 - Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications [2-4, D]:

4.1 Both of the following:

- High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium)

OR

4.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Symbicort [budesonide/formoterol], Breo Ellipta [fluticasone/vilanterol])

AND

5 - Age greater than or equal to 6 years [1]

AND

6 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name: Nucala	
Diagnosis	Severe Asthma
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications) [C]

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications

AND

3 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name: Nucala	
Diagnosis	Chronic rhinosinusitis with nasal polyps (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP)

AND

2 - Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone) [10, 11]

AND

3 - Used in combination with another agent for CRSwNP [J]

AND

4 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Otolaryngologist
- Pulmonologist

Product Name: Nucala	
Diagnosis	Chronic rhinosinusitis with nasal polyps (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS; 0-8 scale], improvement in nasal obstruction symptoms via visual analog scale [VAS; 0-10 scale])

AND

2 - Used in combination with another agent for CRSwNP [J]

AND

3 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Otolaryngologist
- Pulmonologist

Product Name: Nucala

Diagnosis	Eosinophilic Granulomatosis with Polyangiitis (EGPA)
Approval Length	12 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA)

AND

2 - Patient's disease has relapsed or is refractory to standard of care therapy (i.e., corticosteroid treatment with or without immunosuppressive therapy) [F, 7]

AND

3 - Patient is currently receiving corticosteroid therapy (e.g., prednisolone, prednisone) [F, 7]

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Rheumatologist
- Allergist/Immunologist

Product Name: Nucala	
Diagnosis	Eosinophilic Granulomatosis with Polyangiitis (EGPA)
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., increase in remission time)

Product Name: Nucala	
Diagnosis	Hypereosinophilic Syndrome (HES)
Approval Length	12 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hypereosinophilic syndrome (HES)

AND

2 - Patient has been diagnosed for at least 6 months

AND

3 - Verification that other non-hematologic secondary causes have been ruled out (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy)

AND

4 - Patient is Fip1-like1-platelet-derived growth factor receptor alpha (FIP1L1-PDGFRA)-negative

AND

5 - Patient has uncontrolled HES defined as both of the following:

- History of 2 or more flares within the past 12 months [I]
- Pre-treatment blood eosinophil count greater than or equal to 1000 cells/microliter

AND

6 - Trial and failure, contraindication, or intolerance to one of the following:

- Corticosteroid therapy (e.g., prednisone)
- Cytotoxic/immunosuppressive therapy (e.g., hydroxyurea, cyclosporine, imatinib)

AND

7 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Hematologist

Product Name: Nucala	
Diagnosis	Hypereosinophilic Syndrome (HES)
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduction in flares, decreased blood eosinophil count, reduction in corticosteroid dose)

3 . Background

Clinical Practice Guidelines

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 1. Low, medium and high daily doses of inhaled corticosteroids in adolescents and adults 12 years and older [6]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)

	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	> 500-1000	> 1000
Beclometasone dipropionate (DPI or pMDI, extrafine particle*, HFA)	100-200	> 200-400	> 400
Budesonide (DPI, or pMDI, standard particle, HFA)	200-400	> 400-800	> 800
Ciclesonide (pMDI, extrafine particle*, HFA)	80-160	> 160-320	> 320
Fluticasone furoate (DPI)	100		200
Fluticasone propionate (DPI)	100-250	> 250-500	> 500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	> 250-500	> 500
Mometasone furoate (DPI)	Depends on DPI device – see product information		
Mometasone furoate (pMDI, standard particle, HFA)	200-400		> 400

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.

***This is not a table of equivalence**,* but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply potency equivalence. Doses may be country -specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

4 . Endnotes

A. Patients included across the 3 pivotal studies (DREAM, MENSA, and SIRIUS) [2-4] were characterized with clinical features of severe refractory asthma per American Thoracic Society (ATS) criteria [5]. Per the ATS: "Severe asthma is defined as asthma which

requires treatment with high dose inhaled corticosteroids (ICS) plus a second controller (and/or systemic corticosteroids) to prevent it from becoming ‘uncontrolled’ or which remains ‘uncontrolled’ despite this therapy.’’ This definition includes patients who received an adequate trial of these therapies in whom treatment was stopped due to lack of response. In patients greater than 6 years of age, ‘‘Gold Standard/International Guidelines treatment’’ is high dose ICS plus a long-acting beta 2-agonist (LABA), leukotriene modifier or theophylline and/or continuous or near continuous systemic corticosteroids as background therapy."

B. Inclusion criteria was modified from the DREAM study to the MENSA study to be limited to patients with eosinophils greater than or equal to 150 cells/mcL in the peripheral blood at screening or greater than or equal to 300 cells/mcL at some time during the previous year [3].
C. The primary endpoint for the DREAM and MENSA studies was the annual rate of clinically significant asthma exacerbations as a composite of the required use of systemic corticosteroids for at least 3 days, admission, or ED visit. Both studies showed mepolizumab-treated patients experienced a significant improvement in exacerbation rates compared with baseline and compared with placebo. [2, 3]
D. The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention update lists anti-interleukin- 5 treatment or anti-interleukin 5 receptor treatment as an add on option for patients with severe eosinophilic asthma that is uncontrolled on two or more controllers plus as-needed reliever medication (Step 4-5 treatment). [6]
E. Asthma treatment can often be reduced, once good asthma control has been achieved and maintained for three months and lung function has hit a plateau. However the approach to stepping down will depend on patient specific factors (e.g., current medications, risk factors). At this time evidence for optimal timing, sequence and magnitude of treatment reductions is limited. It is feasible and safe for most patients to reduce the ICS dose by 25-50% at three month intervals, but complete cessation of ICS is associated with a significant risk of exacerbations [6].
F. Nucala was approved for Eosinophilic Granulomatosis with Polyangiitis (EGPA) based on the results from the pivotal, 52-week, Phase III MIRRA study. MIRRA looked at the efficacy and safety of 300 mg of mepolizumab administered SQ every four weeks versus placebo as add-on therapy to standard of care (corticosteroids plus or minus immunosuppressants) in 136 patients with relapsing and/or refractory EGPA. MIRRA reported statistically significant outcomes with both co-primary endpoints (i.e., accrued time in remission and proportion of patients achieving remission) in favor of the treatment group [7, 8].
G. The GINA Global Strategy for Asthma Management and Prevention update recommends that patients with asthma should be reviewed regularly to monitor their symptom control, risk factors and occurrence of exacerbations, as well as to document the response to any treatment changes. Ideally, response to Type 2-targeted therapy should be re-evaluated every 3-6 months, including re-evaluation of the need for ongoing biologic therapy for patients with good response to Type 2 targeted therapy. [6]
H. Per P&T Committee, February 2019, revised exacerbation requirement to mirror other IL-5 antagonists.
I. Historical flares were defined as a worsening of HES-related clinical symptoms or a blood eosinophil count requiring an escalation in therapy. [1]
J. Other agents used for CRSwNP include intranasal corticosteroids and nasal saline.

5 . References

1. Nucala prescribing information. GlaxoSmithKline LLC. Philadelphia, PA. March 2023.
2. Pavord ID, Korn S, Howarth P, et al. Mepolizumab for severe eosinophilic asthma (DREAM): a multicentre, double-blind, placebo-controlled trial. Lancet. 2012;380: 651-59.
3. Ortega HG, Liu MC, Pavord ID, et al. Mepolizumab treatment in patients with severe eosinophilic asthma. N Engl J Med. 2014;371(13):1198-1207.
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8. GlaxoSmithKline Press Release. GSK achieves approval for Nucala (mepolizumab) for the treatment of eosinophilic granulomatosis with polyangiitis (EGPA) for adults in the US. Website. Available from: https://www.gsk.com/en-gb/media/press-releases/gsk-achieves-approval-for-nucala-mepolizumab-for-the-treatment-of-eosinophilic-granulomatosis-with-polyangiitis-egpa-for-adults-in-the-us/. Accessed March 11, 2021.
9. ClinicalTrials.gov Web site. https://clinicaltrials.gov/ct2/show/NCT03085797. Accessed August 15, 2021.
10. Peters AT, Spector S, Hsu J, et al. Diagnosis and management of rhinosinusitis: a practice parameter update. Ann Allergy Asthma Immunol. 2014;113(4):347-85.
11. Orlandi RR, Kingdom TT, Hwang PH, et al. International consensus statement on allergy and rhinology: rhinosinusitis. Int Forum Allergy Rhinol. 2016 Feb; Suppl 1:S22-209.

6 . Revision History

Date	Notes
4/24/2023	2023 UM Annual Review. No criteria changes. Background updates

Prior Authorization Guideline

Guideline Name	Octreotide Products - PA, NF

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	1/19/2001
P&T Revision Date:	11/14/2019 ; 07/15/2020 ; 09/16/2020 ; 12/16/2020 ; 11/18/2021 ; 01/19/2022 ; 11/17/2022

1 . Indications

Drug Name: Sandostatin (octreotide acetate)
Acromegaly Indicated to reduce blood levels of growth hormone and IGF-1 (somatomedin C) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses. The goal is to achieve normalization of growth hormone and IGF-I (somatomedin C) levels. In patients with acromegaly, Sandostatin reduces growth hormone to within normal ranges in 50% of patients and reduces IGF-I (somatomedin C) to within normal ranges in 50%-60% of patients. Since the effects of pituitary irradiation may not become maximal for several years, adjunctive therapy with Sandostatin to reduce blood levels of growth hormone and IGF-I (somatomedin C) offers potential benefit before the effects of irradiation are manifested. Improvement in clinical signs and symptoms, or reduction in tumor size or rate of growth, were not shown in clinical trials performed with Sandostatin; these trials were not optimally designed to detect such effects. **Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing** Indicated for the symptomatic treatment of patients with metastatic carcinoid tumors where it suppresses or inhibits the severe diarrhea and flushing episodes associated with the disease. Sandostatin studies were not designed to show an effect on the size, rate of growth or development of metastases.

Vasoactive Intestinal Peptide Tumors (VIPomas), for Symptomatic Treatment of Diarrhea Indicated for the treatment of the profuse watery diarrhea associated with VIP-secreting tumors. Sandostatin studies were not designed to show an effect on the size, rate of growth or development of metastases.

Drug Name: Sandostatin LAR Depot (octreotide acetate)

General Indicated in patients in whom initial treatment with Sandostatin Injection has been shown to be effective and tolerated.

Acromegaly Indicated for long-term maintenance therapy in acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option. The goal of treatment in acromegaly is to reduce GH and IGF-1 levels to normal.

Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing Indicated for long-term treatment of the severe diarrhea and flushing episodes associated with metastatic carcinoid tumors. Limitation of Use: The effect of Sandostatin LAR on tumor size, rate of growth and development of metastases, has not been determined.

Vasoactive Intestinal Peptide Tumors (VIPomas), for Symptomatic Treatment of Diarrhea Indicated for long-term treatment of the profuse watery diarrhea associated with VIP-secreting tumors. Limitation of Use: The effect of Sandostatin LAR on tumor size, rate of growth and development of metastases, has not been determined.

Drug Name: Bynfezia (octreotide acetate injection)

Acromegaly Indicated to reduce blood levels of growth hormone (GH) and insulin-like growth factor 1 (IGF-1) [somatomedin C] in adult patients with acromegaly who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses. Limitations of Use: In patients with acromegaly, the effect of Bynfezia Pen on improvement in clinical signs and symptoms, reduction in tumor size, and rate of growth has not been determined.

Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing Indicated for the treatment of adult patients with severe diarrhea and flushing episodes associated with metastatic carcinoid tumors. Limitations of Use: In patients with carcinoid syndrome, the effect of Bynfezia Pen on the tumor size, rate of growth and development of metastases has not been determined.

Vasoactive Intestinal Peptide Tumors (VIPomas), for Symptomatic Treatment of Diarrhea Indicated for the treatment of adult patients with the profuse watery diarrhea associated with VIP-secreting tumors. Limitations of Use: In patients with VIPomas, the effect of Bynfezia Pen on the tumor size, rate of growth and development of metastases has not been determined.

Drug Name: Mycapssa (octreotide capsule, delayed release)

Acromegaly Indicated for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide.

2 . Criteria

Product Name: Brand Sandostatin, Generic octreotide, Sandostatin LAR, Bynfezia	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - One of the following:

2.1 Inadequate response to one of the following:

- Surgery
- Pituitary irradiation

OR

2.2 Not a candidate for surgical resection or pituitary irradiation

AND

3 - Trial and failure, contraindication, or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses

AND

4 - One of the following:

4.1 Patient has had a trial of short-acting generic octreotide and responded to and tolerated therapy (Applies to Sandostatin LAR only)

OR

4.2 Trial and failure, or intolerance to generic octreotide (Applies to Brand Sandostatin and Bynfezia only)

Product Name: Mycapssa	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - One of the following:

2.1 Inadequate response to one of the following:

- Surgery
- Pituitary irradiation

OR

2.2 Not a candidate for surgical resection or pituitary irradiation

AND

3 - Patient has responded to and tolerated treatment with generic octreotide or lanreotide

Product Name: Brand Sandostatin, Generic octreotide, Sandostatin LAR, Bynfezia, Mycapssa	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size)

Product Name: Brand Sandostatin, Bynfezia	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - One of the following:

2.1 Inadequate response to one of the following:

- Surgery
- Pituitary irradiation

OR

2.2 Not a candidate for surgical resection or pituitary irradiation

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic octreotide

Product Name: Mycapssa	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - One of the following:

2.1 Inadequate response to one of the following:

- Surgery
- Pituitary irradiation

OR

2.2 Not a candidate for surgical resection or pituitary irradiation

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming patient has responded to and tolerated treatment with generic octreotide or lanreotide

Product Name: Brand Sandostatin, Generic octreotide, Sandostatin LAR, Bynfezia	
Diagnosis	Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea or flushing episodes

AND

2 - One of the following:

2.1 Patient has had a trial of short-acting generic octreotide and responded to and tolerated therapy (Applies to Sandostatin LAR only)

OR

2.2 Trial and failure, or intolerance to generic octreotide (Applies to Brand Sandostatin and Bynfezia only)

Product Name: Brand Sandostatin, Generic octreotide, Sandostatin LAR, Bynfezia	
Diagnosis	Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of an improvement in the number of diarrhea or flushing episodes

Product Name: Brand Sandostatin, Bynfezia	
Diagnosis	Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea or flushing episodes

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic octreotide

Product Name: Brand Sandostatin, Generic octreotide, Sandostatin LAR, Bynfezia	
Diagnosis	Vasoactive Intestinal Peptide Tumors, for Symptomatic Treatment of Diarrhea
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea

AND

2 - One of the following:

2.1 Patient has had a trial of short-acting generic octreotide and responded to and tolerated therapy (Applies to Sandostatin LAR only)

OR

2.2 Trial and failure, or intolerance to generic octreotide (Applies to Brand Sandostatin and Bynfezia only)

Product Name: Brand Sandostatin, Generic octreotide, Sandostatin LAR, Bynfezia	
Diagnosis	Vasoactive Intestinal Peptide Tumors, for Symptomatic Treatment of Diarrhea
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of an improvement in the number of diarrhea episodes

Product Name: Brand Sandostatin, Bynfezia	
Diagnosis	Vasoactive Intestinal Peptide Tumors, for Symptomatic Treatment of Diarrhea
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic octreotide

3 . References

1. Sandostatin Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. May 2021.
2. Sandostatin LAR Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. March 2021.
3. Octreotide Prescribing Information. Mylan Institutional LLC. Morgantown, WV. June 2021.
4. Bynfezia Prescribing Information. Sun Pharmaceutical Industries, Inc. Cranbury, NJ. April 2020.
5. Mycapssa Prescribing Information. MW Encap Ltd. Scotland, UK. June 2020.

4 . Revision History

Date	Notes
11/22/2022	Annual review: no criteria changes.

Prior Authorization Guideline

Guideline Name	Odomzo (sonidegib)

Guideline Note:

Effective Date:	11/1/2022
P&T Approval Date:	10/13/2015
P&T Revision Date:	09/16/2020 ; 09/15/2021 ; 9/21/2022

1 . Indications

Drug Name: Odomzo (sonidegib)
Locally advanced basal cell carcinoma (BCC) Indicated for the treatment of adult patients with locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy.

2 . Criteria

Product Name: Odomzo	
Diagnosis	Basal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of locally advanced basal cell carcinoma [2]

AND

2 - One of the following:

- Cancer has recurred following surgery or radiation therapy
- Patient is not a candidate for surgery or radiation therapy

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist [A]
- Oncologist

Product Name: Odomzo	
Diagnosis	Basal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. Verified with consultant that other specialists such as Dermatologists may prescribe sonidegib in addition to Oncologists. [3]

4 . References

1. Odomzo Prescribing Information. Sun Pharmaceutical Industries, Inc. Cranbury, NJ. May 2019.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Basal Cell Skin Cancer. v.2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nmsc.pdf. Accessed August 13, 2021.
3. Per clinical consult with oncologist, February 24, 2011.

5 . Revision History

Date	Notes
9/8/2022	Annual Review - No criteria updates

Prior Authorization Guideline

Guideline Name	Olumiant (baricitinib) - PA, NF

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	8/16/2018
P&T Revision Date:	09/18/2019 ; 10/16/2019 ; 12/18/2019 ; 04/15/2020 ; 09/16/2020 ; 04/21/2021 ; 07/21/2021 ; 10/20/2021 ; 03/16/2022 ; 04/20/2022 ; 06/15/2022 ; 08/18/2022 ; 10/19/2022 ; 12/14/2022 ; 4/19/2023

1 . Indications

Drug Name: Olumiant (baricitinib)
Rheumatoid Arthritis (RA) Indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) blockers. Limitation of Use: Not recommended for use in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine. **Coronavirus Disease 2019 (COVID-19)** Indicated for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). **Alopecia Areata (AA)** Indicated for the treatment of adult patients with severe alopecia areata. Limitations of Use: Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.

2 . Criteria

Product Name: Olumiant	
Diagnosis	Rheumatoid Arthritis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide
- sulfasalazine

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia, Enbrel, Humira, Amjevita, Simponi)

AND

5 - One of the following:

5.1 All of the following:

5.1.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab) or Amjevita (adalimumab-atto)
- Rinvoq (upadacitinib)
- Simponi (golimumab)
- Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER)

AND

5.1.2 Trial and failure, contraindication, or intolerance to BOTH of the following:

- Actemra (tocilizumab)
- Orencia (abatacept)

OR

5.2 For continuation of prior Olumiant therapy, defined as no more than a 45-day gap in therapy

AND

6 - Not used in combination with other Janus kinase (JAK) inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)**

Notes	*Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T NF inhibitor. **Olumiant may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral co rticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Olumiant	
Diagnosis	Rheumatoid Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)**

Notes	**Olumiant may be used with concomitant methotrexate, topical or inh aled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Olumiant	
Diagnosis	Rheumatoid Arthritis
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide
- sulfasalazine

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia, Enbrel, Humira, Amjevita, Simponi)

AND

5 - One of the following:

5.1 All of the following:

5.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab) or Amjevita (adalimumab-atto)
- Rinvoq (upadacitinib)
- Simponi (golimumab)
- Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER)

AND

5.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to BOTH of the following:

- Actemra (tocilizumab)
- Orencia (abatacept)

OR

5.2 Both of the following:

5.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Olumiant therapy, defined as no more than a 45-day gap in therapy

AND

5.2.2 Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

6 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)**

Notes	*Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor. **Olumiant may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Olumiant	
Diagnosis	Coronavirus disease 2019 (COVID-19)
Approval Length	14 Day(s)
Guideline Type	Prior Authorization, Non Formulary

Approval Criteria

1 - Diagnosis of COVID-19

AND

2 - Patient is hospitalized

AND

3 - Patient requires one of the following:

- Supplemental oxygen
- Non-invasive mechanical ventilation
- Invasive mechanical ventilation
- Extracorporeal membrane oxygenation (ECMO)

Product Name: Olumiant	
Diagnosis	Alopecia Areata
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of alopecia areata

AND

2 - Patient has at least 50% scalp hair loss [1, 4]

AND

3 - Other causes of hair loss have been ruled out (e.g., androgenetic alopecia, trichotillomania, tinea capitis, psoriasis) [4]

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - Not used in combination with other Janus kinase (JAK) inhibitors, biologic immunomodulators, cyclosporine, or potent immunosuppressants (e.g., azathioprine)*

Notes	*Olumiant may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Olumiant	
Diagnosis	Alopecia Areata
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Not used in combination with other Janus kinase (JAK) inhibitors, biologic immunomodulators, cyclosporine, or potent immunosuppressants (e.g., azathioprine)*

Notes	*Olumiant may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Olumiant	
Diagnosis	Alopecia Areata
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of alopecia areata

AND

2 - Patient has at least 50% scalp hair loss [1, 4]

AND **3** - Other causes of hair loss have been ruled out (e.g., androgenetic alopecia, trichotillomania, tinea capitis, psoriasis) [4] **AND** **4** - Prescribed by or in consultation with a dermatologist **AND** **5** - Not used in combination with other Janus kinase (JAK) inhibitors, biologic immunomodulators, cyclosporine, or potent immunosuppressants (e.g., azathioprine)*	
Notes	*Olumiant may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

3 . References

1. Olumiant Prescribing Information. Eli Lilly and Company. Indianapolis, IN. June 2022.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.
3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.
4. King B, Ohyama M, Kwon O, et al. Two phase 3 trials of baricitinib for alopecia areata. N Engl J Med 2022;386:1687-99.

4 . Revision History

Date	Notes
4/5/2023	Annual review - no criteria changes; background updates

Prior Authorization Guideline

Guideline Name	Omega-3-Acid Derivatives

Guideline Note:

Effective Date:	11/1/2022
P&T Approval Date:	9/18/2019
P&T Revision Date:	01/15/2020 ; 03/18/2020 ; 09/16/2020 ; 12/16/2020 ; 09/15/2021 ; 11/18/2021 ; 09/21/2022 ; 10/19/2022

1 . Indications

Drug Name: Vascepa (icosapent ethyl)
Severe Hypertriglyceridemia Indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (greater than or equal to 500 mg/dL) hypertriglyceridemia. Limitations of Use: The effect of Vascepa on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined. The effect of Vascepa on cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined. **Prevention of Cardiovascular Events** Indicated as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (greater than or equal to 150 mg/dL) and 1) established cardiovascular disease or 2) diabetes mellitus and 2 or more additional risk factors for cardiovascular disease.
Drug Name: Lovaza (omega-3-acid ethyl esters)
Severe Hypertriglyceridemia Indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (greater than or equal to 500 mg per dL) hypertriglyceridemia (HTG). Usage Considerations: Patients should be placed on an appropriate lipid-lowering diet before receiving Lovaza and should continue this diet during treatment with Lovaza. Limitations of Use: The effect of Lovaza on the risk for pancreatitis has

not been determined. The effect of Lovaza on cardiovascular mortality and morbidity has not been determined.

2 . Criteria

Product Name: Brand Lovaza, Brand Vascepa, Generic icosapent ethyl	
Diagnosis	Severe Hypertriglyceridemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hypertriglyceridemia

AND

2 - Patient has a pre-treatment triglyceride level greater than or equal to 500 mg/dL

AND

3 - Applies to Brand Lovaza ONLY: Trial and failure, contraindication or intolerance to generic omega-3-acid ethyl esters

Product Name: Brand Lovaza, Brand Vascepa, Generic icosapent ethyl	
Diagnosis	Severe Hypertriglyceridemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Brand Vascepa, Generic icosapent ethyl	
Diagnosis	Prevention of Cardiovascular Events
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of hypertriglyceridemia

AND

1.2 Patient has a pre-treatment triglyceride level of 150 mg/dL to 499 mg/dL [2,3]

AND

2 - One of the following:

2.1 Patient has established cardiovascular disease (CVD) (e.g., coronary artery disease, cerebrovascular or carotid disease, peripheral artery disease, etc.) [2]

OR

2.2 Both of the following:

2.2.1 Diagnosis of diabetes mellitus [2]

AND

2.2.2 Patient has two or more risk factors for developing cardiovascular disease (see background section for definitions) [2, 4]

AND

3 - Medication will be used as an adjunct to maximally tolerated statin therapy, unless there is a contraindication or intolerance to statin therapy [2]

Product Name: Brand Vascepa, Generic icosapent ethyl	
Diagnosis	Prevention of Cardiovascular Events
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Medication continues to be used as an adjunct to maximally tolerated statin therapy, unless there is a contraindication or intolerance to statin therapy [2]

3 . Background

Benefit/Coverage/Program Information

REDUCE-IT Trial Inclusion Criteria for Secondary Prevention Risk Category (Established Cardiovascular Disease) [4]

Man or woman greater than or equal to 45 years of age with one or more of the following:

1. Documented **coronary artery disease** (CAD):

- Documented multi vessel CAD (greater than or equal to 50% stenosis in at least two major epicardial coronary arteries – with or without antecedent revascularization);
- Documented prior MI; or
- Hospitalization for high-risk non-ST-segment elevation acute coronary syndrome (NSTE-ACS) (with objective evidence of ischemia: ST-segment deviation or biomarker positivity).

2. Documented **cerebrovascular or carotid disease**:

- Documented prior ischemic stroke;
- Symptomatic carotid artery disease with greater than or equal to 50% carotid arterial stenosis;
- Asymptomatic carotid artery disease with greater than or equal to 70% carotid arterial stenosis per angiography or duplex ultrasound; or
- History of carotid revascularization (catheter-based or surgical).

3. Documented **peripheral arterial disease** (PAD):

- Ankle-brachial index (ABI) less than 0.9 with symptoms of intermittent claudication; or
- History of aorto-iliac or peripheral arterial intervention (catheter-based or surgical).

REDUCE-IT Trial definition of risk factors for cardiovascular disease

- Men greater than or equal to 55 years and women greater than or equal to 65 years
- Cigarette smoker or stopped smoking within the past 3 months
- Hypertension (pretreatment blood pressure greater than or equal to 140 mmHg systolic or greater than or equal to 90 mmHg diastolic)
- HDL-C less than or equal to 40 mg/dL for men or less than or equal to 50 mg/dL for women
- High-sensitivity C-reactive protein greater than 3.0 mg/L
- Creatinine clearance greater than 30 and less than 60 mL/min
- Retinopathy
- Micro- or macro-albuminuria

Definition of maximally tolerated statin therapy

- HIGH-INTENSITY statin therapy (i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg) or is unable to tolerage

  OR

- If unable to tolerate HIGH-INTENSITY statin, then MODERATE-INTENSITY statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 20-40 mg, pravastatin 40-80 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily, or Livalo (pitavastatin) 2-4 mg] or unable to tolerate

OR

- If unable to tolerate MODERATE-INTENSITY statin, then LOW-INTENSITY statin therapy [i.e., simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, Livalo (pitavastatin) 1 mg]

OR

- Unable to tolerate low- or moderate-, and high-intensity statins because of contraindications; intolerable and persistent (i.e., more than 2 weeks) symptoms for low- or moderate-, and high-intensity statins: Myalgia (muscle symptoms without CK elevations) or Myositis (muscle symptoms with CK elevations less than 10 times ULN); or rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN [A, 3]

4 . Endnotes

A. In patients treated with statins, it is recommended to measure creatine kinase levels in individuals with severe statin-associated muscle symptoms. [3]

5 . References

1. Lovaza prescribing information. GlaxoSmithKline. Research Triangle Park, NC. September 2020.
2. Vascepa prescribing information. Amarin Pharma Inc. Bedminster, NJ. December 2019.
3. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2019; 73:e285-e350.
4. Supplement to: Bhatt DL, Steg PG, Miller M, et al. Cardiovascular risk reduction with icosapent ethyl for hypertriglyceridemia. N Engl J Med 2019;380:11-22. DOI: 10.1056/NEJMoa1812792

6 . Revision History

Date	Notes
10/4/2022	Addition of new generic strength for Vascepa

Prior Authorization Guideline

Guideline Name	Oncology Admin - Optum Specialty Fusion & Cancer Guidance Program (MBM)

Guideline Note:

Effective Date:	3/1/2023
P&T Approval Date:	1/20/2021
P&T Revision Date:	01/19/2022 ; 07/20/2022 ; 1/18/2023

Note:

This guideline should be used for clients who have elected to participate in the Optum Specialty Fusion program or Medical Benefit Management (MBM) Cancer Guidance Program to review in scope drugs when used for cancer indications.

1 . Criteria

Product Name: In Scope Drug	
Diagnosis	Cancer Indications
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria	

1 - The drug is being used as indicated by National Comprehensive Cancer Network (NCCN) guidelines with a Category of Evidence and Consensus of 1, 2A, or 2B

2 . Revision History

Date	Notes
1/4/2023	Annual review: No updates required.

Prior Authorization Guideline

Guideline Name	Oncology Injectable

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	12/19/2018
P&T Revision Date:	02/13/2020 ; 03/18/2020 ; 08/13/2020 ; 03/17/2021 ; 10/20/2021 ; 11/18/2021 ; 03/16/2022 ; 09/21/2022 ; 10/19/2022 ; 01/18/2023 ; 03/15/2023 ; 5/18/2023

1 . Criteria

Product Name: Adcetris, Aliqopa, Arzerra, Blincyto, Cyramza, Elzonris, Erbitux, Keytruda, Margenza, Opdivo, Padcev, Portrazza, Rylaze, Tecentriq, Yervoy	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Prescribed medication is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.1.2 Both of the following labeling requirements have been confirmed:

1.1.2.1 All components of the FDA approved indication are met (e.g., concomitant use, previous therapy requirements, age limitations, testing requirements, etc.)

AND

1.1.2.2 Prescribed medication will be used at a dose which is within FDA recommendations

OR

1.2 Meets the off-label administrative guideline criteria

AND

2 - Prescribed by or in consultation with an oncologist

2 . Revision History

Date	Notes
5/1/2023	Program Update

Prior Authorization Guideline

Guideline Name	Onpattro (patisiran) & Tegsedi (inotersen)

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	10/17/2018
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Onpattro (patisiran), Tegsedi (inotersen)
Hereditary transthyretin-mediated amyloidosis Indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

2 . Criteria

Product Name: Onpattro or Tegsedi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) with polyneuropathy

AND

2 - Patient has a transthyretin (TTR) mutation (e.g., V30M) [1-4]

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - One of the following [2, 4]:

- Patient has a baseline polyneuropathy disability (PND) score ≤ IIIb
- Patient has a baseline familial amyloidotic polyneuropathy (FAP) stage of 1 or 2
- Patient has a baseline neuropathy impairment score (NIS) between 5 and 130 for Onpattro or a baseline neuropathy impairment score (NIS) between 10 and 130 for Tegsedi

AND

5 - Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy) [2, 4]

Product Name: Onpattro or Tegsedi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has demonstrated a benefit from therapy (e.g., improved neurologic impairment, slowing of disease progression, quality of life assessment)

AND

2 - One of the following [2, 4]:

- Patient continues to have a polyneuropathy disability (PND) score ≤ IIIb
- Patient continues to have a familial amyloidotic polyneuropathy (FAP) stage of 1 or 2
- Patient continues to have a neuropathy impairment score (NIS) between 5 and 130 for Onpattro or a neuropathy impairment score (NIS) between 10 and 130 for Tegsedi

3 . References

1. Onpattro Prescribing Information. Alnylam Pharmaceuticals, Inc. Cambridge, MA. January 2023.
2. Adams D, Suhr OB, Dyck PJ, et al. Trial design and rationale for APOLLO, a phase 3, placebo-controlled study of patisiran in patients with hereditary ATTR amyloidosis with polyneuropathy. BMC Neurol. 2017;17:181.
3. Tegsedi Prescribing Information. Akcea Therapeutics, Inc. Boston, MA. June 2022.
4. Benson MD, Waddington-Cruz M, Berk JL, et al. Inotersen treatment for patients with hereditary transthyretin amyloidosis. N Engl J Med. 2018;379(1):22-31.

4 . Revision History

Date	Notes
3/6/2023	2023 Annual Review.

Prior Authorization Guideline

Guideline Name	Onureg (azacitidine)

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	11/12/2020
P&T Revision Date:	11/18/2021 ; 11/17/2022

1 . Indications

Drug Name: Onureg (azacitidine)
Acute Myeloid Leukemia (AML) Indicated for continued treatment of adult patients with acute myeloid leukemia who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy.

2 . Criteria

Product Name: Onureg	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - Patient has received previous treatment with an intensive induction chemotherapy regimen (e.g., cytarabine + daunorubicin, cytarabine + idarubicin, etc.) [2]

AND

3 - Patient has achieved one of the following:

- first complete remission (CR)
- complete remission with incomplete blood count recovery (CRi)

AND

4 - Patient is not able to complete intensive curative therapy

AND

5 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Onureg	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Onureg prescribing information. Celgene Corporation. Summt, NJ. May 2021.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Acute Myeloid Leukemia. v4.2020. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed September 29, 2021.

4 . Revision History

Date	Notes
11/2/2022	2022 Annual Review

Prior Authorization Guideline

Guideline Name	Ophthalmic Antihistamines

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	11/16/2010
P&T Revision Date:	10/16/2019 ; 10/21/2020 ; 10/20/2021 ; 11/17/2022

1 . Indications

Drug Name: LASTACAFT (alcaftadine)
Allergic Conjunctivitis Indicated for the prevention of itching associated with allergic conjunctivitis.
Drug Name: ZERVIATE (cetirizine)
Allergic Conjunctivitis Indicated for the treatment of ocular itching associated with allergic conjunctivitis.

2 . Criteria

Product Name: Lastacaft, Zerviate	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure, contraindication, or intolerance to both of the following generics or preferred brands:

- azelastine
- olopatadine

3 . References

1. Lastacaft Prescribing Information. Allergan, Inc, Irvine, CA. June 2020.
2. Zerviate Prescribing Information. Eyevance Pharmaceuticals, Lakewood, NJ. June 2020.

4 . Revision History

Date	Notes
11/2/2022	2022 Annual Review

Prior Authorization Guideline

Guideline Name	Ophthalmic NSAIDs

Guideline Note:

Effective Date:	12/1/2022
P&T Approval Date:	11/16/2010
P&T Revision Date:	10/16/2019 ; 10/21/2020 ; 10/20/2021 ; 10/19/2022

1 . Indications

Drug Name: BROMSITE (bromfenac)
Postoperative Inflammation and Prevention of Ocular Pain Indicated for the treatment of postoperative inflammation and prevention of ocular pain in patients undergoing cataract surgery.
Drug Name: ILEVRO (nepafenac)
Postoperative inflammation Indicated for the treatment of pain and inflammation associated with cataract surgery.
Drug Name: NEVANAC (nepafenac)
Postoperative inflammation Indicated for the treatment of pain and inflammation associated with cataract surgery.

2 . Criteria

Product Name: Ilevro, Nevanac	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - One of the following:

2.1 Patient is greater than 10 but less than 18 years of age [A]

OR

2.2 Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to BOTH of the following:

2.2.1 One of the following generics:

- Diclofenac ophthalmic solution
- Flurbiprofen ophthalmic solution
- Ketorolac ophthalmic solution

AND

2.2.2 Prolensa

Product Name: Bromsite	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to BOTH of the following:

2.1 One of the following generics:

- Diclofenac ophthalmic solution
- Flurbiprofen ophthalmic solution
- Ketorolac ophthalmic solution

AND

2.2 Prolensa

3 . Endnotes

A. Pediatric patients age greater than10 but less than 18 years of age are allowed to bypass the trial and failure requirement because Ilevro and Nevanac are approved for this pediatric population, but not Bromsite. The safety and efficacy in pediatric patients below the age of 18 years have not been established for Bromsite. [1, 2, 3]

4 . References

1. Bromsite Prescribing Information. Sun Pharmaceutical Industries, Inc.; Cranbury, NJ. July 2021.
2. Ilevro Prescribing Information. Alcon Laboratories, Inc.; Fort Worth, TX. January 2019.
3. Nevanac Prescribing Information. Alcon Laboratories, Inc.; Fort Worth, TX. November 2020.

5 . Revision History

Date	Notes
10/6/2022	2022 UM Annual Review.

Prior Authorization Guideline

Guideline Name	Opioid Quantity Limit Overrides

Guideline Note:

Effective Date:	12/1/2022
P&T Approval Date:	2/16/2010
P&T Revision Date:	11/14/2019 ; 11/12/2020 ; 11/18/2021 ; 10/19/2022

Note:

Note: The Opioid Quantity Limit Override Administrative Guideline should be used for single opioids that do not have an FDA-maximum dose. For opioids with an FDA-maximum dose, such as APAP-containing opioid products, please refer to the standard Quantity Limit Override Administrative Guideline or the drug-specific guideline, if applicable.

1 . Criteria

Diagnosis	For Malignant Cancer Pain
Approval Length	5 year(s)
Guideline Type	Administrative
Approval Criteria	

1 - In the absence of an opioid-specific quantity limit override guideline, the following approval criteria will be used:

1.1 Diagnosis of malignant (cancer) pain*

Notes	Authorization will be issued for long-term therapy. *For oral fentanyl products, please refer to the drug-specific quantity limit override criteria in the “Oral Fentanyl Products” guideline.

Diagnosis	For Non-Malignant Pain
Approval Length	1 year(s)
Guideline Type	Administrative

Approval Criteria

1 - In the absence of an opioid-specific quantity limit override guideline, the following approval criteria will be used:

1.1 Prescribed by a pain specialist or by pain management consultation

AND

1.2 The prescriber maintains and provides chart documentation of the patient’s evaluation, including all of the following:

- An appropriate patient medical history and physical examination
- A description of the nature and intensity of the pain
- Documentation of appropriate dose escalation
- Documentation of ongoing, periodic review of the course of opioid therapy
- An updated, comprehensive treatment plan (the treatment plan should state objectives that will be used to determine treatment success, such as pain relief or improved physical and/or psychosocial function)
- Verification that the risks and benefits of the use of the controlled substance have been discussed with the patient, significant other(s), and/or guardian

2 . Revision History

Date	Notes

10/19/2022	Annual review

Prior Authorization Guideline

Guideline Name	Opioid Risk Management

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	
P&T Revision Date:	10/16/2019 ; 03/18/2020 ; 04/15/2020 ; 04/15/2020 ; 04/15/2020 ; 04/15/2020 ; 07/15/2020 ; 10/21/2020 ; 12/16/2020 ; 03/17/2021 ; 04/21/2021 ; 10/20/2021 ; 10/21/2021 ; 02/17/2022 ; 07/20/2022 ; 11/17/2022 ; 11/17/2022 ; 5/18/2023

1 . Criteria

Product Name: Short-Acting Opioids	
Diagnosis	Cancer or end-of-life care
Approval Length	12 month(s)
Guideline Type	Quantity Limit
Approval Criteria **1** - Diagnosis of cancer or end of life care	
Notes	Note: Patients with a cancer drug in their prescription claims history wi thin the previous 365 days will not be subject to a max daily dose, day

	supply, or fill restriction. Additionally, if criteria is approved patients wi ll not be subject to a max daily dose, day supply, or fill restriction.

Product Name: Short-Acting Opioids	
Diagnosis	Postoperative Pain Management
Approval Length	14 Day(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Medication is being used to treat postoperative pain

AND

2 - Medication is not being prescribed for pain related to a dental procedure

AND

3 - The dose being prescribed is the dose that the patient was stable on prior to discharge

Notes	*Patients with a cancer drug in their prescription claims history within t he previous 365 days will not be subject to a max daily dose, day sup ply, or fill restriction. Additionally, if criteria is approved patients will no t be subject to a max daily dose, day supply, or fill restriction.

Product Name: Short-Acting Opioids	
Diagnosis	All Other Diagnoses
Approval Length	6 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Prescriber certifies that there is an active treatment plan that includes but is not limited to a specific treatment objective and the use of other pharmacological and non-pharmacological agents for pain relief as appropriate

AND

2 - Prescriber certifies that there has been an informed consent document signed and an addiction risk assessment has been performed

AND

3 - Prescriber certifies that a written/signed agreement between prescriber and patient addressing issues of prescription management, diversion, and the use of other substances exists

Notes	Note: Patients with a cancer drug in their prescription claims history within the previous 365 days will not be subject to a max daily dose, day supply, or fill restriction. Additionally, if criteria is approved patients will not be subject to a max daily dose, day supply, or fill restriction. If the prescriber is unable to certify written documentation to meet criterion (2) and/or (3), written or verbal attestation from the provider may be accepted confirming that the prescriber (or prescriber's representative) has verbally addressed criterion (2) and/or (3) with the patient.

Product Name: Opioid Cough Medications	
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older

Product Name: Opioid Cough Medications*	
Diagnosis	Greater than the maximum dose as specified in the product prescribing information OR compendia for off-label uses (in the absence of a drug-specific guideline)*
Approval Length	60 Day(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - One of the following:

1.1 Quantity limit override requests must involve an FDA-approved indication

OR

1.2 Quantity limit override requests involving off-label indications must meet off-label guideline approval criteria

AND

2 - One of the following:

2.1 The maximum doses specified under the quantity restriction have been tried for an adequate period of time and been deemed ineffective in the treatment of the member's disease or medical condition

OR

2.2 If lower doses have not been tried, there is clinical support (i.e., clinical literature, patient attributes, or characteristics of the drug) that the number of doses available under the quantity restriction will be ineffective in the treatment of the member's disease or medical condition

AND

3 - One of the following:**

3.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

OR

3.2 Higher dose or quantity is supported by one of following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System

Notes	*This guideline only applies in the absence of a drug-specific quantity l imit override guideline. No override requests will be permitted for acet aminophen, alone or in combination with other agents, which will exce ed a total of 4 grams of acetaminophen per day. **NOTE: Published bi omedical literature may be used as evidence to support safety and ad ditional efficacy at higher than maximum doses for the diagnosis provi ded.

Product Name: Long Acting Opioids: Nucynta ER	
Diagnosis	Cancer or End-of-Life Care
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of cancer

OR

1.2 Patient is receiving opioids as part of end-of-life care

AND

2 - Trial and failure, contraindication or intolerance to at least two of the following preferred products

- Hydromorphone ER
- Morphine sulfate ER
- Oxymorphone ER
- Hysingla ER
- Oxycontin
- Xtampza ER

Notes	If the member does not meet the medical necessity reauthorization au thorization criteria requirements, a denial should be issued and a maxi mum 30-day authorization may be authorized one time for the request

	ed drug/strength combination up to the requested quantity and/or MM E for transition to an alternative treatment.

Product Name: Long Acting Opioids: Nucynta ER	
Diagnosis	Non-Cancer/End-of-Life Care Diagnosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Patient has moderate to severe chronic pain that is non-neuropathic

AND

1.1.2 One of the following:

1.1.2.1 For patients that are filling the prescribed medication for the first time, prior to the start of therapy with the prescribed medication, the patient has failed an adequate (minimum 4 week) trial of a short-acting opioid [Document drug(s), dose, duration and date of trial]

OR

1.1.2.2 Patient is established on the prescribed medication and this prescription is for continuation of therapy

OR

1.2 All of the following:

1.2.1 Patient has moderate to severe neuropathic pain or fibromyalgia

AND

1.2.2 Unless contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (Document drug(s), dose, duration and date of trial)

AND

1.2.3 Unless contraindicated, the patient has not exhibited an adequate response to at least 6-8 weeks of treatment with a tricyclic antidepressant (e.g., amitriptyline, nortriptyline, imipramine) titrated to a therapeutic dose (Document drug(s), dose, duration and date of trial)

AND

1.2.4 One of the following:

1.2.4.1 For patients that are filling the prescribed medication for the first time, prior to the start of therapy with the prescribed medication, the patient has failed an adequate (minimum 4 week) trial of a short-acting opioid [Document drug(s), dose, duration and date of trial]

OR

1.2.4.2 Patient is established on the prescribed medication and this prescription is for continuation of therapy

AND

2 - None of the following:

- For use as an as-needed PRN analgesic
- For pain that is mild or not expected to persist for an extended period of time
- For acute pain
- For postoperative pain, unless the patient is already receiving chronic opioid therapy prior to surgery, or if postoperative pain is expected to be moderate to severe and persist for an extended period of time

AND

3 - Trial and failure, contraindication or intolerance to at least two of the following preferred products

- Hydromorphone ER
- Morphine sulfate ER
- Oxymorphone ER
- Hysingla ER
- Oxycontin
- Xtampza ER

Notes	If the member does not meet the medical necessity reauthorization au thorization criteria requirements, a denial should be issued and a maxi mum 30-day authorization may be authorized one time for the request ed drug/strength combination up to the requested quantity and/or MM E for transition to an alternative treatment.

Product Name: Long Acting Opioids: Nucynta ER	
Diagnosis	Non-Cancer/End-of-Life Care Diagnosis
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation has been provided addressing ALL of the following

- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a nonopioid analgesic and/or nonpharmacologic intervention
- Patient demonstrates meaningful improvement in pain and function using a validated instrument (e.g., Brief Pain Inventory)
- Patient has been screened for substance abuse/opioid dependence using a validated instrument (e.g., DAST-10)
- Rationale for not tapering and discontinuing
- Patient has been screened for comorbid mental health
- If a state prescription drug monitoring program (PDMP) is available, the prescriber has identified there are no concurrently prescribed controlled substances from PDMP
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the

prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression • Total daily morphine equivalent dose	
Notes	If the member does not meet the medical necessity reauthorization au thorization criteria requirements, a denial should be issued and a maxi mum 30-day authorization may be authorized one time for the request ed drug/strength combination up to the requested quantity and/or MM E for transition to an alternative treatment.

Product Name: Long Acting Opioids: generic transdermal fentanyl patches, generic methadone 5 mg tablets, generic methadone 10 mg tablets, brand MS CONTIN, generic morphine sulfate ER, generic oxymorphone ER, Brand HYSINGLA ER, OXYCONTIN, generic oxycodone ER, Xtampza ER, generic hydrocodone ER, Generic Morphine Sulfate ER	
Diagnosis	Cancer or End-of-Life Care
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of cancer

OR

1.2 Patient is receiving opioids as part of end-of-life care

Product Name: Long Acting Opioids: generic transdermal fentanyl patches, generic methadone 5 mg tablets, generic methadone 10 mg tablets, brand MS CONTIN, generic morphine sulfate ER, generic oxymorphone ER, Brand HYSINGLA ER, OXYCONTIN, generic oxycodone ER, Xtampza ER, generic hydrocodone ER, Generic Morphine Sulfate ER	
Diagnosis	Non-Cancer/End of Life Care Diagnosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Patient has moderate to severe chronic pain that is non-neuropathic

AND

1.1.2 One of the following:

1.1.2.1 For patients that are filling the prescribed medication for the first time, prior to the start of therapy with the prescribed medication, the patient has failed an adequate (minimum 4 week) trial of a short-acting opioid [Document drug(s), dose, duration and date of trial]

OR

1.1.2.2 Patient is established on the prescribed medication and this prescription is for continuation of therapy

OR

1.2 All of the following:

1.2.1 Patient has moderate to severe neuropathic pain or fibromyalgia

AND

1.2.2 Unless contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (Document drug(s), dose, duration and date of trial)

AND

1.2.3 Unless contraindicated, the patient has not exhibited an adequate response to at least

6-8 weeks of treatment with a tricyclic antidepressant (e.g., amitriptyline, nortriptyline, imipramine) titrated to a therapeutic dose (Document drug(s), dose, duration and date of trial)

AND

1.2.4 One of the following:

1.2.4.1 For patients that are filling the prescribed medication for the first time, prior to the start of therapy with the prescribed medication, the patient has failed an adequate (minimum 4 week) trial of a short-acting opioid [Document drug(s), dose, duration and date of trial]

OR

1.2.4.2 Patient is established on the prescribed medication and this prescription is for continuation of therapy

AND

2 - None of the following:

- For use as an as-needed PRN analgesic
- For pain that is mild or not expected to persist for an extended period of time
- For acute pain
- For postoperative pain, unless the patient is already receiving chronic opioid therapy prior to surgery, or if postoperative pain is expected to be moderate to severe and persist for an extended period of time

Notes	If the member is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not m eet the medical necessity initial authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity and/or MME for transition to an alternative trea tment.

Product Name: Long Acting Opioids: generic transdermal fentanyl patches, generic methadone 5 mg tablets, generic methadone 10 mg tablets, brand MS CONTIN, generic morphine sulfate ER, generic oxymorphone ER, Brand HYSINGLA ER, OXYCONTIN, generic oxycodone ER, Xtampza ER, generic hydrocodone ER, Generic Morphine Sulfate ER	
Diagnosis	Non-Cancer/End-of-Life Care Diagnosis

Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation has been provided addressing ALL of the following:

- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a nonopioid analgesic and/or nonpharmacologic intervention
- Patient demonstrates meaningful improvement in pain and function using a validated instrument (e.g. Brief Pain Inventory)
- Patient has been screened for substance abuse/opioid dependence using a validated instrument (e.g. DAST-10)
- Rationale for not tapering and discontinuing opioid
- Patient has been screened for comorbid mental health conditions
- If a state prescription drug monitoring program (PDMP) is available, the prescriber has identified there are no concurrently prescribed controlled substances from PDMP
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- Total daily morphine equivalent dose

Notes	If the member does not meet the medical necessity reauthorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity and/or MME for transition to an alternative treatment.

Product Name: Brand Butrans, generic buprenorphine patch, Brand Belbuca*	
Diagnosis	Cancer or End-of-Life Care
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is being treated for cancer related pain or pain associated with end-of-life

Notes	*Prior authorization may not apply depending on the plan

Product Name: Brand Butrans, generic buprenorphine patch, Brand Belbuca*	
Diagnosis	Non- Cancer Pain
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is being treated for pain severe enough to require daily, around-the-clock, longer-term opioid treatment

AND

2 - None of the following:

- For use as an as-needed PRN analgesic
- For pain that is mild or not expected to persist for an extended period of time
- For acute pain
- For opioid dependence

AND

3 - The patient is not receiving other long-acting opioids concurrently

Notes	*Prior authorization may not apply depending on the plan. If the member is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity initial authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity and/or MME for transition to an alternative treatment.

Product Name: Brand Butrans, generic buprenorphine patch, Brand Belbuca*,	
Diagnosis	Non-Cancer Pain
Approval Length	6 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation has been provided addressing ALL of the following

- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a nonopioid analgesic and/or nonpharmacologic intervention
- Patient demonstrates meaningful improvement in pain and function using a validated instrument (e.g. Brief Pain Inventory)
- Patient has been screened for substance abuse/opioid dependence using a validated instrument (e.g. DAST-10)
- Rationale for not tapering and discontinuing opioid
- Patient has been screened for comorbid mental health conditions
- If a state prescription drug monitoring program (PDMP) is available, the prescriber has identified there are no concurrently prescribed controlled substances from PDMP
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- Total daily morphine equivalent dose

Notes	*Prior authorization may not apply depending on the plan. If the memb er does not meet the medical necessity reauthorization authorization c riteria requirements, a denial should be issued and a maximum 30-da y authorization may be authorized one time for the requested drug/str ength combination up to the requested quantity and/or MME for transit ion to an alternative treatment.

2 . References

1. Zohydro ER Prescribing Information.Currax Pharmaceuticals LLC. October 2019.

3 . Revision History

Date	Notes
5/22/2023	Removed inactive products

Prior Authorization Guideline

Guideline Name	Oral Fentanyl Products

Guideline Note:

Effective Date:	10/1/2022
P&T Approval Date:	11/16/2001
P&T Revision Date:	08/15/2019 ; 09/16/2020 ; 09/15/2021 ; 8/18/2022

1 . Indications

Drug Name: Abstral (fentanyl)
Breakthrough pain Indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, or at least 25 mcg of transdermal fentanyl/hour, or at least 30 mg of oral oxycodone daily, or at least 8 mg of oral hydromorphone daily or at least 25 mg oral oxymorphone daily, or an equianalgesic dose of another opioid medication daily for a week or longer. Patients must remain on around-the-clock opioids when taking Abstral. Limitations of Use: As a part of the TIRF REMS Access program, Abstral may be dispensed only to outpatients enrolled in the program. For inpatient administration of Abstral (e.g., hospitals, hospices, and long-term care facilities that prescribe for inpatient use), patient and prescriber enrollment is not required.
Drug Name: Actiq (fentanyl citrate) oral transmucosal lozenge
Breakthrough pain Indicated for the management of breakthrough pain in cancer patients 16 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily, at least 25 mg oral oxymorphone daily, or an

equianalgesic dose of another opioid daily for a week or longer. Patients must remain on around-the-clock opioids when taking Actiq. This product must not be used in opioid non-tolerant patients because life-threatening respiratory depression and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason, Actiq is contraindicated in the management of acute or postoperative pain. Actiq is intended to be used only in the care of opioid-tolerant cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Limitations of Use: As a part of the TIRF REMS Access program, Actiq Q may be dispensed only to outpatients enrolled in the program. For inpatient administration of Actiq (e.g., hospitals, hospices, and long-term care facilities that prescribe for inpatient use), patient and prescriber enrollment is not required.

Drug Name: Fentora (fentanyl buccal tablet)

Breakthrough pain Indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg/hr of transdermal fentanyl, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily, at least 25 mg oral oxymorphone daily, or an equianalgesic dose of another opioid daily for a week or longer. Patients must remain on around-the-clock opioids while taking Fentora. This product must not be used in opioid non-tolerant patients because life-threatening hypoventilation and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason, Fentora is contraindicated in the management of acute or postoperative pain. Fentora is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Limitations of Use: As a part of the TIRF REMS Access program, Fentora may be dispensed only to outpatients enrolled in the program. For inpatient administration of Fentora (e.g., hospitals, hospices, and long-term care facilities that prescribe for inpatient use), patient and prescriber enrollment is not required.

Drug Name: Lazanda (fentanyl) nasal spray

Breakthrough pain Indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking at least: 60 mg of oral morphine/day, 25 mcg of transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, or an equianalgesic dose of another opioid for a week or longer. Patients must remain on around-the-clock opioids when taking Lazanda. Lazanda is contraindicated for patients who are not already tolerant to opioids because life-threatening respiratory depression and death could occur in patients not taking chronic opioids. For this reason, Lazanda is contraindicated in the management of acute or postoperative pain, including headache/migraine, or dental pain. Lazanda is intended to be prescribed only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Limitations of Use: As a part of the TIRF REMS Access program, Lazanda may be dispensed only to outpatients enrolled in the program.For inpatient administration of Lazanda (e.g., hospitals,

hospices, and long-term care facilities that prescribefor inpatient use), patient enrollment is not required.

Drug Name: Subsys (fentanyl sublingual spray)

Breakthrough pain Indicated for the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid daily for a week or longer. Patients must remain on around-the-clock opioids when taking Subsys . This product must not be used in opioid non-tolerant patients because life-threatening respiratory depression and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason, Subsys is contraindicated in the management of acute or postoperative pain. Subsys is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Limitations of Use As part of the Transmucosal Immediate-Release Fentanyl (TIRF) REMS ACCESS Program, Subsys may be dispensed only to outpatients enrolled in the program. For inpatient administration (e.g., hospitals, hospices, and long-term care facilities that prescribe for inpatient use) of Subsys, patient enrollment is not required.

2 . Criteria

Product Name: Abstral*, Brand Actiq, Fentora*, Generic fentanyl citrate*, Lazanda*, or Subsys	
Approval Length	12
Guideline Type	Prior Authorization

Approval Criteria

1 - For the management of breakthrough cancer pain [A]

AND

2 - Patient must have at least a one week history of one of the following medications to demonstrate tolerance to opioids: [3, 4, B]

- Morphine sulfate at doses of greater than or equal to 60 mg/day
- Fentanyl transdermal patch at doses greater than or equal to 25 µg/hr

- Oxycodone at a dose of greater than or equal to 30 mg/day
- Oral hydromorphone at a dose of greater than or equal to 8 mg/day
- Oral oxymorphone at a dose of greater than or equal to 25 mg/day
- An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day)

AND

3 - History of failure or intolerance to generic fentanyl lozenge

AND

4 - The patient is currently taking a long-acting opioid around the clock for cancer pain

AND

5 - Prescribed by or in consultation with one of the following:

- Pain specialist
- Oncologist
- Hematologist
- Hospice care specialist
- Palliative care specialist

Notes	*Product may be excluded depending on the plan

Product Name: Generic fentanyl lozenge	
Approval Length	12
Guideline Type	Prior Authorization

Approval Criteria

1 - For the management of breakthrough cancer pain [A]

AND

2 - Patient must have at least a one week history of one of the following medications to demonstrate tolerance to opioids: [3, 4, B]

- Morphine sulfate at doses of greater than or equal to 60 mg/day
- Fentanyl transdermal patch at doses greater than or equal to 25 µg/hr
- Oxycodone at a dose of greater than or equal to 30 mg/day
- Oral hydromorphone at a dose of greater than or equal to 8 mg/day
- Oral oxymorphone at a dose of greater than or equal to 25 mg/day
- An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day)

AND

3 - The patient is currently taking a long-acting opioid around the clock for cancer pain

AND

4 - Prescribed by or in consultation with one of the following:

- Pain specialist
- Oncologist
- Hematologist
- Hospice care specialist
- Palliative care specialist

Product Name: Abstral*, Brand Actiq, Fentora*, Generic fentanyl citrate*, Generic fentanyl lozenge, Lazanda*, or Subsys	
Approval Length	12
Guideline Type	Quantity Limit

Approval Criteria

1 - For the management of breakthrough cancer pain

AND

2 - Prescribed by or in consultation with one of the following:

- Pain specialist
- Oncologist
- Hematologist
- Hospice care specialist
- Palliative care specialist

AND

3 - The prescriber maintains and provides chart documentation of the patient's evaluation, including all of the following: [3]

- An appropriate patient medical history and physical examination
- A description of the nature and intensity of the pain
- Documentation of appropriate dose escalation
- Documentation of ongoing, periodic review of the course of opioid therapy
- An updated, comprehensive treatment plan (the treatment plan should state objectives that will be used to determine treatment success, such as pain relief or improved physical and/or psychosocial function)
- Verification that the risks and benefits of the use of the controlled substance have been discussed with the patient, significant other(s), and/or guardian

Notes	*Product may be excluded depending on the plan.

3 . Endnotes

A. Abstral, Actiq, Fentora, Lazanda, and Subsys are intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain [1, 2, 5, 6]
B. Abstral, Actiq, Fentora, Lazanda, and Subsys are only intended for patients who are opioid tolerant. Patients considered opioid tolerant are those who are taking at least 60 mg morphine/day, at least 25 mcg transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer. [1, 2, 5, 6]

4 . References

1. Actiq Prescribing Information. Cephalon. North Wales, PA. March 2021.
2. Fentora Prescribing Information. Cephalon. North Wales, PA. March 2021.

3. American Academy of Pain Medicine. The use of opioids for the treatment of chronic pain (2013). Available at: http://www.painmed.org/files/use-of-opioids-for-the-treatment-of-chronic-pain.pdf. Accessed August 12, 2020.
4. Abstral Prescribing Information. Sentynl Therapeutics, Inc. Solana Beach, CA. October 2019.
5. Lazanda Prescribing Information. West Therapeutic Development, LLC. March 2021.
6. Subsys Prescribing Information. INSYS Therapeutics, Inc. Chandler, AZ. April 2021.

5 . Revision History

Date	Notes
8/19/2022	Annual review - updated references.

Prior Authorization Guideline

Guideline Name	Orencia (abatacept)

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	1/28/2008
P&T Revision Date:	09/18/2019 ; 10/16/2019 ; 04/15/2020 ; 09/16/2020 ; 12/16/2020 ; 04/21/2021 ; 02/17/2022 ; 03/16/2022 ; 04/20/2022 ; 10/19/2022 ; 12/14/2022 ; 4/19/2023

1 . Indications

Drug Name: Orencia (abatacept) IV and SC
Rheumatoid Arthritis (RA) Indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis. Limitations of Use: The concomitant use of Orencia with other potent immunosuppressants (e.g., biologic disease-modifying antirheumatic drugs [DMARDs], Janus kinase [JAK] inhibitors) is not recommended. **Polyarticular Juvenile Idiopathic Arthritis (PJIA)** Indicated for the treatment of patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA). Limitations of Use: The concomitant use of Orencia with other potent immunosuppressants (e.g., biologic DMARDs, JAK inhibitors) is not recommended. **Psoriatic Arthritis (PsA)** Indicated for the treatment of adult patients with active psoriatic arthritis (PsA). Limitations of Use: The concomitant use of Orencia with other potent immunosuppressants (e.g., biologic DMARDs, JAK inhibitors) is not recommended.
Drug Name: Orencia (abatacept) IV
Prophylaxis for Acute Graft versus Host Disease (aGVHD) Indicated for the prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and

methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor. Limitations of Use: The concomitant use of Orencia with other potent immunosuppressants (e.g., biologic DMARDs, JAK inhibitors) is not recommended.

2 . Criteria

Product Name: Orencia IV or Orencia SC	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide
- sulfasalazine

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab) or Amjevita (adalimumab-atto)
- Rinvoq (upadacitinib)
- Simponi (golimumab)
- Xeljanz/XR (tofacitinib/ER)

OR

4.2 For continuation of prior Orencia therapy, defined as no more than a 45-day gap in therapy

Notes	*Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Orencia IV or Orencia SC	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Orencia IV or Orencia SC	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4]:

- leflunomide
- methotrexate

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Enbrel (etanercept)
- Humira (adalimumab) or Amjevita (adalimumab-atto)
- Xeljanz (tofacitinib)

OR

4.2 For continuation of prior Orencia therapy, defined as no more than a 45-day gap in therapy

Notes	* Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Orencia IV or Orencia SC	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Orencia IV or Orencia SC	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis (PsA)

AND

2 - One of the following [5]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab) or Amjevita (adalimumab-atto)
- Simponi (golimumab)
- Stelara (ustekinumab)
- Skyrizi (risankizumab-rzaa)
- Tremfya (guselkumab)
- Rinvoq (upadacitinib)
- Xeljanz/XR (tofacitinib/ER)

OR

4.2 For continuation of prior Orencia therapy, defined as no more than a 45-day gap in therapy

Product Name: Orencia IV or Orencia SC	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 5]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name: Orencia IV	
Diagnosis	Prophylaxis for Acute Graft versus Host Disease (aGVHD)
Approval Length	2 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Used for prophylaxis of acute graft versus host disease (aGVHD)

AND

2 - Patient is 2 years of age or older

AND

3 - Patient will receive hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor

AND

4 - Recommended antiviral prophylactic treatment for Epstein-Barr Virus (EBV) reactivation (e.g., acyclovir) will be administered prior to Orencia and continued for six months after HSCT

AND

5 - Used in combination with both of the following:

- calcineurin inhibitor (e.g., cyclosporine, tacrolimus)
- methotrexate

3 . References

1. Orencia prescribing information. Bristol-Myers Squibb Company. Princeton, NJ. December 2021.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.
3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.
4. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Rheumatol. 2019;71(6):846-863.
5. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.

4 . Revision History

Date	Notes
4/5/2023	Annual review - no criteria changes

Prior Authorization Guideline

Guideline Name	Orgovyx (relugolix)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	2/18/2021
P&T Revision Date:	03/17/2021 ; 02/17/2022 ; 3/15/2023

1 . Indications

Drug Name: Orgovyx (relugolix)
Prostate Cancer Indicated for the treatment of adult patients with advanced prostate cancer.

2 . Criteria

Product Name: Orgovyx	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of advanced prostate cancer

AND

2 - Disease is one of the following:

- Evidence of biochemical or clinical relapse following local primary intervention with curative intent
- Newly diagnosed androgen-sensitive metastatic disease
- Advanced localized disease unlikely to be cured by local primary intervention with curative intent

AND

3 - Prescribed by or in consultation with one of the following:

- Urologist
- Oncologist

Product Name: Orgovyx	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Documentation of serum testosterone level less than 50 ng/dL

3 . References

1. Orgovyx Prescribing Information. Myovant Sciences, Inc. Brisbane, CA. September 2022.

4 . Revision History

Date	Notes
2/27/2023	2023 UM Annual Review. No changes to criteria. Updated references .

Prior Authorization Guideline

Guideline Name	Orkambi (lumacaftor/ivacaftor)

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	6/10/2015
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 10/19/2022 ; 4/19/2023

1 . Indications

Drug Name: Orkambi (lumacaftor/ivacaftor)
Cystic fibrosis (CF) Indicated for the treatment of cystic fibrosis (CF) in patients age 1 years and older who are homozygous for the F508del mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene. Limitations of Use: The efficacy and safety of Orkambi have not been established in patients with CF other than those homozygous for the F508del mutation.

2 . Criteria

Product Name: Orkambi (100 mg - 125 mg) tablet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by an FDA-cleared cystic fibrosis mutation test or Clinical Laboratory Improvement Amendments (CLIA)-approved facility

AND

3 - Patient is 6 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Specialist affiliated with a cystic fibrosis care center
- Pulmonologist

Product Name: Orkambi (200 mg - 125 mg) tablet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by an FDA-cleared cystic fibrosis mutation test or Clinical Laboratory Improvement Amendments (CLIA)-approved facility

AND

3 - Patient is 12 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Specialist affiliated with a cystic fibrosis care center
- Pulmonologist

Product Name: Orkambi (100 mg - 125 mg) tablet, Orkambi (200 mg - 125 mg) tablet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (i.e., improvement in lung function [forced expiratory volume in one second {FEV1}], decreased number of pulmonary exacerbations)

Product Name: Orkambi (100 mg - 125 mg) granules packet, Orkambi (150 mg - 188 mg) granules packet, Orkambi (75 mg - 94 mg) granules packet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by an FDA-cleared cystic fibrosis mutation test or Clinical Laboratory Improvement Amendments (CLIA)-approved facility

AND

3 - One of the following:

3.1 Patient is 1 through 5 years of age

OR

3.2 Both of the following:

- Patient is 6 years of age or greater
- Patient is unable to swallow oral tablets

AND

4 - Prescribed by or in consultation with one of the following:

- Specialist affiliated with a cystic fibrosis care center
- Pulmonologist

Product Name: Orkambi (100 mg - 125 mg) granules packet, Orkambi (150 mg - 188 mg) granules packet, Orkambi (75 mg - 94 mg) granules packet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (i.e., improvement in lung function [forced expiratory volume in one second {FEV1}], decreased number of pulmonary exacerbations)

AND

2 - One of the following:

2.1 Patient is 1 through 5 years of age

OR

2.2 Both of the following:

- Patient is 6 years of age or greater
- Patient is unable to swallow oral tablets

3 . References

1. Orkambi Prescribing Information. Vertex Pharmaceuticals Incorporated. Boston, MA. February 2023.

4 . Revision History

Date	Notes
4/6/2023	Annual review: No criteria changes. Updated references.

Prior Authorization Guideline

Guideline Name	Orserdu (elacestrant)

Guideline Note:

Effective Date:	6/1/2023

1 . Indications

Drug Name: Orserdu (elacestrant)
Breast Cancer Indicated for the treatment of postmenopausal women or adult men, with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

2 . Criteria

Product Name: Orserdu	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of breast cancer	

AND

2 - Disease is one of the following:

- Advanced
- Metastatic

AND

3 - Disease is estrogen receptor (ER)-positive

AND

4 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

5 - Presence of estrogen receptor (ESR1) mutation(s) as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

6 - Disease has progressed following at least one line of endocrine therapy [e.g., Faslodex (fulvestrant), Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)] [A, 1, 3]

AND

7 - Prescribed by or in consultation with an oncologist

Product Name: Orserdu	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on therapy	

3 . Endnotes

A. Per clinical consult, treatment can be with an aromatase inhibitor, with or without fulvestrant, with or without CD4/6 inhibitors, as not all patients are candidates for CD4/6 inhibitors [3]

4 . References

1. Orserdu Prescribing Information. Stemline Therapeutics, Inc., New York, NY. January 2023.
2. Clinicaltrials.gov. Phase 3 Trial of Elacestrant vs. Standard of Care for the Treatment of Patients With ER+/HER2- Advanced Breast Cancer (EMERALD). Available at https://www.clinicaltrials.gov/ct2/results?cond=&term=nct03778931&cntry=&state=&city=&dist=. Accessed March 7, 2023.
3. Clinical Consult with an oncologist. March 16, 2023.
4. National Comprehensive Cancer Network(NCCN) Clinical Practice Guidelines in Oncology. Breast Cancer. V3.2023. Available at https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed March 16, 2023.

5 . Revision History

Date	Notes
5/10/2023	update guideline

Prior Authorization Guideline

Guideline Name	Otezla (apremilast)

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	5/21/2014
P&T Revision Date:	10/16/2019 ; 09/16/2020 ; 10/21/2020 ; 10/20/2021 ; 03/16/2022 ; 10/19/2022

1 . Indications

Drug Name: Otezla (apremilast)
Psoriatic Arthritis (PsA) Indicated for the treatment of adult patients with active psoriatic arthritis. **Plaque Psoriasis (PsO)** Indicated for the treatment of adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy. **Oral Ulcers Associated with Behçet's Disease** Indicated for the treatment of adult patients with oral ulcers associated with Behçet's Disease.

2 . Criteria

Product Name: Otezla	
Diagnosis	Psoriatic Arthritis (PsA)

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [2]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Product Name: Otezla	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 2]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name: Otezla	
Diagnosis	Plaque psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of plaque psoriasis

AND

2 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

3 - Prescribed by or in consultation with a dermatologist

Product Name: Otezla	
Diagnosis	Plaque psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1, 4]:

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name: Otezla	
Diagnosis	Oral Ulcers Associated with Behçet's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Behçet's Disease

AND

2 - Patient has active oral ulcers

Product Name: Otezla	
Diagnosis	Oral Ulcers Associated with Behçet's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduction in pain from oral ulcers or reduction in number of oral ulcers)

3 . References

1. Otezla Prescribing Information. Celgene Corp. Summit, NJ. December 2021.
2. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
3. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.
4. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.

4 . Revision History

Date	Notes
10/23/2022	Further clinical detail and criteria added

Prior Authorization Guideline

Guideline Name	Overactive Bladder Agents

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	3/20/2019
P&T Revision Date:	12/18/2019 ; 03/18/2020 ; 03/17/2021 ; 07/21/2021 ; 03/16/2022 ; 08/18/2022 ; 3/15/2023

1 . Indications

Drug Name: Gelnique (oxybutynin chloride)
Overactive Bladder Symptoms Indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.

2 . Criteria

Product Name: Gelnique	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria	

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to two of the following: [2]

- Myrbetriq tablets
- generic darifenacin ER
- generic oxybutynin immediate-release (IR)/extended-release (ER)
- generic solifenacin
- generic tolterodine IR/ER
- generic trospium IR/ER
- generic fesoterodine ER

3 . References

1. Gelnique prescribing information. Allergan USA, Inc. Madison. NJ. March 2019.
2. American Urological Association. Guideline on Diagnosis and Treatment of Non-Neurogenic Overactive Bladder (OAB) in Adults (2019). https://www.auanet.org/guidelines/overactive-bladder-(oab)-guideline. Accessed February 14, 2022.

4 . Revision History

Date	Notes
3/15/2023	Annual review - added FDA approved indication criterion.

Prior Authorization Guideline

Guideline Name	Oxandrolone

Guideline Note:

Effective Date:	9/1/2022
P&T Approval Date:	9/30/2002
P&T Revision Date:	07/15/2020 ; 07/21/2021 ; 7/20/2022

1 . Indications

Drug Name: Oxandrolone
Promote weight gain Indicated as adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma, and in some patients who without definite pathophysiologic reasons fail to gain or to maintain normal weight, to offset the protein catabolism associated with prolonged administration of corticosteroids **Bone pain** Indicated for the relief of the bone pain frequently accompanying osteoporosis

2 . Criteria

Product Name: Oxandrolone	
Diagnosis	Weight gain
Approval Length	3 Month [A]
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Used as adjunctive therapy to promote weight gain

AND

2 - Diagnosis of one of the following:

- Extensive surgery
- Chronic infections
- Severe trauma
- Failure to gain or maintain at least 90% of ideal body weight without definite pathophysiologic reasons

AND

3 - Trial and failure, contraindication, or intolerance to nutritional supplements

AND

4 - A nutritional consult was performed

Product Name: Oxandrolone	
Diagnosis	Weight gain
Approval Length	3 Month [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy as evidenced by an improvement in weight gain or increase in lean body mass

Product Name: Oxandrolone	
Diagnosis	Bone pain
Approval Length	1 Month [A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of bone pain associated with osteoporosis

Product Name: Oxandrolone	
Diagnosis	Protein catabolism
Approval Length	3 Month [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Used to counterbalance protein catabolism associated with chronic corticosteroid administration

Product Name: Oxandrolone	
Diagnosis	Protein catabolism
Approval Length	3 Month [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy as evidenced by an improvement in weight gain or increase in lean body mass

3 . Endnotes

A. Per oxandrolone prescribing information, a course of therapy of 2 to 4 weeks is usually adequate, and may be repeated intermittently as indicated. [1]

4 . References

1. Oxandrolone Prescribing Information. Upsher-Smith Laboratories, LLC. Maple Grove, MN. July 2020.

5 . Revision History

Date	Notes
7/6/2022	Annual Review, no criteria changes

Prior Authorization Guideline

Guideline Name	Padcev (enfortumab vedotin-ejfv)

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	2/13/2020
P&T Revision Date:	02/18/2021 ; 09/15/2021 ; 02/17/2022 ; 2/16/2023

1 . Indications

Drug Name: Padcev (enfortumab vedotin-ejfv)
Urothelial Cancer Indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC) who: • have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and platinum-containing chemotherapy, or • are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy.

2 . Criteria

Product Name: Padcev	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of locally advanced or metastatic urothelial cancer (mUC)

AND

2 - Both of the following:

2.1 Patient has received prior treatment with one of the following immune checkpoint inhibitors (CPI), unless contraindicated: [A]

- Programmed death receptor-1 (PD-1) inhibitor [e.g.,Opdivo (nivolumab), Keytruda (pembrolizumab)]
- Programmed death-ligand 1 (PD-L1) inhibitor [e.g., Tecentriq (atezolizumab), Imfinzi (durvalumab), Bavencio (avelumab)]

AND

2.2 One of the following:

- Patient has received prior treatment with a platinum-based chemotherapy (e.g., carboplatin, cisplatin)
- Patient is ineligible for cisplatin-containing chemotherapy [B]

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Padcev	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. Immune checkpoint inhibitor (CPI) is defined as a programmed cell death protein 1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor [e.g., Opdivo (nivolumab), Keytruda (pembrolizumab), Tecentriq (atezolizumab), Imfinzi (durvalumab), Bavencio (avelumab)]. [2]
B. In the clinical trial EV-201, Padcev was evaluated in patients that had locally advanced or metastatic urothelial cancer who received prior treatment with a PD-1 or PD-L1 inhibitor and were CISplatin ineligible. [1, 5,6]

4 . References

1. Padcev Prescribing Information. Astellas Pharma US, Inc. Northbrook, IL. October 2022.
2. ClinicalTrials.gov Web site. https://clinicaltrials.gov/ct2/show/NCT03219333. Accessed January 14, 2021.
3. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Bladder Cancer v.3.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed January 9, 2023
4. Rosenberg JE, O'Donnell PH, Balar AV, et al. Pivotal trial of enfortumab vedotin in urothelial carcinoma after platinum and anti-programmed death 1/programmed death ligand 1 therapy. J Clin Oncol. 2019; https://doi.org/10.1200/JCO.19.01140.
5. ClinicalTrials.gov Web site. https://clinicaltrials.gov/ct2/show/record/NCT03219333. Accessed August 15, 2021
6. Yu EY, Petrylak DP, O'Donnell PH, et al. Enfortumab vedotin after PD-1 or PD-L1 inhibitors in cisplatin-ineligible patients with advanced urothelial carcinoma (EV 201): a multicentre, single-arm, phase 2 trial [published correction appears in Lancet Oncol. 2021 Jun;22(6):e239]. Lancet Oncol. 2021;22(6):872-882. doi:10.1016/S1470-2045(21)00094-2

5 . Revision History

Date	Notes
2/6/2023	Annual Review, no changes to criteria

Prior Authorization Guideline

Guideline Name	PCSK9 Inhibitors - PA, NF

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	5/20/2015
P&T Revision Date:	11/14/2019 ; 02/13/2020 ; 03/17/2021 ; 06/16/2021 ; 08/19/2021 ; 11/18/2021 ; 03/16/2022 ; 06/15/2022 ; 3/15/2023

1 . Indications

Drug Name: Repatha (evolocumab)
Prevention of Cardiovascular Events Indicated in adults with established cardiovascular disease to reduce the risk of myocardial infarction, stroke, and coronary revascularization. **Primary Hyperlipidemia (Including Heterozygous Familial Hypercholesterolemia)** Indicated as an adjunct to diet, alone or in combination with other low density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C. **Heterozygous Familial Hypercholesterolemia (HeFH)** Indicated as an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 10 years and older with HeFH, to reduce LDL-C **Homozygous Familial Hypercholesterolemia** Indicated as an adjunct to other LDL-C-lowering therapies in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH), to reduce LDL-C
Drug Name: Praluent (alirocumab)

Prevention of Cardiovascular Events Indicated to reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease.

Primary Hyperlipidemia (Including Heterozygous Familial Hypercholesterolemia) Indicated as an adjunct to diet, alone or in combination with other low density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C.

Homozygous Familial Hypercholesterolemia Indicated as an adjunct to other LDL-C lowering therapies in adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.

2 . Criteria

Product Name: Repatha	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

1.1 Both of the following:

1.1.1 Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following: [1-2, B]

1.1.1.1 Both of the following: [4]

1.1.1.1.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age) [4]

AND

1.1.1.1.2 One of the following: [4]

- Family history of myocardial infarction in first-degree relative less than 60 years of age
- Family history of myocardial infarction in second-degree relative less than 50 years of age
- Family history of LDL-C greater than 190 mg/dL in first- or second-degree relative
- Family history of familial hypercholesterolemia in first- or second-degree relative [21]
- Family history of tendinous xanthomata and/or arcus cornealis in first- or second-degree relative

OR

1.1.1.2 Both of the following:

1.1.1.2.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age) [4]

AND

1.1.1.2.2 One of the following:

- Functional mutation in the LDL receptor, ApoB, or PCSK9 gene [3-4]
- Tendinous xanthomata [3-4]
- Arcus cornealis before age 45 [3]

AND

1.1.2 Patient is 10 years of age or older

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD) as confirmed by one of the following: [1, 2, 5]

- Acute coronary syndromes
- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization
- Stroke
- Transient ischemic attack

- Peripheral arterial disease presumed to be of atherosclerotic origin

OR

1.3 Primary hyperlipidemia

AND

2 - One of the following: [1, 2, 5]

2.1 Patient has been receiving at least 12 consecutive weeks of HIGH-INTENSITY statin therapy [i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg] and will continue to receive a HIGH-INTENSITY statin at maximally tolerated dose

OR

2.2 Both of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms: [I]

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

2.2.2 One of the following:

2.2.2.1 Patient has been receiving at least 12 consecutive weeks of MODERATE-INTENSITY statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 20-40 mg, pravastatin 40-80 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily, or Livalo (pitavastatin) 2-4 mg] and will continue to receive a MODERATE-INTENSITY statin at maximally tolerated dose

OR

2.2.2.2 Patient has been receiving at least 12 consecutive weeks of LOW-INTENSITY statin therapy [i.e., simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-

40 mg, Livalo (pitavastatin) 1 mg] and will continue to receive a LOW-INTENSITY statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low- or moderate-, and high-intensity statins as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms for low- or moderate-, and high-intensity statins: [I]

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times ULN)

OR

2.4 Patient has a labeled contraindication to all statins

OR

2.5 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN [5]

AND

3 - One of the following: [8-9, 17-18]

3.1 Documentation of one of the following LDL-C values while on maximally tolerated lipid-lowering therapy within the last 120 days:

- LDL-C greater than or equal to 100 mg/dL with ASCVD
- LDL-C greater than or equal to 130 mg/dL without ASCVD

OR

3.2 Both of the following:

3.2.1 Documentation of one of the following LDL-C values while on maximally tolerated lipid lowering therapy within the last 120 days:

- LDL-C between 70 mg/dL and 99 mg/dL with ASCVD

- LDL-C between 100 mg/dL and 129 mg/dL without ASCVD

AND

3.2.2 One of the following: [F]

3.2.2.1 Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy [A]

OR

3.2.2.2 Patient has a history of contraindication, or intolerance to ezetimibe

OR

3.3 Both of the following:

3.3.1 Patient has been receiving PCSK9 therapy as adjunct to maximally tolerated lipid lowering therapy (e.g., statins, ezetimibe)

AND

3.3.2 LDL-C values drawn within the past 12 months while on maximally tolerated lipid lowering therapy is within normal limits

Product Name: Praluent (F)	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - One of the following diagnoses:

1.1 Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following: [1-2, B]

1.1.1 Both of the following: [4]

1.1.1.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age) [4]

AND

1.1.1.2 One of the following: [4]

- Family history of myocardial infarction in first-degree relative less than 60 years of age
- Family history of myocardial infarction in second-degree relative less than 50 years of age
- Family history of LDL-C greater than 190 mg/dL in first- or second-degree relative
- Family history of familial hypercholesterolemia in first- or second-degree relative [21]
- Family history of tendinous xanthomata and/or arcus cornealis in first- or second-degree relative

OR

1.1.2 Both of the following:

1.1.2.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age) [4]

AND

1.1.2.2 One of the following:

- Functional mutation in the LDL receptor, ApoB, or PCSK9 gene [3-4]
- Tendinous xanthomata [3-4]
- Arcus cornealis before age 45 [3]

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD) as confirmed by one of the following: [1, 2, 5]

- Acute coronary syndromes
- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization
- Stroke
- Transient ischemic attack
- Peripheral arterial disease presumed to be of atherosclerotic origin

OR

1.3 Primary hyperlipidemia

AND

2 - One of the following: [1, 2, 5]

2.1 Patient has been receiving at least 12 consecutive weeks of HIGH-INTENSITY statin therapy [i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg] and will continue to receive a HIGH-INTENSITY statin at maximally tolerated dose

OR

2.2 Both of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms: [I]

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

2.2.2 One of the following:

2.2.2.1 Patient has been receiving at least 12 consecutive weeks of MODERATE-INTENSITY statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 20-

40 mg, pravastatin 40-80 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily, or Livalo (pitavastatin) 2-4 mg] and will continue to receive a MODERATE-INTENSITY statin at maximally tolerated dose

OR

2.2.2.2 Patient has been receiving at least 12 consecutive weeks of LOW-INTENSITY statin therapy [i.e., simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, Livalo (pitavastatin) 1 mg] and will continue to receive a LOW-INTENSITY statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low- or moderate-, and high-intensity statins as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms for low- or moderate-, and high-intensity statins: [I]

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times ULN)

OR

2.4 Patient has a labeled contraindication to all statins

OR

2.5 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN [5]

AND

3 - One of the following: [8-9, 17-18]

3.1 Documentation of one of the following LDL-C values while on maximally tolerated lipid-lowering therapy within the last 120 days:

- LDL-C greater than or equal to 100 mg/dL with ASCVD
- LDL-C greater than or equal to 130 mg/dL without ASCVD

OR

3.2 Both of the following:

3.2.1 Documentation of one of the following LDL-C values while on maximally tolerated lipid lowering therapy within the last 120 days:

- LDL-C between 70 mg/dL and 99 mg/dL with ASCVD
- LDL-C between 100 mg/dL and 129 mg/dL without ASCVD

AND

3.2.2 One of the following: [F]

3.2.2.1 Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy [A]

OR

3.2.2.2 Patient has a history of contraindication, or intolerance to ezetimibe

OR

3.3 Both of the following:

3.3.1 Patient has been receiving PCSK9 therapy as adjunct to maximally tolerated lipid lowering therapy (e.g., statins, ezetimibe)

AND

3.3.2 LDL-C values drawn within the past 12 months while on maximally tolerated lipid lowering therapy is within normal limits

AND

4 - Trial and failure, contraindication, or intolerance to Repatha

Product Name: Repatha, Praluent (F)	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient continues to receive other lipid-lowering therapy (e.g., statins, ezetimibe) at the maximally tolerated dose

OR

1.2 Patient has a documented inability to take other lipid-lowering therapy (e.g., statins, ezetimibe)

AND

2 - Documentation of a reduction in LDL-C levels while on Repatha or Praluent therapy

Product Name: Praluent (NF)	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following diagnoses:

1.1 Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following: [1-2, B]

1.1.1 Both of the following: [4]

1.1.1.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age) [4]

AND

1.1.1.2 One of the following: [4]

- Family history of myocardial infarction in first-degree relative less than 60 years of age
- Family history of myocardial infarction in second-degree relative less than 50 years of age
- Family history of LDL-C greater than 190 mg/dL in first- or second-degree relative
- Family history of familial hypercholesterolemia in first- or second-degree relative [21]
- Family history of tendinous xanthomata and/or arcus cornealis in first- or second-degree relative

OR

1.1.2 Both of the following:

1.1.2.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age) [4]

AND

1.1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting one of the following:

- Functional mutation in the LDL receptor, ApoB, or PCSK9 gene [3-4]
- Tendinous xanthomata [3-4]
- Arcus cornealis before age 45 [3]

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD) as confirmed by one of the following: [1, 2, 5]

- Acute coronary syndromes
- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization
- Stroke
- Transient ischemic attack
- Peripheral arterial disease presumed to be of atherosclerotic origin

OR

1.3 Primary hyperlipidemia

AND

2 - One of the following: [1, 2, 5]

2.1 Patient has been receiving at least 12 consecutive weeks of HIGH-INTENSITY statin therapy [i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg] and will continue to receive a HIGH-INTENSITY statin at maximally tolerated dose

OR

2.2 Both of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms: [I]

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

2.2.2 One of the following:

2.2.2.1 Patient has been receiving at least 12 consecutive weeks of MODERATE-INTENSITY statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 20-

40 mg, pravastatin 40-80 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily, or Livalo (pitavastatin) 2-4 mg] and will continue to receive a MODERATE-INTENSITY statin at maximally tolerated dose

OR

2.2.2.2 Patient has been receiving at least 12 consecutive weeks of LOW-INTENSITY statin therapy [i.e., simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, Livalo (pitavastatin) 1 mg] and will continue to receive a LOW-INTENSITY statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low- or moderate-, and high-intensity statins as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms for low- or moderate-, and high-intensity statins: [I]

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times ULN)

OR

2.4 Patient has a labeled contraindication to all statins

OR

2.5 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN [5]

AND

3 - One of the following: [8-9, 17-18]

3.1 Submission of medical records (e.g., laboratory values) documenting one of the following LDL-C values while on maximally tolerated lipid-lowering therapy within the last 120 days:

- LDL-C greater than or equal to 100 mg/dL with ASCVD
- LDL-C greater than or equal to 130 mg/dL without ASCVD

OR

3.2 Both of the following:

3.2.1 Submission of medical records (e.g., laboratory values) documenting one of the following LDL-C values while on maximally tolerated lipid lowering therapy within the last 120 days:

- LDL-C between 70 mg/dL and 99 mg/dL with ASCVD
- LDL-C between 100 mg/dL and 129 mg/dL without ASCVD

AND

3.2.2 One of the following: [F]

3.2.2.1 Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy [A]

OR

3.2.2.2 Patient has a history of contraindication, or intolerance to ezetimibe

OR

3.3 Both of the following:

3.3.1 Patient has been receiving PCSK9 therapy as adjunct to maximally tolerated lipid lowering therapy (e.g., statins, ezetimibe)

AND

3.3.2 Submission of medical records (e.g., laboratory values) documenting LDL-C values drawn within the past 12 months while on maximally tolerated lipid lowering therapy is within normal limits

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Repatha

Product Name: Praluent (NF)	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following:

1.1 Patient continues to receive other lipid-lowering therapy (e.g., statins, ezetimibe) at the maximally tolerated dose

OR

1.2 Patient has a documented inability to take other lipid-lowering therapy (e.g., statins, ezetimibe)

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting a reduction in LDL-C levels while on Praluent therapy

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Repatha

Product Name: Repatha

Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia as confirmed by one of the following: [11-13]

1.1 Genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (i.e., LDLRAP1 or ARH)

OR

1.2 Both of the following:

1.2.1 One of the following:

- Untreated/pre-treatment LDL-C greater than 500 mg/dL
- Treated LDL-C greater than 300 mg/dL

AND

1.2.2 One of the following:

- Xanthoma before 10 years of age
- Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

AND

2 - One of the following:

2.1 Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe)

OR

2.2 Patient has a documented inability to take other lipid-lowering therapy (e.g., statin, ezetimibe)

AND

3 - Patient is 10 years of age or older

Product Name: Praluent (F)	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia as confirmed by one of the following: [11-13]

1.1 Genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (i.e., LDLRAP1 or ARH)

OR

1.2 Both of the following:

1.2.1 One of the following:

- Untreated/pre-treatment LDL-C greater than 500 mg/dL
- Treated LDL-C greater than 300 mg/dL

AND

1.2.2 One of the following:

- Xanthoma before 10 years of age

- Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

AND

2 - One of the following:

2.1 Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe)

OR

2.2 Patient has a documented inability to take other lipid-lowering therapy (e.g., statin, ezetimibe)

AND

3 - Trial and failure, contraindication, or intolerance to Repatha

Product Name: Repatha, Praluent (F)	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient continues to receive other lipid-lowering therapy (e.g., statin, ezetimibe)

OR

1.2 Patient has a documented inability to take other lipid-lowering therapy (e.g., statin, ezetimibe)

AND

2 - Documentation of LDL-C reduction while on Repatha or Praluent therapy

Product Name: Praluent (NF)	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of homozygous familial hypercholesterolemia as confirmed by one of the following: [11-13]

1.1 Genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (i.e., LDLRAP1 or ARH)

OR

1.2 Both of the following:

1.2.1 One of the following:

- Untreated/pre-treatment LDL-C greater than 500 mg/dL
- Treated LDL-C greater than 300 mg/dL

AND

1.2.2 One of the following:

- Xanthoma before 10 years of age
- Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

AND

2 - One of the following:

2.1 Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe)

OR

2.2 Patient has a documented inability to take other lipid-lowering therapy (e.g., statin, ezetimibe)

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Repatha

Product Name: Praluent (NF)	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following:

1.1 Patient continues to receive other lipid-lowering therapy (e.g., statin, ezetimibe)

OR

1.2 Patient has a documented inability to take other lipid-lowering therapy (e.g., statin, ezetimibe)

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting LDL-C reduction while on Praluent therapy

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Repatha

3 . Endnotes

A. Per the 2018 ACC/AHA national treatment guidelines, adherence, response to therapy, and adverse effects should be monitored within 4 -12 weeks following LDL-C lowering medication initiation or dose adjustment, repeated every 3 to 12 months as needed. [5]
B. In the Praluent and Repatha pivotal trials that enrolled patients with HeFH, the diagnosis of HeFH was made either by genotyping or clinical criteria ("definite FH" using either the Simon Broome or WHO/Dutch Lipid Network criteria). [1-4]
C. IMPROVE-IT was a prospective RCT evaluating the addition of ezetimibe to simvastatin 40 mg in a high-risk patient population for secondary prevention over 7 years. The addition of ezetimibe significantly reduced ASCVD events, albeit very modestly (HR 0.936; 95% CI 0.887, 0.988; p = 0.016; number needed to treat [NNT] = 50). [6]
D. Lipid specialists are physicians certified by the American Board of Clinical Lipidology (ABCL) or the Accreditation Council for Clinical Lipidology (ACCL). [15, 16]
E. Per the 2018 ACC/AHA national treatment guidelines, it is reasonable to use the following as indicators of anticipated therapeutic response to the recommended intensity of statin therapy. Focus is on the intensity of the statin therapy. As an aid to monitoring: a) High-intensity statin therapy generally results in an average LDL-C reduction of greater than or equal to 50% from the untreated baseline; b) Moderate-intensity statin therapy generally results in an average LDL-C reduction of 30 to 49% from the untreated baseline. [5]
F. Per the 2017 ACC/AHA non-statin decision pathway update, for patients who are maximized on statin therapy with baseline LDL-C 70-189 mg/dL, it is reasonable to consider the addition of either ezetimibe or a PCSK9 inhibitor based on considerations of the additional percent LDL-C reduction desired. Ezetimibe may be favored in patients who require < 25% additional lowering of LDL-C. [17] In patients with clinical ASCVD who are judged to be very high risk with LDL-C 70 mg/dL or higher and considered for PCSK9 inhibitor therapy, maximally tolerated LDL-C lowering therapy should include maximally tolerated statin therapy and ezetimibe. [5]
G. FOURIER, a double blind, placebo controlled, RCT was the first completed cardiovascular outcomes trial for the PCSK9 inhibitors. The trial enrolled 27,564 high-risk patients with cardiovascular disease and LDL-C levels greater than or equal to 70

mg/dL while receiving optimized lipid-lowering therapy (99.7% of patients were receiving moderate- or high-intensity statins). The composite endpoint of CV death, myocardial infarction, stroke, hospitalization for unstable angina, and coronary revascularization occurred in 9.8% of evolocumab-treated patients vs. 11.3% of placebo-treated patients (treatment difference of 1.5%; HR 0.85; 95% CI, 0.79 to 0.92; $p < 0.001$) during a median follow-up period of 26 months. No benefit was identified in CV death or death from any cause. [20]

H. Use of PCSK9 inhibitors for the primary prevention of cardiovascular events and/or for the lowering of low-density lipoprotein cholesterol (LDL-C) in patients with primary hyperlipidemia who do not have heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease (ASCVD) is not supported by the 2018 ACC/AHA Cholesterol Clinical Practice Guidelines. Per consult with cardiologist, use of PCSK9 inhibitors for primary prevention should be limited to the FH population. [5, 22]
I. In patients treated with statins, it is recommended to measure creatine kinase levels in individuals with severe statin-associated muscle symptoms. [5]
J.

4 . References

1. Praluent Prescribing Information. Regeneron Pharmaceuticals, Inc. Tarrytown, NY. April 2021.
2. Repatha Prescribing Information. Amgen Inc. Thousand Oaks, CA. October 2021.
3. WHO Familial Hypercholesterolemia Consultation Group. Familial Hypercholesterolemia (FH): report of a second WHO consultation. Geneva: World Health Organization; 1999.
4. Scientific Steering Committee on behalf of the Simon Broome Register Group. Risk of fatal coronary heart disease in familial hypercholesterolaemia. BMJ. 1991;303:893-6.
5. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2019; 73:e285-e350.
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15. American Board of Clinical Lipidology website. www.lipidboard.org. Accessed March 11, 2021.
16. Accreditation Council for Clinical Lipidology website. www.lipidspecialist.org. Accessed March 11, 2021.
17. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2017 Focused Update of the 2016 ACC expert consensus decision pathway on the role of non-statin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk. J Am Coll Cardiol. 2017;70:1785-1822.
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21. Per clinical drug consult with cardiologist. November 17, 2017.
22. Per clinical drug consult with cardiologist. January 23, 2019.
23. Per clinical drug consult with cardiologist. April 13, 2021.
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5 . Revision History

Date	Notes
3/31/2023	Annual Review - addition of broader diagnosis of Primary Hyperlipide mia where appropriate.

Prior Authorization Guideline

Guideline Name	Perjeta (pertuzumab)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	8/21/2012
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Perjeta (pertuzumab)
Metastatic Breast Cancer (first-line therapy) Indicated in combination with trastuzumab and docetaxel for the treatment of patients with human epidermal growth factor receptor (HER2)-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease. **Neoadjuvant Treatment of Breast Cancer** Indicated for use in combination with trastuzumab and chemotherapy for the neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer. **Early Breast Cancer** Indicated for the use in combination with trastuzumab and chemotherapy as adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence **Off Label Uses: Metastatic Breast Cancer (second-line therapy)** May be considered in combination with trastuzumab with or without cytotoxic therapy (eg, vinorelbine or taxane) for one line of therapy beyond first-line therapy in patients previously treated with chemotherapy and trastuzumab in the absence of pertuzumab. [3]

2 . Criteria

Product Name: Perjeta	
Diagnosis	Metastatic breast cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of human epidermal growth factor receptor (HER2)-positive metastatic breast cancer

AND

2 - One of the following:

2.1 Both of the following: [2,A]

2.1.1 Patient has not received prior anti-HER2 therapy or chemotherapy for metastatic disease

AND

2.1.2 Used in combination with both of the following:

- Herceptin (trastuzumab)
- A taxane (e.g., docetaxel, paclitaxel)

OR

2.2 Both of the following:

2.2.1 Patient was previously treated with chemotherapy and Herceptin (trastuzumab) without Perjeta

AND

2.2.2 Used in combination with Herceptin (trastuzumab)

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Perjeta	
Diagnosis	Metastatic breast cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Perjeta	
Diagnosis	Early Stage, Locally-Advanced, or Inflammatory Breast Cancer - Neoadjuvant
Approval Length	6 Month* [B]
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses: [C]

- HER2-positive early stage breast cancer
- HER2-positive locally advanced breast cancer
- HER2-positive inflammatory breast cancer

AND

2 - Used in combination with both of the following: [C]

- Herceptin (trastuzumab)
- Chemotherapy

AND

3 - Prescribed by or in consultation with an oncologist

Notes	*There is insufficient evidence to recommend continued use of Perjeta for greater than 6 cycles for early breast cancer. [1]

Product Name: Perjeta	
Diagnosis	Early Breast Cancer - At High Risk of Recurrence - Adjuvant Treatment
Approval Length	12 Month [D]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HER2- positive early breast cancer

AND

2 - Patient is at high risk of recurrence

AND

3 - Used in combination with both of the following:

- Herceptin (trastuzumab)
- Chemotherapy

AND

4 - Prescribed by or in consultation with an oncologist

3 . Endnotes

A. Perjeta is used for recurrent or metastatic human epidermal growth factor receptor 2-positive disease that is either hormone receptor-negative or hormone receptor-positive and endocrine therapy refractory or with symptomatic visceral disease: (1) as preferred first-line therapy in combination with trastuzumab with docetaxel or paclitaxel; or (2) may be considered in combination with trastuzumab with or without cytotoxic therapy (eg, vinorelbine or taxane) for one line of therapy beyond first-line therapy in patients previously treated with chemotherapy and trastuzumab in the absence of pertuzumab. [3]
B. The safety of Perjeta administered for greater than 6 cycles for early breast cancer has not been established. Perjeta should be administered every 3 weeks for 3 to 6 cycles as part of one of the following treatment regimens for early breast cancer. [1,4]
C. A pertuzumab-containing regimen can be administered to patients with T2 or N1, HER2-positive, early stage breast cancer. Patients who have not received a neoadjuvant pertuzumab-containing regimen can receive adjuvant pertuzumab. [2]
D. Perjeta and trastuzumab were administered intravenously every 3 weeks starting on Day 1 of the first taxane-containing cycle, for a total of 52 weeks (up to 18 cycles) or until recurrence or unmanageable toxicities [1]

4 . References

1. Perjeta Prescribing Information. Genentech, Inc. San Francisco, CA. February 2021.
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3. National Comprehensive Cancer Network. NCCN Drugs & Biologics Compendium: Pertuzumab. 2020. Available at: http://www.nccn.org/professionals/drug_compendium/MatrixGenerator/Matrix.aspx?AID=383. Accessed March 10, 2021.
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5 . Revision History

Date	Notes
2/28/2023	2023 UM Annual Review. No changes.

Prior Authorization Guideline

Guideline Name	Piqray (alpelisib)

Guideline Note:

Effective Date:	9/1/2022
P&T Approval Date:	7/17/2019
P&T Revision Date:	07/15/2020 ; 07/21/2021 ; 7/20/2022

1 . Indications

Drug Name: Piqray (alpelisib)
Advanced or Metastatic Breast Cancer Indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.

2 . Criteria

Product Name: Piqray	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced or metastatic breast cancer

AND

2 - Disease is hormone receptor (HR)-positive

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

4 - Cancer is PIK3CA-mutated as detected by an FDA-approved test (therascreen PIK3CA RGQ PCR Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

5 - Patient is one of the following:

- Postmenopausal woman
- Male

AND

6 - Used in combination with fulvestrant

AND

7 - Disease has progressed on or after an endocrine-based regimen

AND **8** - Prescribed by or in consultation with an oncologist

Product Name: Piqray	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on therapy	

3 . References

1. Piqray Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. May 2022.

4 . Revision History

Date	Notes
7/5/2022	2022 Annual Review- no criteria changes

Prior Authorization Guideline

Guideline Name	Polivy (polatuzumab vedotin-piiq)

Guideline Note:

Effective Date:	10/1/2022
P&T Approval Date:	8/15/2019
P&T Revision Date:	08/13/2020 ; 11/12/2020 ; 08/19/2021 ; 8/18/2022

1 . Indications

Drug Name: Polivy (polatuzumab vedotin-piiq)
Diffuse Large B-cell Lymphoma (DLBCL) Indicated for use in combination with bendamustine and a rituximab product for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, after at least two prior therapies. Accelerated approval was granted for this indication based on complete response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

2 . Criteria

Product Name: Polivy	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of diffuse large B-cell lymphoma (DLBCL)

AND

2 - Disease is one of the following:

- Relapsed
- Refractory

AND

3 - Used in combination with bendamustine and a rituximab product

AND

4 - Patient has received at least two prior therapies for DLBCL (e.g., RCHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone], HSCT [hematopoietic stem cell transplantation], CAR T [chimeric antigen receptor T-cell] therapy, RCEPP [rituximab, cyclophosphamide, etoposide, prednisone, procarbazine], GemOx [gemcitabine, oxaliplatin] with or without rituximab) [2]

AND

5 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Polivy	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Polivy Prescribing Information. Genentech, Inc. South San Francisco, CA. September 2020.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. B-Cell Lymphomas. v.4.2021. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed July 13, 2022.

4 . Revision History

Date	Notes
7/13/2022	2022 Annual Review

Prior Authorization Guideline

Guideline Name	Pomalyst (pomalidomide)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	2/19/2013
P&T Revision Date:	05/14/2020 ; 07/15/2020 ; 05/20/2021 ; 05/19/2022 ; 5/18/2023

1 . Indications

Drug Name: Pomalyst (pomalidomide)
Multiple myeloma Indicated, in combination with dexamethasone, for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy. **Kaposi Sarcoma** Indicated for the treatment of: 1) Adult patients with AIDS-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy (HAART). 2) Kaposi sarcoma (KS) in adult patients who are HIV-negative. Note: this indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

2 . Criteria

Product Name: Pomalyst	
Diagnosis	Multiple Myeloma

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - Trial and failure, contraindication, or intolerance to at least two prior therapies including both of the following:

- Revlimid (lenalidomide)
- proteasome inhibitor (e.g., Velcade [bortezomib], Kyprolis [carfilzomib])

AND

3 - Patient has experienced disease progression on or within 60 days of completion of last therapy

AND

4 - Used in combination with dexamethasone

AND

5 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Pomalyst	
Diagnosis	Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of AIDS-related Kaposi sarcoma

AND

1.1.2 Patient has failed highly active antiretroviral therapy (HAART) [A]

OR

1.2 Both of the following:

1.2.1 Diagnosis of Kaposi sarcoma

AND

1.2.2 Patient is HIV-negative

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Pomalyst	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria
1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. HAART (highly active antiretroviral therapy) is synonymous to ART (antiretroviral therapy) which refers to the daily use of a combination of HIV medicines (called an HIV regimen) to treat HIV infection. A person's initial HIV regimen generally includes three antiretroviral (ARV) drugs from at least two different HIV drug classes. [3]

4 . References

1. Pomalyst Prescribing Information, Celgene Corporation, Summit, NJ. December 2022.
2. National Comprehensive Cancer (NCCN) Drugs & Biologics Compendium [internet database]. Updated periodically. Available at: http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed April 6, 2023.
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5 . Revision History

Date	Notes
5/3/2023	Annual review - updated references.

Prior Authorization Guideline

Guideline Name	Prior Authorization Administrative Guideline

Guideline Note:

Effective Date:	12/1/2022
P&T Approval Date:	2/15/2011
P&T Revision Date:	10/16/2019 ; 10/21/2020 ; 10/20/2021 ; 10/19/2022

Note:

The purpose of this guideline is to establish policies and procedures on how to handle (1) formulary drugs with a prior authorization requirement that do not have official criteria posted or available, and (2) new FDA-approved indications, which are not addressed in the existing drug-specific prior authorization guideline. This guideline will not apply to drugs that are benefit exclusions, drugs with step therapy edits, drugs that require quantity limit review only, non-formulary drugs, or drugs that are not reviewed for prior authorization.

1 . Criteria

Product Name: Drugs with a prior authorization requirement for which a guideline is unavailable, OR new FDA-approved indications which are not addressed in the existing drug-specific prior authorization guideline	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Prescribed medication is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.1.2 Both of the following labeling requirements have been confirmed:

1.1.2.1 All components of the FDA approved indication are met (e.g., concomitant use, previous therapy requirements, age limitations, testing requirements, etc.)

AND

1.1.2.2 Prescribed medication will be used at a dose which is within FDA recommendations

OR

1.2 Meets the off-label administrative guideline criteria

Notes	This guideline should not be used to address step therapy.

2 . Revision History

Date	Notes
9/21/2022	2022 Annual Review

Prior Authorization Guideline

Guideline Name	Prolia (denosumab)

Guideline Note:

Effective Date:	10/1/2022
P&T Approval Date:	8/17/2010
P&T Revision Date:	07/15/2020 ; 08/13/2020 ; 08/19/2021 ; 8/18/2022

1 . Indications

Drug Name: Prolia (denosumab)
Treatment of postmenopausal women with osteoporosis at high risk for fracture Indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral, and hip fractures. **Treatment to increase bone mass in men with osteoporosis at high risk for fracture** Indicated for treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. **Treatment of bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer [A]** Indicated as a treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. In these patients Prolia also reduced the incidence of vertebral fractures. NOTE: The use of Prolia for the treatment of bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer should not be confused with the use of Xgeva (another injectable formulation of denosumab) for the prevention of skeletal-related events (SREs) in patients with bone metastases from solid tumors (including breast cancer and prostate

cancer).

Treatment of bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer [B] Indicated as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. NOTE: The use of Prolia for the treatment of bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer should not be confused with the use of Xgeva (another injectable formulation of denosumab) for the prevention of skeletal-related events (SREs) in patients with bone metastases from solid tumors (including breast cancer and prostate cancer).

Treatment of Glucocorticoid-Induced Osteoporosis Indicated for the treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months. High risk of fracture is defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

2 . Criteria

Product Name: Prolia	
Diagnosis	Bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer
Approval Length	12 months [D]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of nonmetastatic prostate cancer

AND

2 - Patient is undergoing androgen deprivation therapy with one of the following: [11,A]

2.1 Luteinizing hormone-releasing hormone (LHRH)/gonadotropin releasing hormone (GnRH) agonist [e.g., Eligard/Lupron (leuprolide), Trelstar (triptorelin), Vantas (histrelin), and Zoladex (goserelin)]

OR

2.2 Bilateral orchiectomy (i.e., surgical castration)

AND

3 - One of the following:

3.1 Age greater than or equal to 70 years [11,C]

OR

3.2 Both of the following:

3.2.1 Age less than 70 years [11]

AND

3.2.2 One of the following:

3.2.2.1 Bone mineral density (BMD) scan T-score less than -1.0 (1.0 standard deviation or greater below the mean for young adults) [11]

OR

3.2.2.2 History of one of the following resulting from minimal trauma: [9,11]

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

AND

4 - Trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., zoledronic acid) [19]

Product Name: Prolia	
Diagnosis	Bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer
Approval Length	12 months [D]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is undergoing androgen deprivation therapy with one of the following: [11,A]

1.1 Luteinizing hormone-releasing hormone (LHRH)/gonadotropin releasing hormone (GnRH) agonist [e.g., Eligard/Lupron (leuprolide), Trelstar (triptorelin), Vantas (histrelin), and Zoladex (goserelin)]

OR

1.2 Bilateral orchiectomy (i.e., surgical castration)

AND

2 - No evidence of metastases

AND

3 - Patient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.)

Product Name: Prolia	
Diagnosis	Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer

Approval Length	12 months [D]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Patient is receiving adjuvant aromatase inhibitor therapy (e.g., Arimidex [anastrozole], Aromasin [exemestane], Femara [letrozole]) [12,B]

AND

3 - One of the following:

3.1 Bone mineral density (BMD) scan T-score less than -1.0 (1.0 standard deviation or greater below the mean for young adults) [12,E]

OR

3.2 History of one of the following resulting from minimal trauma: [9]

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

AND

4 - Trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., alendronate) [20]

Product Name: Prolia

Diagnosis	Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer
Approval Length	12 months [D]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving adjuvant aromatase inhibitor therapy (e.g., Arimidex [anastrozole], Aromasin [exemestane], Femara [letrozole]) [12]

AND

2 - Patient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.)

Product Name: Prolia	
Diagnosis	Postmenopausal women with osteoporosis or osteopenia at a high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of postmenopausal osteoporosis or osteopenia [2,5]

AND

2 - One of the following: [5,17]

2.1 Bone mineral density (BMD) scan indicative of osteoporosis: T-score less than or equal to -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

OR

2.2 Both of the following:

2.2.1 BMD scan indicative of osteopenia: T-score between -1.0 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1.0) in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

OR

2.3 History of one of the following resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

AND

3 - Trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., alendronate)

Product Name: Prolia	
Diagnosis	Postmenopausal women with osteoporosis or osteopenia at a high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.) without significant adverse effects

Product Name: Prolia	
Diagnosis	Increase bone mass in men at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is a male with osteoporosis or osteopenia

AND

2 - One of the following: [16,17]

2.1 Bone mineral density (BMD) scan indicative of osteoporosis: T-score less than or equal to -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

OR

2.2 Both of the following:

2.2.1 BMD scan indicative of osteopenia: T-score between -1.0 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1.0) in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

OR

2.3 History of one of the following resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

AND

3 - Trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., alendronate)

Product Name: Prolia	
Diagnosis	Increase bone mass in men at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.) without significant adverse effects

Product Name: Prolia	
Diagnosis	Glucocorticoid-induced osteoporosis at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of glucocorticoid-induced osteoporosis

AND

2 - Patient is initiating or continuing on greater than or equal to 7.5 mg/day of prednisone (or its equivalent) and is expected to remain on glucocorticoid therapy for at least 6 months

AND

3 - One of the following: [F]

3.1 BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site)

OR

3.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

OR

3.3 History of one of the following fractures resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

AND

4 - Trial and failure, contraindication, or intolerance to one bisphosphonate (e.g., alendronate) [G]

Product Name: Prolia	
Diagnosis	Glucocorticoid-induced osteoporosis at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.) without significant adverse effects

3 . Definitions

Definition	Description
Bone mineral density (BMD) [3]	A risk factor for fractures. By DXA, BMD is expressed as the amount of mineralized tissue in the area scanned (g/cm(to the power of 2)); with some technologies, BMD is expressed as the amount per volume of bone (g/cm(to the power of 3)). Hip BMD by DXA is considered the best predictor of hip fracture; it appears to predict other types of fractures as well as measurements made at other skeletal sites. Spine BMD may be preferable to assess changes early in menopause and after bilateral ovariectomy.
Dual x-ray absorptiometry (DXA) [3]	A diagnostic test used to assess bone density in the spine, hip, or wrist using radiation exposure about one tenth that of a standard chest x-ray. Central DXA (spine, hip) is the preferred measurement for definitive diagnosis and for monitoring the effects of therapy.
Fracture [3]	Breakage of a bone, either complete or incomplete. Most studies of osteoporosis focus on hip, vertebra and/or distal forearm fractures. Vertebral fractures include morphometric as well as clinical fractures.

Osteopenia [3]	The designation for bone density between 1.0 and 2.5 standard deviations below the mean for young normal adults (T-score between -1 and -2.5).
Osteoporosis [3]	A chronic, progressive disease characterized by low bone mass, microarchitectural deterioration and decreased bone strength, bone fragility and a consequent increase in fracture risk; bone density 2.5 or more standard deviations below the young normal mean (T-score at or below -2.5).
Peripheral DXA [3]	A DXA test used to assess bone density in the forearm, finger and heel.
Quantitative computed tomography (QCT) [3]	A diagnostic test used to assess bone density; reflects three-dimensional bone mineral density. Usually used to assess the lumbar spine, but has been adapted for other skeletal sites. It is also possible to measure trabecular and cortical bone density in the periphery by peripheral QCT (pQCT).
Quantitative ultrasound densitometry (QUS) [3]	A diagnostic test used to assess bone density at the calcaneus or patella. Ultrasound measurements correlate only modestly with other assessments of bone density in the same patient, yet some prospective studies indicate that ultrasound may predict fractures as well as other measures of bone density.
Remodeling [3]	The ongoing dual processes of bone formation and bone resorption after cessation of growth.
Resorption [3]	The loss of substance (in this case, bone) through physiological or pathological means.
Risk factors [3]	For osteoporotic fractures, includes low BMD, parental history of hip fracture, low body weight, previous fracture, smoking, excess alcohol intake, glucocorticoid use, secondary osteoporosis (e.g., rheumatoid arthritis) and history of falls. These readily accessible and commonplace factors are associated with the risk of hip fracture and, in most cases, with that of vertebral and other types of fracture as well.
Severe or “established” osteoporosis [3]	Osteoporosis characterized by bone density that is 2.5 standard deviations or more below the young normal mean (T-score at or below -2.5), accompanied by the occurrence of at least one fragility-related fracture.
T-score [3]	In describing bone mineral density, the number of standard deviations above or below the mean for young normal adults of the same sex.

Z-score [3]	In describing bone mineral density, the number of standard deviations above or below the mean for persons of the same age and sex.

4 . Endnotes

A. Androgen deprivation therapy (ADT) is commonly used in the treatment of prostate cancer. ADT can be accomplished using luteinizing hormone-releasing hormone (LHRH) agonists (medical castration), also known as gonadotropin releasing hormone (GnRH) agonists, or bilateral orchiectomy (surgical castration), which are equally effective. [13] Examples of LHRH agonists include Eligard/Lupron (leuprolide), Trelstar (triptorelin), Vantas (histrelin), and Zoladex (goserelin).
B. Aromatase inhibitors (AIs) include selective, nonsteroidal AIs (Arimidex [anastrozole] and Femara [letrozole]) and steroidal AIs (Aromasin [exemestane]).
C. Meta-analyses have shown that advancing age increases fracture risk beyond that predicted by age related loss of BMD. Although typical changes in BMD would predict a 4-fold increase in fracture risk from ages 50 to 90 years, fracture risk actually increases 30-fold. Estimated fracture rates using FRAX calculations reflect a strong influence of older age on risk for clinical fracture. When clinical factors were used without BMD in one cross-sectional study, FRAX estimated that 76.6% of men in their 70s and virtually all men 80 years old or older exceeded the NOF recommended risk threshold for drug therapy. [14]
D. Most men run a 2-year course of androgen deprivation therapy while most women receive treatment with aromatase inhibitors for about 5 years. A one year treatment authorization is reasonable. [15]
E. Owing to the rate of bone loss associated with breast cancer treatments (i.e., aromatase inhibitors), and uncertainties about the interaction between aromatase inhibitor use and BMD for fracture risk, the threshold for intervention has been set at a higher level than that generally recommended for postmenopausal osteoporosis. [8]
F. According to the American College of Rheumatology (ACR) guidelines for the prevention and treatment of glucocorticoid-induced osteoperosis, patients considered at high risk of fractures are as follows: (a) prior osteoporotic fracture, (b) a hip or spine BMD T-score less than or equal to -2.5, or (c) FRAX 10-year risk of hip or major osteoporotic fracture at 3 percent or more and 20 percent or more, respectively. [18]
G. According to ACR, oral bisphosphonates are considered first-line for patients with glucocorticod-induced osteoperosis at high risk for fractures. For patients in whom oral bisphosphonates are not appropriate, IV bisphosphonates should be considered. [18]

5 . References

1. Prolia prescribing information. Amgen Inc. Thousand Oaks, CA. May 2022.
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9. Body JJ, Bergmann P, Boonen S, et al. Management of cancer treatment-induced bone loss in early breast cancer and prostate cancer – a consensus paper of the Belgian Bone Club. Osteoporos Int. 2007;18:1439-1450.
10. Hillner BE, Ingle JN, Chlebowski RT, et al. American Society of Clinical Oncology 2003 update on the role of bisphosphonates and bone health issues in women with breast cancer. J Clin Oncol. 2003;21:4042-4057.
11. Smith MR, Egerdie B, Toriz NH, et al. Denosumab in men receiving androgen-deprivation therapy for prostate cancer. N Engl J Med. 2009;361:745-755.
12. Ellis GK, Bone HG, Chlebowski R, et al. Randomized trial of denosumab in patients receiving adjuvant aromatase inhibitors for nonmetastatic breast cancer. J Clin Oncol. 2008 Oct 20. 26:2875-4882.
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6 . Revision History

Date	Notes
8/4/2022	2022 Annual Review - No changes to criteria, updated background in formation

Prior Authorization Guideline

Guideline Name	Promacta (eltrombopag)

Guideline Note:

Effective Date:	4/1/2022
P&T Approval Date:	2/17/2009
P&T Revision Date:	02/13/2020 ; 05/14/2020 ; 02/18/2021 ; 2/17/2022

1 . Indications

Drug Name: Promacta (eltrombopag)
Treatment of Thrombocytopenia in Patients with Persistent or Chronic Idiopathic Thrombocytopenic Purpura (ITP) Indicated for the treatment of thrombocytopenia in adult and pediatric patients 1 year and older with persistent or chronic immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Promacta should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. **Treatment of Thrombocytopenia in Patients with Hepatitis C Infection** Indicated for the treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. Promacta should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy. Limitations of use: • Safety and efficacy have not been established in combination with direct-acting antiviral agents used without interferon for treatment of chronic hepatitis C infection. **Treatment of Severe Aplastic Anemia** Indicated in combination with standard immunosuppressive therapy for the first-line treatment of adult and pediatric patients 2 years and older with severe aplastic anemia. Indicated for the treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.

2 . Criteria

Product Name: Promacta	
Diagnosis	Persistent or Chronic Idiopathic Thrombocytopenic Purpura (ITP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Persistent ITP
- Chronic ITP
- Relapsed/refractory ITP [8]

AND

2 - Baseline platelet count is less than 30,000/mcL [2, 3, 8]

AND

3 - Trial and failure, contraindication, or intolerance to one of the following: [2, 3, 8]

- Corticosteroids
- Immunoglobulins
- Splenectomy

AND

4 - Patient’s degree of thrombocytopenia and clinical condition increase the risk of bleeding

AND

5 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Promacta	
Diagnosis	Persistent or Chronic Idiopathic Thrombocytopenic Purpura (ITP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Promacta therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding

Product Name: Promacta	
Diagnosis	First-Line for Severe Aplastic Anemia
Approval Length	6 Months [A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe aplastic anemia

AND

2 - Used for first-line treatment (i.e., patient has not received prior immunosuppressive therapy with any equine antithymocyte globulin plus cyclosporine, alemtuzumab, or high dose cyclophosphamide) [1]

AND

3 - Patient meets at least TWO of the following [9, 10]:

- Absolute neutrophil count < 500/mcL
- Platelet count < 20,000/mcL
- Absolute reticulocyte count < 60,000/mcL

AND

4 - Used in combination with standard immunosuppressive therapy (e.g., Atgam [antithymocyte globulin equine] and cyclosporine) [1]

AND

5 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Promacta	
Diagnosis	Refractory Severe Aplastic Anemia
Approval Length	16 weeks [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of refractory severe aplastic anemia

AND

2 - Trial and failure, contraindication, or intolerance to immunosuppressive therapy with antithymocyte globulin (ATG) and cyclosporine [5-7]

AND

3 - Patient has thrombocytopenia defined as platelet count less than 30,000/mcL

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Promacta	
Diagnosis	Refractory Severe Aplastic Anemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Promacta therapy as evidenced by an increase in platelet count

Product Name: Promacta	
Diagnosis	Chronic Hepatitis C-Associated Thrombocytopenia
Approval Length	3 Months [C]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C-associated thrombocytopenia

AND

2 - One of the following:

2.1 Planning to initiate and maintain interferon-based treatment [1]

OR

2.2 Currently receiving interferon-based treatment

AND

3 - Prescribed by or in consultation with one of the following:

- Hematologist/oncologist
- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

Product Name: Promacta	
Diagnosis	Chronic Hepatitis C-Associated Thrombocytopenia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 For patients that started treatment with Promacta prior to initiation of treatment with interferon, Promacta will be approved when both of the following criteria are met:

1.1.1 Currently on antiviral interferon therapy for treatment of chronic hepatitis C [1]

AND

1.1.2 Documentation that the patient reached a threshold platelet count that allows initiation of antiviral interferon therapy with Promacta treatment by week 9 [C]

OR

1.2 For patients that started treatment with Promacta while on concomitant treatment with interferon, Promacta will be approved based on the following criterion:

1.2.1 Currently on antiviral interferon therapy for treatment of chronic hepatitis C

3 . Endnotes

A. The prescribing information states that the total duration of Promacta treatment for first-line severe aplastic anemia is 6 months. [1]
B. In patients with severe aplastic anemia, hematologic response requires dose titration, generally up to 150 mg, and may take up to 16 weeks after starting Promacta. The dose should be adjusted every 2 weeks as necessary to achieve the target platelet count greater than or equal to 50 x 10^9/L. If no hematologic response has occurred after 16 weeks of therapy with Promacta, therapy should be discontinued. [1]
C. Promacta was studied in two phase 3 trials for chronic hepatitis C-associated thrombocytopenia in two periods. Patients received Promacta in the first period for a maximum of 9 weeks in order to achieve a pre-specified threshold platelet count (greater than or equal to 90 x 10^9/L for Trial 1 and greater than or equal to 100 x 10^9/L for Trial 2); if the pre-specified threshold platelet count was reached, initiation of antiviral therapy in combination with interferon and ribavirin was administered for up to 48 weeks in the second period. The lowest dose of Promacta should be used to achieve and maintain a platelet count necessary to initiate and maintain interferon-based therapy. Dose adjustments are based upon the platelet count response. [1]

4 . References

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5 . Revision History

Date	Notes
1/6/2022	2022 Annual Review: Updated indication and diagnosis criteria to incl ude 'Persistent ITP', updated background information

Prior Authorization Guideline

Guideline Name	Proton Pump Inhibitors

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	2/15/2011
P&T Revision Date:	09/18/2019 ; 09/16/2020 ; 10/21/2020 ; 08/19/2021 ; 08/18/2022 ; 02/16/2023 ; 04/19/2023

1 . Indications

Drug Name: Aciphex (rabeprazole)
Treatment of Symptomatic Gastroesophageal Reflux Disease (GERD) in Adults Indicated for the treatment of daytime and nighttime heartburn and other symptoms associated with GERD in adults for up to 4 weeks. **Healing of Erosive or Ulcerative GERD in Adults** Indicated for short-term (4 to 8 weeks) treatment in the healing and symptomatic relief of erosive or ulcerative GERD. For those patients who have not healed after 8 weeks of treatment, an additional 8-week course of Aciphex may be considered. **Maintenance of Healing of Erosive or Ulcerative GERD in Adults** Indicated for maintaining healing and reduction in relapse rates of heartburn symptoms in patients with erosive or ulcerative gastroesophageal reflux disease (GERD Maintenance). Controlled studies do not extend beyond 12 months. **Pathological Hypersecretory Conditions including Zollinger-Ellison Syndrome in Adults** Indicated for the long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome. **Helicobacter pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence in**

Adults In combination with amoxicillin and clarithromycin as a three drug regimen, indicated for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or history within the past 5 years) to eradicate H. pylori. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence. In patients who fail therapy, susceptibility testing should be done. If resistance to clarithromycin is demonstrated or susceptibility testing is not possible, alternative antimicrobial therapy should be instituted.

Healing of Duodenal Ulcers in Adults Indicated for short-term (up to 4 weeks) treatment in the healing and symptomatic relief of duodenal ulcers. Most patients heal within 4 weeks.

Short-term Treatment of Symptomatic GERD in Adolescent Patients 12 years of Age and Older Indicated for the treatment of symptomatic GERD in adolescents 12 years of age and above for up to 8 weeks.

Drug Name: Aciphex Sprinkle (rabeprazole)

Patients 1 to 11 Years of Age Indicated for treatment of GERD in pediatric patients 1 to 11 years of age for up to 12 weeks.

Drug Name: Dexilant (dexlansoprazole)

Symptomatic Non-Erosive GERD Indicated in patients 12 years of age and older for the treatment of heartburn associated with symptomatic non-erosive GERD for 4 weeks.

Healing of Erosive Esophagitis Indicated in patients 12 years of age and older for healing of all grades of erosive esophagitis for up to 8 weeks.

Maintenance of Healed Erosive Esophagitis Indicated in patients 12 years of age and older to maintain healing of erosive esophagitis and relief of heartburn for up to six months in adults and 16 weeks in patients 12 to 17 years of age.

Drug Name: Esomeprazole strontium

Healing of Erosive Esophagitis Indicated for the short-term treatment (4 to 8 weeks) in the healing and symptomatic resolution of diagnostically confirmed erosive esophagitis. For those patients who have not healed after 4 to 8 weeks of treatment, an additional 4 to 8 week course of esomeprazole strontium may be considered.

Maintenance of Healing of Erosive Esophagitis Indicated to maintain symptom resolution and healing of erosive esophagitis. Controlled studies do not extend beyond 6 months.

Symptomatic Gastroesophageal Reflux Disease Indicated for short-term treatment (4 to 8 weeks) of heartburn and other symptoms associated with GERD in adults.

Risk Reduction of NSAID-Associated Gastric Ulcer in Adults Indicated for the reduction in the occurrence of gastric ulcers associated with continuous NSAID therapy in patients at risk for developing gastric ulcers. Patients are considered to be at risk either due to their age (greater than or equal to 60) and/or documented history of gastric ulcers. Controlled studies do not extend beyond 6 months.

H. pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence in Adults In combination with amoxicillin and clarithromycin, indicated for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or history of within the past 5 years) to eradicate H. pylori. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence. In patients who fail therapy, susceptibility testing should be done. If resistance to clarithromycin is demonstrated or susceptibility testing is not possible, alternative antimicrobial therapy should be instituted.

Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome in Adults Indicated for the long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison Syndrome.

Drug Name: Konvomep (omeprazole and sodium bicarbonate)

Gastric Ulcer Indicated for the short-term treatment (4 to 8 weeks) of active benign gastric ulcer in adults.

Reduction of Risk of Upper Gastrointestinal Bleeding in Critically Ill Patients Indicated for the reduction of risk of upper gastrointestinal (GI) bleeding in critically ill adult patients.

Drug Name: Nexium (esomeprazole)

Symptomatic GERD Indicated for short-term treatment (4 to 8 weeks) of heartburn and other symptoms associated with GERD in adults and children 1 year or older.

Healing of Erosive Esophagitis Indicated for the short-term treatment (4 to 8 weeks) in the healing and symptomatic resolution of diagnostically confirmed erosive esophagitis. For those patients who have not healed after 4 to 8 weeks of treatment, an additional 4 to 8 week course of Nexium may be considered. In infants 1 month to less than 1 year, Nexium is indicated for short-term treatment (up to 6 weeks) of erosive esophagitis due to acid-medicated GERD.

Maintenance of Healing of Erosive Esophagitis Indicated for the maintenance of healing of erosive esophagitis in adults. Controlled studies do not extend beyond 6 months.

Pathological Hypersecretory Conditions including Zollinger-Ellison Syndrome Indicated for the long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome, in adults.

Helicobacter pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence In combination with amoxicillin and clarithromycin, indicated for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or history of within the past 5 years) to eradicate H. pylori. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence. In patients who fail therapy, susceptibility testing should be done. If resistance to clarithromycin is demonstrated or susceptibility testing is not possible, alternative antimicrobial therapy should be instituted.

Risk Reduction of NSAID-Associated Gastric Ulcer Indicated for the reduction in the occurrence of gastric ulcers associated with continuous NSAID therapy in adult patients at risk for developing gastric ulcers. Patients are considered to be at risk due to their age (60

years and older) and/or documented history of gastric ulcers. Controlled studies do not extend beyond 6 months.

Drug Name: Prevacid (lansoprazole)

Short-Term Treatment of Active Duodenal Ulcer Indicated for short-term treatment (for 4 weeks) for healing and symptom relief of active duodenal ulcer in adults.

H. pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence In combination with amoxicillin plus clarithromycin as triple therapy, indicated for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or one-year history of a duodenal ulcer) to eradicate H. pylori. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence. In combination with amoxicillin as dual therapy, indicated for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or one-year history of a duodenal ulcer) who are either allergic or intolerant to clarithromycin or in whom resistance to clarithromycin is known or suspected. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence.

Maintenance of Healed Duodenal Ulcers Indicated to maintain healing of duodenal ulcers in adults. Controlled studies do not extend beyond 12 months.

Short-Term Treatment of Active Benign Gastric Ulcer Indicated for short-term treatment (up to 8 weeks) for healing and symptom relief of active benign gastric ulcer in adults.

Healing of NSAID-Associated Gastric Ulcer Indicated in adults for the treatment of NSAID-associated gastric ulcer in patients who continue NSAID use. Controlled studies did not extend beyond 8 weeks.

Risk Reduction of NSAID-Associated Gastric Ulcer Indicated in adults for reducing the risk of NSAID-associated gastric ulcers in patients with a history of a documented gastric ulcer who require the use of an NSAID. Controlled studies did not extend beyond 12 weeks.

Short-Term Treatment of Symptomatic GERD Indicated for short-term treatment in adults and pediatric patients 12 to 17 years of age (up to eight weeks) and pediatric patients one to 11 years of age (up to 12 weeks) for the treatment of heartburn and other symptoms associated with GERD.

Maintenance of Healing of Erosive Esophagitis Indicated in adults to maintain healing of EE. Controlled studies did not extend beyond 12 months.

Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome Indicated in adults for the long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome.

Short-Term Treatment of Erosive Esophagitis Indicated for short-term treatment in adults and pediatric patients 12 to 17 years of age (up to eight weeks) and pediatric patients one to 11 years of age (up to 12 weeks) for healing and symptom relief of all grades of erosive esophagitis. For adults who do not heal with Prevacid for 8 weeks (5 to 10%), it may be

helpful to give an additional 8 weeks of treatment. If there is a recurrence of erosive esophagitis, an additional 8-week course of Prevacid may be considered.

Drug Name: Prilosec (omeprazole)

Treatment of Active Duodenal Ulcer Indicated for short-term treatment of active duodenal ulcer in adults. Most patients heal within four weeks. Some patients may require an additional four weeks of therapy.

Helicobacter pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence In combination with clarithromycin and amoxicillin, indicated for treatment of patients with H. pylori infection and duodenal ulcer disease (active or up to 1-year history) to eradicate H. pylori in adults. In combination with clarithromycin, indicated for treatment of patients with H. pylori infection and duodenal ulcer disease to eradicate H. pylori in adults. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence. Among patients who fail therapy, Prilosec with clarithromycin is more likely to be associated with the development of clarithromycin resistance as compared with triple therapy. In patients who fail therapy, susceptibility testing should be done. If resistance to clarithromycin is demonstrated or susceptibility testing is not possible, alternative antimicrobial therapy should be instituted.

Gastric Ulcer (adults) Indicated for short-term treatment (4 to 8 weeks) of active benign gastric ulcer in adults.

Treatment of Symptomatic GERD (adults and pediatric patients) Indicated for the treatment of heartburn and other symptoms associated with GERD for up to 4 weeks in patients 1 year of age and older.

Maintenance of Healing of Erosive Esophagitis Indicated for the maintenance healing of EE due to acid-mediated GERD in patients 1 year of age and older. Controlled studies do not extend beyond 12 months.

Pathological Hypersecretory Conditions (adults) Indicated for the long-term treatment of pathological hypersecretory conditions (e.g., Zollinger-Ellison syndrome, multiple endocrine adenomas and systemic mastocytosis) in adults.

Erosive Esophagitis Indicated for the short-term treatment (4 to 8 weeks) of erosive esophagitis due to acid-mediated GERD that has been diagnosed by endoscopy in patients 1 year of age and older. The efficacy of Prilosec used for longer than 8 weeks in these patients has not been established. If a patient does not respond to 8 weeks of treatment, an additional 4 weeks of treatment may be given. If there is recurrence of erosive esophagitis or GERD symptoms, additional 4 to 8 week courses of omeprazole may be considered. Also indicated for the short-term treatment (up to 6 weeks) of erosive esophagitis due to acid-mediated GERD in pediatric patients 1 month to less than 1 year of age.

Drug Name: Protonix (pantoprazole)

Short-Term Treatment of Erosive Esophagitis Associated With GERD Indicated in adults and pediatric patients five years of age and older for the short-term treatment (up to 8 weeks) in the healing and symptomatic relief of erosive esophagitis. For those adult patients who have not healed after 8 weeks of treatment, an additional 8-week course of Protonix may be

considered. Safety of treatment beyond 8 weeks in pediatric patients has not been established.

Maintenance of Healing of Erosive Esophagitis Indicated for maintenance of healing of erosive esophagitis and reduction in relapse rates of daytime and nighttime heartburn symptoms in adult patients with GERD. Controlled studies did not extend beyond 12 months.

Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome Indicated for the long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome.

Drug Name: Zegerid (omeprazole/sodium bicarbonate)

Duodenal Ulcer Indicated for short-term treatment of active duodenal ulcer. Most patients heal within four weeks. Some patients may require an additional four weeks of therapy.

Gastric Ulcer Indicated for short-term treatment (4-8 weeks) of active benign gastric ulcer.

Symptomatic GERD Indicated for the treatment of heartburn and other symptoms associated with GERD for up to 4 weeks.

Maintenance of Healing of Erosive Esophagitis Due to Acid-Mediated GERD Indicated to maintain healing of erosive esophagitis due to acid-mediated GERD. Controlled studies do not extend beyond 12 months.

Reduction of Risk of Upper Gastrointestinal Bleeding in Critically Ill Patients (40 mg oral suspension only) Indicated for the reduction of risk of upper GI bleeding in critically ill patients.

Erosive Esophagitis due to acid-mediated GERD Indicated for the short-term treatment (4 to 8 weeks) of erosive esophagitis due to acid-mediated GERD which has been diagnosed by endoscopy in adults. The efficacy of ZEGERID used for longer than 8 weeks in patients with EE has not been established. If a patient does not respond to 8 weeks of treatment, an additional 4 weeks of treatment may be given. If there is recurrence of EE or GERD symptoms (e.g., heartburn), additional 4 to 8-week courses of ZEGERID may be considered.

2 . Criteria

Product Name: Aciphex Sprinkle, Brand Aciphex tablets, Authorized Brand Alternative Rabeprazole Sprinkle, Brand Dexilant capsules, Esomeprazole strontium capsules, Brand Prevacid capsules, Brand Prevacid Solutab, Brand Prilosec capsules, Prilosec suspension, Brand Protonix tablets, Brand Protonix suspension, Brand Zegerid capsules, Brand Zegerid suspension, First-Lansoprazole suspension, or First-Omeprazole suspension, Konvomep suspension	
Approval Length	12 month(s)

Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure or intolerance to at least two of the following:

- esomeprazole
- lansoprazole (capsule)
- omeprazole
- pantoprazole
- rabeprazole (tablets)
- dexlansoprazole

Product Name: Aciphex Sprinkle*, Brand Aciphex tablets*, Authorized Brand Alternative Rabeprazole Sprinkle*, Generic rabeprazole tablets, Brand Dexilant capsules, Esomeprazole strontium capsules*, Brand Nexium capsules, Generic esomeprazole capsules, Nexium suspension, Brand Prevacid capsules*, Generic lansoprazole capsules, Brand Prevacid Solutab*, Generic lansoprazole orally disintegrating tablets, Brand Prilosec capsules*, Generic omeprazole capsules, Prilosec suspension*, Brand Protonix tablets*, Generic pantoprazole tablets, Brand Protonix suspension*, Generic pantoprazole suspension, Brand Zegerid capsules*, Generic omeprazole-sodium bicarbonate capsules, Brand Zegerid suspension*, Generic omeprazole-sodium bicarbonate suspension, Generic dexlansoprazole capsules	
Diagnosis	Twice-daily (BID) PPI Therapy**
Guideline Type	Quantity Limit

Approval Criteria

1 - One of the following:

1.1 Trial and inadequate response to once daily PPI regimen

OR

1.2 A once daily PPI regimen is not appropriate to treat the patient's condition

AND

2 - Requested dose does not exceed maximum dose range found in labeling or supported by one of the following off label compendia for the requested product^:

- American Hospital Formulary Service Drug Information
- Micromedex Drug System
- Clinical research in two articles from major peer reviewed medical journals that present data supporting requested dose as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal

Notes	Authorization of therapy will be issued for 12 months for all diagnoses, except for H. pylori eradication. For H. pylori eradication, authorization will be issued for 14 days. *These products may require step therapy. **Requests for greater than twice-daily dosing must be reviewed using the Quantity Limit General Administrative Guideline. ^Support found in labeling or compendia should be evaluated regardless of indication.

3 . Background

Clinical Practice Guidelines

BID Max Range Dosing Table [12-15]

***Intent of table below is to provide a quick reference for BID dosing range listed by requested product. If the requested dose exceeds max dose listed below, PA team members should still review at point of request for clinical appropriateness as off label support continuously evolves. [Last Reviewed: 8/3/22]**

	Aciphex (rabeprazole)	Dexilant (dexlansoprazole)	Esomeprazole strontium	Nexium (esomeprazole)	Prevacid	Prilosec (omeprazole)	Protonix	Zegerid (omeprazole/sodium

					(Lanso prazole)		(panto prazole)	bicarbonat e)
DO SE RA NG E	20 to 60 mg BID	30 mg BID	49.3 mg BID (Max = 240 mg/day)	20 to 40 mg BID (Max = 240 mg/day)	30 to 90 mg BID	20 to 40mg BID (Max = 360 mg/day ; divide doses above **80mg)**	40 to 80 mg BID (Max = 240 mg/day)	No BID support found at time of last annual review

4 . Endnotes

A. Both strengths of Zegerid capsule and powder for oral suspension have identical sodium bicarbonate content, respectively. Do not substitute two 20 mg capsules/packets for one 40 mg dose [4].

5 . References

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2. Aciphex Sprinkle Prescribing Information. Cerecor, Inc. Rockville, MD June 2018.
3. Esomeprazole Strontium Prescribing Information. Amneal Pharmaceuticals LLC. Glasgow, KY. January 2021.
4. Prilosec Prescribing Information. AstraZeneca Pharmaceuticals LP. wilmington, DE. March 2022.
5. Protonix Prescribing Information. Wyeth Pharmaceuticals, Inc. Philadelphia, PA. March 2022.
6. Zegerid Prescribing Information. Salix Pharmaceuticals. Bridgewater, NJ. March 2022.
7. Dexilant Prescribing Information. Takeda Pharmaceuticals America, Inc. Deerfield, IL. March 2022.

8. Nexium Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. March 2022.
9. Prevacid Prescribing Information. Takeda Pharmaceuticals, Inc. Deerfield, IL. March 2022.
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12. Micromedex solutions Web site. http://www.micromedexsolutions.com/home/dispatch. Accessed August 19, 2020.
13. Frazzoni M, Manno M, De Micheli E, Savarino V. Intra-oesophageal acid suppression in complicated gastro-oesophageal reflux disease: esomeprazole versus lansoprazole. Dig Liver Dis. 2006;38(2):85-90.
14. Huaiyuan G, Ma H, Wang J. Proton pump inhibitor therapy for the treatment of laryngopharyngeal reflux: a meta-analysis of randomized controlled trials. J Clin Gastroenterol. 2016;50(4):295-300.
15. Rees JRE, Lao-Sirieix P, Wong A, Fitzgerald RC. Treatment for Barrett's oesophagus. Cochrane Database of Syst Rev. 2010;1. Art. No.: CD004060. doi:10.1002/14651858.CD004060.pub2.
16. Konvomep Prescribing Information. Azurity Pharmaceuticals, Inc. Woburn, MA. December 2022.

6 . Revision History

Date	Notes
4/24/2023	Removed Brand Dexilant as ST option and added it as a target drug t o ST guideline

Prior Authorization Guideline

Guideline Name	Provigil (modafinil), Nuvigil (armodafinil)

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	5/21/1999
P&T Revision Date:	08/15/2019 ; 11/14/2019 ; 04/15/2020 ; 09/16/2020 ; 11/12/2020 ; 11/12/2020 ; 11/18/2021 ; 11/17/2022

1 . Indications

Drug Name: Provigil (modafinil)
Narcolepsy Indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy. **Obstructive sleep apnea (OSA)** Indicated to improve wakefulness in adult patients with excessive sleepiness associated with obstructive sleep apnea (OSA). Limitations of Use: Provigil is indicated to treat excessive sleepiness and not as treatment for the underlying obstruction. If continuous positive airway pressure (CPAP) is the treatment of choice for a patient, a maximal effort to treat with CPAP for an adequate period of time should be made prior to initiating and during treatment with Provigil for excessive sleepiness. **Shift work disorder (SWD)** Indicated to improve wakefulness in adult patients with excessive sleepiness associated with shift work disorder. **Off Label Uses: Fatigue due to multiple sclerosis (MS)** In a double-blind, placebo-controlled study, treatment with modafinil significantly improved fatigue symptoms compared with placebo in patients with multiple sclerosis (MS) [5,7] **Adjunctive therapy for the treatment of major depressive disorder (MDD) or bipolar disorder** In a meta-analysis of 4 MDD RCTs and 2 bipolar depression RCTs, adjunctive

treatment with modafinil improved overall depression scores, remission rates, and fatigue symptoms. [5,9]

Drug Name: Nuvigil (armodafinil)

Narcolepsy Indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy.

Obstructive sleep apnea (OSA) Indicated to improve wakefulness in adult patients with excessive sleepiness associated with obstructive sleep apnea (OSA). Limitations of Use: Nuvigil is indicated to treat excessive sleepiness and not as treatment for the underlying obstruction. If continuous positive airway pressure (CPAP) is the treatment of choice for a patient, a maximal effort to treat with CPAP for an adequate period of time should be made prior to initiating Nuvigil for excessive sleepiness.

Shift work disorder (SWD) Indicated to improve wakefulness in adult patients with excessive sleepiness associated with shift work disorder.

2 . Criteria

Product Name: Generic armodafinil, Generic modafinil, Brand Nuvigil, or Brand Provigil	
Diagnosis	Obstructive Sleep Apnea (OSA)
Approval Length	6 Months [G]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of obstructive sleep apnea defined by one of the following: [1,4,10]

1.1 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [6,10,D, F]

OR

1.2 Both of the following: [6,10,D, F]

1.2.1 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

AND

1.2.2 One of the following symptoms:

- Unintentional sleep episodes during wakefulness
- Daytime sleepiness
- Unrefreshing sleep
- Fatigue
- Insomnia
- Waking up breath holding, gasping, or choking
- Loud snoring
- Breathing interruptions during sleep

AND

2 - Both of the following:

2.1 Standard treatments for the underlying obstruction (e.g., continuous positive airway pressure [CPAP], bi-level positive airway pressure [BPAP], etc.) have been used for 3 months or longer [5]

AND

2.2 Patient is fully compliant with standard treatment(s) for the underlying obstruction.

AND

3 - Trial and failure or intolerance to modafinil (applies to Provigil only)

AND

4 - Trial and failure or intolerance to armodafinil (applies to Nuvigil only)

Product Name: Generic armodafinil, Generic modafinil, Brand Nuvigil, or Brand Provigil	
Diagnosis	Obstructive Sleep Apnea (OSA)
Approval Length	6 Months [G]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient continues to be fully compliant on concurrent standard treatment(s) for the underlying obstruction (e.g., CPAP, BPAP, etc.)

AND

2 - Patient is experiencing relief of symptomatic hypersomnolence with use

Product Name: Generic armodafinil, Generic modafinil, Brand Nuvigil, or Brand Provigil	
Diagnosis	Shift Work Disorder (SWD)
Approval Length	6 Months [G]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Shift Work Disorder confirmed by one of the following: [10,12]

1.1 Symptoms of excessive sleepiness or insomnia, for at least 3 months, which is temporally associated with a work period (usually night work) that occurs during the habitual sleep phase

OR

1.2 Sleep study demonstrating loss of a normal sleep wake pattern (i.e., disturbed chronobiologic rhythmicity)

AND

2 - Confirmation that no other medical conditions or medications are causing the symptoms of excessive sleepiness or insomnia [10,12]

AND

3 - Trial and failure or intolerance to modafinil (applies to Provigil only)

AND

4 - Trial and failure or intolerance to armodafinil (applies to Nuvigil only)

Product Name: Generic armodafinil, Generic modafinil, Brand Nuvigil, or Brand Provigil	
Diagnosis	Shift Work Disorder (SWD)
Approval Length	6 Months [G]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Generic modafinil, Brand Provigil	
Diagnosis	Fatigue due to MS (off-label) [5,7,E]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis (MS)

AND

2 - Patient is experiencing fatigue

AND

3 - Used in combination with standard educational therapies (e.g., psychoeducation, behavioral programs, scheduled naps, additional non-pharmacological therapies, etc.)

AND

4 - Trial and failure or intolerance to modafinil (applies to Provigil only)

Product Name: Generic modafinil, Brand Provigil	
Diagnosis	Fatigue due to MS (off-label) [5,7,E]
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is experiencing relief of fatigue with therapy

AND

2 - Used in combination with standard educational therapies (e.g., psychoeducation, behavioral programs, scheduled naps, additional non-pharmacological therapies, etc.)

Product Name: Generic armodafinil, Generic modafinil, Brand Nuvigil, or Brand Provigil	
Diagnosis	Narcolepsy

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [1,4,10,A-C]

AND

2 - Trial and failure or intolerance to modafinil (applies to Provigil only)

AND

3 - Trial and failure or intolerance to armodafinil (applies to Nuvigil only)

Product Name: Generic armodafinil, Generic modafinil, Brand Nuvigil, or Brand Provigil	
Diagnosis	Narcolepsy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Generic modafinil, Brand Provigil	
Diagnosis	Adjunctive therapy for the treatment of major depressive disorder or bipolar depression (off-label)[5,9]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Treatment-resistant depression, defined as both of the following:

1.1 Diagnosis of one of the following [9]:

- Major depressive disorder (MDD)
- Bipolar depression

AND

1.2 History of failure, contraindication, or intolerance to at least two antidepressants from different classes (e.g., SSRIs, SNRIs, bupropion)

AND

2 - Used as adjunctive therapy

AND

3 - Trial and failure or intolerance to modafinil (applies to Provigil only)

Product Name: Generic modafinil, Brand Provigil	
Diagnosis	Adjunctive therapy for the treatment of major depressive disorder or bipolar depression (off-label)[5,9]
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Used as adjunctive therapy

Product Name: Generic armodafinil 50 mg, Generic modafinil 100 mg, Brand Nuvigil 50 mg, or Brand Provigil 100 mg	
Guideline Type	Quantity Limit

Approval Criteria

1 - One of the following:

1.1 Quantity limit override requests must involve an FDA-approved indication.

OR

1.2 Quantity limit override requests involving off-label indications must meet off-label guideline requirements.

AND

2 - One of the following:

2.1 For titration purposes (one time authorization)

OR

2.2 Requested strength/dose is commercially unavailable

OR

2.3 Patient is on a dose alternating schedule

Notes	Authorization will be issued for the length of therapy based on indication, except for titration purposes (Narcolepsy: 12 months, All other indications: 6 months). Not to exceed maximum FDA-approved dose.

Product Name: Generic modafinil 200 mg, Brand Provigil 200 mg	
Guideline Type	Quantity Limit

Approval Criteria

1 - One of the following:

1.1 Quantity limit override requests must involve an FDA-approved indication.

OR

1.2 Quantity limit override requests involving off-label indications must meet off-label guideline requirements.

AND

2 - History of inadequate response to Provigil 200 mg/day

AND

3 - One of the following:**

3.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

OR

3.2 Higher dose or quantity is supported by one of following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System

Notes	Authorization will be issued for the length of therapy based on indicati on (Narcolepsy: 12 months, All other indications: 6 months). **NOTE: Published biomedical literature may be used as evidence to support s afety and additional efficacy at higher than maximum doses for the dia gnosis provided.

Product Name: Generic armodafinil 150 mg, Brand Nuvigil 150 mg, Generic armodafinil 200 mg, Brand Nuvigil 200 mg, Generic armodafinil 250 mg, or Brand Nuvigil 250 mg	
Guideline Type	Quantity Limit

Approval Criteria

1 - One of the following:

1.1 Quantity limit override requests must involve an FDA-approved indication.

OR

1.2 Quantity limit override requests involving off-label indications must meet off-label guideline requirements.

AND

2 - One of the following**

2.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

OR

2.2 Higher dose or quantity is supported by one of following compendia

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System

Notes	Authorization will be issued for the length of therapy based on indicati on, except for titration purposes (Narcolepsy: 12 months, All other indi cations: 6 months). Not to exceed maximum FDA-approved dose. NO

	TE: Published biomedical literature may be used as evidence to supp ort safety and additional efficacy at higher than maximum doses for th e diagnosis provided.

Product Name: Brand Provigil 200mg, Generic modafinil 200mg	
Diagnosis	Narcolepsy: Twice-daily (BID) Therapy**
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [1,4,10,A-C]

AND

2 - One of the following

2.1 Trial and inadequate response to once daily treatment

OR

2.2 A once daily treatment is not appropriate to treat the patient's condition

AND

3 - Requested dose does not exceed maximum dose range found in labeling or supported by one of the following off label compendia for the requested product:

- American Hospital Formulary Service Drug Information
- Micromedex Drug System
- Clinical research in two articles from major peer reviewed medical journals that present data supporting requested dose as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal

Notes	**Requests for greater than twice-daily dosing must be reviewed using the Quantity Limit General Administrative Guideline.

3 . Definitions

Definition	Description
Cataplexy [3]	A sudden loss of muscle tone that leads to feelings of weakness and a loss of voluntary muscle control.
CPAP (continuous positive airway pressure) [3]	Delivers pressurized air from a machine into airways through a specially designed mask that is worn during sleep.
Multiple sleep latency test (MSLT) [3]	Assesses the severity of sleepiness by measuring the speed of falling asleep during a series of nap trials.
Narcolepsy [3]	A neurological condition in which people experience excessive daytime sleepiness, cataplexy, sleep paralysis, hallucinations and intermittent, uncontrollable sleep attacks during the daytime.
Non-Rapid Eye Movement (NREM) sleep [3]	One of the two basic states of sleep; consists of Stages 1, 2 (light sleep) and 3,4 (deep sleep).
Obstructive sleep apnea (OSA) [3]	The most common kind of sleep apnea. It is caused by a blockage of the upper airway.
Polysomnography [3]	A test that records sleep architecture (i.e. the amount of NREM and REM sleep, number of arousals) and a variety of body functions during sleep, including breathing patterns, heart rhythms and limb movements. It is most commonly done to evaluate for sleep apnea.
Rapid Eye Movement (REM) sleep [3]	One of the two basic states of sleep. REM sleep, also known as "dream sleep," is characterized by rapid eye movements, and more irregular breathing and heart rate compared to NREM sleep.

4 . Endnotes

A. The American Academy of Sleep Medicine guidelines list modafinil as a standard patient care strategy (generally accepted patient-care strategy that reflects a high degree of clinical certainty). [2]

B. International Classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy with cataplexy (narcolepsy type 1) include: 1. Daily periods of irrepressible need for sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) for at least 3 months. 2. One or both of the following: cataplexy and a mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques (a SOREMP within 15 minutes of sleep onset on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT); or cerebrospinal fluid (CSF) hypocretin-1 concentration is low (less than 110 pg/mL or one-third of the normative values with the same standardized assay). 3. Exclusion of alternative causes of chronic daytime sleepiness by history, physical exam, and polysomnography. Other conditions that cause chronic daytime sleepiness include insufficient sleep, untreated sleep apnea, periodic limb movements of sleep, and idiopathic hypersomnia (chronic sleepiness but without SOREMPs or other evidence of abnormal REM sleep). In addition, the effects of sedating medications should be excluded. [10,11]
C. International Classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy without cataplexy (narcolepsy type 2) include: 1. Daily periods of irrepressible need for sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) for at least 3 months. 2. Cataplexy is absent 3. CSF hypocretin-1 levels, if measured, must not meet the narcolepsy type 1 criterion. 4. A mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques (a SOREMP within 15 minutes of sleep onset on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT). 5. Exclusion of alternative causes of chronic daytime sleepiness by history, physical exam, and polysomnography. Other conditions that cause chronic daytime sleepiness include insufficient sleep, untreated sleep apnea, periodic limb movements of sleep, and idiopathic hypersomnia (chronic sleepiness but without SOREMPs or other evidence of abnormal REM sleep). In addition, the effects of sedating medications should be excluded. [10.11]
D. International Classification of Sleep Disorders (ICSD-3) diagnostic criteria for obstructive sleep apnea-hypopnea syndrome (OSAHS) include: One of the following: 1. PSG shows greater than or equal to 5 obstructive respiratory events per hour of sleep in a patient with one or more of the following: a. sleepiness, nonrestorative sleep, fatigue or insomnia symptoms b. waking up with breath holding, gasping or choking c. habitual snoring, breathing interruptions, or both noted by a bed partner or other observer d. hypertension, mood disorder, cognitive dysfunction, coronary artery disease, stroke, congestive heart failure, atrial fibrillation, or type 2 diabetes mellitus 2. Greater than or equal to 15 obstructive respiratory events per hour of sleep, regardless of the presence of associated symptoms or comorbidities. In addition, the disorder is not explained by another current sleep disorder, medical or neurological disorder, medication use, or substance use disorder. [10, F, G]
E. Despite lack of good clinical evidence or statement/guideline from a professional society, use of modafinil for fatigue is considered the standard practice in MS patients [8].
F. Examples of obstructive respiratory events include: obstructive and mixed apneas, hypopneas, or respiratory effort related arousals (RERA) [10].
G. The effectiveness of modafinil (greater than 12 weeks for obstructive sleep apnea or SWD) and the effectiveness of armodafinil in long-term use (greater than 12 weeks) have not been systematically evaluated in placebo-controlled trials. [1,4]

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6 . Revision History

Date	Notes
12/15/2022	Removed note from quantity limit section referencing "titration" and " not to exceed maximum FDA-approved dose" per PA team feedback.

Prior Authorization Guideline

Guideline Name	Pulmonary Arterial Hypertension Agents - PA, NF

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	8/15/2005
P&T Revision Date:	07/17/2019 ; 11/14/2019 ; 12/18/2019 ; 02/13/2020 ; 02/18/2021 ; 06/16/2021 ; 10/20/2021 ; 11/18/2021 ; 02/17/2022 ; 07/20/2022 ; 10/19/2022 ; 02/16/2023 ; 03/15/2023 ; 4/19/2023

1 . Indications

Drug Name: Adcirca (tadalafil) Tablets, Alyq (tadalafil) Tablets, Tadliq (tadalafil) Oral Suspension
Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group I) to improve exercise ability. Studies establishing effectiveness included predominately patients with New York Heart Association (NYHA) Functional Class II–III symptoms and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (23%).
Drug Name: Adempas (riociguat) Tablets
Pulmonary Arterial Hypertension (PAH) Indicated for treatment of adults with PAH (WHO Group I) to improve exercise capacity, WHO Functional Class, and to delay clinical worsening. Efficacy was shown in patients on riociguat monotherapy or in combination with endothelin receptor antagonists or prostanoids. Studies establishing effectiveness included predominantly patients with WHO Functional Class II to III and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (25%). **Chronic-Thromboembolic Pulmonary Hypertension (CTEPH)** Indicated for treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH),

(WHO Group 4) after surgical treatment, or inoperable CTEPH, to improve exercise capacity and WHO Functional Class.

Drug Name: Flolan (epoprostenol sodium) Injection

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to improve exercise capacity. Studies establishing effectiveness included predominantly (97%) patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH (49%) or PAH associated with connective tissue diseases (51%).

Drug Name: Letairis (ambrisentan) Tablets

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to 1) improve exercise ability and delay clinical worsening and 2) in combination with tadalafil to reduce the risks of disease progression and hospitalization for worsening PAH, and to improve exercise ability. Studies establishing effectiveness included predominantly patients with WHO Functional Class II-III symptoms and etiologies of idiopathic or heritable PAH (60%) or PAH associated with connective tissue diseases (34%).

Drug Name: Opsumit (macitentan) Tablets

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to reduce the risks of disease progression and hospitalization for PAH. Effectiveness was established in a long-term study in PAH patients with predominantly WHO Functional Class II-III symptoms treated for an average of 2 years. Patients had idiopathic and heritable PAH (57%), PAH caused by connective tissue disorders (31%), and PAH caused by congenital heart disease with repaired shunts (8%).

Drug Name: Orenitram (treprostinil) Tablets

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to delay disease progression and to improve exercise capacity. The studies that established effectiveness included predominately patients with WHO functional class II-III symptoms and etiologies of idiopathic or heritable PAH (66%) or PAH associated with connective tissue disease (26%).

Drug Name: Remodulin (treprostinil sodium) Injection

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to diminish symptoms associated with exercise. Studies establishing effectiveness included patients with NYHA Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (58%), PAH associated with congenital systemic-to-pulmonary shunts (23%), or PAH associated with connective tissue diseases (19%). Indicated to diminish the rate of clinical deterioration in patients with PAH requiring transition from epoprostenol. Consider the risks and benefits of each drug prior to transition.

Drug Name: Revatio (sildenafil) Injection, Tablets, Oral Suspension

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I): 1) In adults to improve exercise ability and delay clinical worsening. 2) in pediatric patients 1 to 17 years old to improve exercise ability and, in pediatric patients too young to perform standardized exercise testing, pulmonary hemodynamics thought to underly improvements in exercise.

Drug Name: Tracleer (bosentan) Tablets, Tablets for Suspension

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I): 1) In adults to improve exercise ability and to decrease clinical worsening. Studies establishing effectiveness included predominantly patients with WHO Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (60%), PAH associated with connective tissue diseases (21%), and PAH associated with congenital heart disease with left-to right shunts (18%). 2) In pediatric patients aged 3 years and older with idiopathic or congenital PAH to improve pulmonary vascular resistance (PVR), which is expected to result in an improvement in exercise ability.

Drug Name: Tyvaso (treprostinil) Inhalation Solution, Tyvaso (treprostinil) DPI Inhalation Powder

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to improve exercise ability. Studies establishing effectiveness included predominately patients with NYHA Functional Class III symptoms and etiologies of idiopathic or heritable PAH (56%) or PAH associated with connective tissue diseases (33%). The effects diminish over the minimum recommended dosing interval of 4 hours; treatment timing can be adjusted for planned activities. While there are long-term data on use of treprostinil by other routes of administration, nearly all controlled clinical experience with inhaled treprostinil has been on a background of bosentan (an endothelin receptor antagonist) or sildenafil (a phosphodiesterase type 5 inhibitor). The controlled clinical experience was limited to 12 weeks in duration.

Pulmonary Hypertension Associated with Interstitial Lung Disease (ILD) Indicated for the treatment of pulmonary hypertension associated with ILD (PH-ILD; WHO Group 3) to improve exercise ability. The study establishing effectiveness predominately included patients with etiologies of idiopathic interstitial pneumonia (IIP) (45%) inclusive of idiopathic pulmonary fibrosis (IPF), combined pulmonary fibrosis and emphysema (CPFE) (25%), and WHO Group 3 connective tissue disease (22%).

Drug Name: Veletri (epoprostenol) Injection

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I) to improve exercise capacity. Studies establishing effectiveness included predominantly patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases.

Drug Name: Ventavis (iloprost) Inhalation Solution

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to improve a composite endpoint consisting of exercise tolerance, symptoms (NYHA Class),

and lack of deterioration. Studies establishing effectiveness included predominately patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH (65%) or PAH associated with connective tissue diseases (23%).
Drug Name: Uptravi (selexipag) Tablets and Injection
Pulmonary Arterial Hypertension Indicated for the treatment of PAH (WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH. Effectiveness was established in a long-term study in PAH patients with WHO Functional Class II-III symptoms. Patients had idiopathic and heritable PAH (58%), PAH associated with connective tissue disease (29%), PAH associated with congenital heart disease with repaired shunts (10%).

2 . Criteria

Product Name: Generic Alyq tablet, Generic tadalafil tablet, Adempas tablet, Brand Flolan injection, Generic epoprostenol injection, Generic ambrisentan tablet, Opsumit tablet, Orenitram tablet, Generic treprostinil injection, Generic sildenafil tablet, Generic bosentan tablet, Tracleer tablet for suspension, Tyvaso inhalation solution, Tyvaso Refill inhalation solution, Tyvaso Starter inhalation solution, Tyvaso DPI, Veletri injection, or Ventavis inhalation solution	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

Product Name: Brand Adcirca tablet, Tadliq oral suspension	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Trial and failure or intolerance to generic tadalfil

Product Name: Brand Letairis tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Trial and failure or intolerance to generic ambrisentan

Product Name: Brand Remodulin injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Trial and failure or intolerance to generic treprostinil

Product Name: Brand Revatio tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Trial and failure or intolerance to generic sildenafil tablet

Product Name: Brand Tracleer tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Trial and failure or intolerance to generic bosentan tablet

Product Name: Brand Revatio injection or Generic sildenafil injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Patient is unable to take oral medications [2]

Product Name: Brand Revatio oral suspension or Generic sildenafil oral suspension

Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - One of the following:

5.1 History of intolerance to generic Revatio tablets

OR

5.2 Patient is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to one of the following:

- Age
- Oral-motor difficulties
- Dysphagia

Product Name: Adempas tablet	
Diagnosis	Chronic Thromboembolic Pulmonary Hypertension (CTEPH)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of inoperable or persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH)

AND

1.1.2 CTEPH is symptomatic

OR

1.2 Patient is currently on any therapy for the diagnosis of CTEPH

AND

2 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

Product Name: Tyvaso inhalation solution, Tyvaso Refill inhalation solution, or Tyvaso Start inhalation solution, Tyvaso DPI	
Diagnosis	Pulmonary Hypertension associated with Interstitial Lung Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary hypertension associated with interstitial lung disease

AND

2 - Diagnosis of pulmonary hypertension associated with interstitial lung disease was confirmed by diagnostic test(s) (e.g., right heart catheterization, doppler echocardiogram, computerized tomography imaging)

AND

3 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

Product Name: Brand Adcirca tablet, Generic tadalafil tablet, Generic Alyq tablet, Tadliq oral suspension, Adempas tablet, Brand Flolan injection, Generic epoprostenol injection, Brand

Letairis tablet, Generic ambrisentan tablet, Opsumit tablet, Orenitram tablet, Brand Remodulin injection, Generic treprostinil injection, Brand Revatio injection, Generic sildenafil injection, Brand Revatio tablet, Generic sildenafil tablet, Brand Revatio oral suspension, Generic sildenafil oral suspension, Brand Tracleer tablet, Generic bosentan tablet, Tracleer tablet for suspension, Tyvaso inhalation solution, Tyvaso Refill inhalation solution, Tyvaso Starter inhalation solution, Tyvaso DPI, Veletri injection, or Ventavis inhalation solution	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Uptravi tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Trial and failure, contraindication, or intolerance to one of the following:

- PDE-5 inhibitor [i.e., Adcirca (tadalafil), Revatio (sildenafil)]
- Adempas (riociguat)

AND

4.1.2 Trial and failure, contraindication, or intolerance to an endothelin receptor antagonist [e.g., Letairis (ambrisentan), Opsumit (macitentan), Tracleer (bosentan)]

OR

4.2 For continuation of prior therapy

AND

5 - Not taken in combination with a prostanoid/prostacyclin analogue [e.g., Flolan (epoprostenol), Ventavis (iloprost), Tyvaso/Remodulin/Orenitram (treprostinil)]

AND

6 - Prescribed by or in consultation with one of the following:

- Pulmonologist

- Cardiologist

Product Name: Uptravi injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Trial and failure, contraindication, or intolerance to one of the following:

- PDE-5 inhibitor [i.e., Adcirca (tadalafil), Revatio (sildenafil)]
- Adempas (riociguat)

AND

4.1.2 Trial and failure, contraindication, or intolerance to an endothelin receptor antagonist [e.g., Letairis (ambrisentan), Opsumit (macitentan), Tracleer (bosentan)]

OR

4.2 For continuation of prior therapy

AND

5 - Not taken in combination with a prostanoid/prostacyclin analogue [e.g., Flolan (epoprostenol), Ventavis (iloprost), Tyvaso/Remodulin/Orenitram (treprostinil)]

AND

6 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

7 - Patient is unable to take oral medications [13]

Product Name: Uptravi tablet/injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Not taken in combination with a prostanoid/prostacyclin analogue [e.g., Flolan (epoprostenol), Ventavis (iloprost), Tyvaso/Remodulin/Orenitram (treprostinil)]

Product Name: Brand Adcirca tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to generic tadalfil

Product Name: Brand Letairis tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to generic ambrisentan

Product Name: Brand Remodulin injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to generic treprostinil

Product Name: Brand Tracleer tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Submission of medical records (e.g., chart notes) confirming pulmonary arterial hypertension is symptomatic

AND

3 - Submission of medical records (e.g., chart notes) confirming one of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to generic bosentan tablet

3 . Endnotes

A. Require right heart catheterization in order to confirm pulmonary arterial hypertension diagnosis: Per clinical consult with cardiologist, PAH specialist, and P&T committee recommendation, February 20, 2014.

4 . References

1. Flolan Prescribing Information. GlaxoSmithKline. Research Triangle Park, NC. August 2021.
2. Revatio Prescribing Information. Pfizer Inc. New York, NY. January 2023.

3. Ventavis Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. March 2022.
4. Tyvaso Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. May 2022.
5. Remodulin Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. July 2021.
6. Adcirca Prescribing Information. Eli Lilly and Company. Indianapolis, IN. September 2020.
7. Letairis Prescribing Information. Gilead Sciences, Inc. Foster City, CA. August 2019.
8. Tracleer Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. July 2022.
9. Veletri Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. July 2022.
10. Opsumit Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. July 2022.
11. Adempas Prescribing Information. Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ. September 2021.
12. Orenitram Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. May 2021.
13. Uptravi Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. July 2022.
14. Alyq Prescribing Information. Teva Pharmaceuticals USA, Inc. North Wales, PA. September 2021.
15. Tyvaso DPI Prescribing Information. United Therapeutics Corporation. Research Triangle Park, NC. May 2022.
16. Tadliq Prescribing Information. CMP Pharma, Inc. Farmville, NC. June 2022.

5 . Revision History

Date	Notes
4/4/2023	Added orenitram titration kit products to guideline.

Prior Authorization Guideline

Guideline Name	Pulmozyme (dornase alfa inhalation solution)

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	5/27/2015
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Pulmozyme (dornase alpha) Inhalation Solution
Cystic Fibrosis Indicated, in conjunction with standard therapies, for the management of pediatric and adult patients with cystic fibrosis (CF) to improve pulmonary function. In CF patients with an FVC ≥ 40% of predicted, daily administration of PULMOZYME has also been shown to reduce the risk of respiratory tract infections requiring parenteral antibiotics.

2 . Criteria

Product Name: Pulmozyme	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF) [2,3]

Product Name: Pulmozyme	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Documentation of positive clinical response (i.e., improvement in lung function [forced expiratory volume in one second {FEV1}], decreased number of pulmonary exacerbations) to therapy

3 . References

1. Pulmozyme Prescribing Information. Genentech, Inc. South San Francisco, CA. July 2021.
2. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic fibrosis pulmonary guidelines. Chronic medications for maintenance of lung health. Am J Respir Crit Care Med. 2013;187(7):680-9.
3. Flume PA, O'Sullivan BP, Robinson KA et al. Cystic fibrosis pulmonary guidelines. Am J Respir Crit Care Med. 2007;176:957-969

4 . Revision History

Date	Notes
4/6/2023	Annual review: No criteria changes.

Prior Authorization Guideline

Guideline Name	Qinlock (ripretinib)

Guideline Note:

Effective Date:	9/1/2022
P&T Approval Date:	7/15/2020
P&T Revision Date:	07/21/2021 ; 7/20/2022

1 . Indications

Drug Name: Qinlock (ripretinib)
Gastrointestinal Stromal Tumor (GIST) Indicated for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib.

2 . Criteria

Product Name: Qinlock	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2 - Disease is advanced

AND

3 - Patient has received prior treatment with three or more kinase inhibitors (e.g., sunitinib, regorafenib), one of which must include imatinib

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Qinlock	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Qinlock Prescribing Information. Deciphera Pharmaceuticals, LLC. Waltham, MA. June 2021.

4 . Revision History

Date	Notes
7/22/2022	Annual review: no criteria changes, updated reference.

Prior Authorization Guideline

Guideline Name	Quantity Limit General

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	5/20/2008
P&T Revision Date:	11/14/2019 ; 08/13/2020 ; 07/21/2021 ; 12/15/2021 ; 04/20/2022 ; 06/15/2022 ; 09/21/2022 ; 09/21/2022 ; 4/19/2023

Note:

For all other drugs subject to quantity limits, may authorize coverage for additional quantities of medications listed on the Standard QL list for patients who meet the following criteria.

1 . Criteria

Product Name: Less than or equal to the maximum dose as specified in the product prescribing information (in the absence of a drug-specific guideline)*	
Approval Length	12 Months (except for titration of loading-dose purposes)
Guideline Type	Administrative
Approval Criteria **1** - One of the following:	

1.1 Quantity limit override requests must involve an FDA-approved indication

OR

1.2 Quantity limit override requests involving off-label indications must meet off-label guideline approval criteria

AND

2 - One of the following:

2.1 For titration or loading-dose purposes (one time authorization)

OR

2.2 Requested strength/dose is commercially unavailable**

OR

2.3 Patient is on a dose alternating schedule

OR

2.4 For topical applications, patient requires a larger quantity to cover a larger surface area

Notes	Not to exceed maximum dose as specified in the product prescribing information or compendia for off-label uses. No override requests will be permitted for acetaminophen, alone or in combination with other agents, which will exceed a total of 4 grams of acetaminophen per day. *This guideline only applies in the absence of a drug-specific quantity limit override guideline. **Commercially available strength/dose requires a formulary drug.

Product Name: Greater than the maximum dose as specified in the product prescribing information (in the absence of a drug-specific guideline)*	
Approval Length	12 month(s)

Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 Quantity limit override requests must involve an FDA-approved indication

OR

1.2 Quantity limit override requests involving off-label indications must meet off-label guideline requirements

AND

2 - One of the following:

2.1 The maximum doses specified under the quantity restriction have been tried for an adequate period of time and been deemed ineffective in the treatment of the member's disease or medical condition

OR

2.2 If lower doses have not been tried, there is clinical support (i.e., clinical literature, patient attributes, or characteristics of the drug) that the number of doses available under the quantity restriction will be ineffective in the treatment of the member's disease or medical condition

AND

3 - One of the following:

3.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

OR

3.2 Higher dose or quantity is supported by one of following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System

OR

3.3 Higher dose or quantity is supported by clinical research in two articles from major peer reviewed medical journals that present data supporting the proposed higher than maximum doses for the diagnosis provided as generally safe and effective

Notes	*This guideline only applies in the absence of a drug-specific quantity l imit override guideline. No override requests will be permitted for acet aminophen, alone or in combination with other agents, which will exce ed a total of 4 grams of acetaminophen per day.

2 . Revision History

Date	Notes
4/5/2023	No criteria change. Removed UHC Core formulary.

Prior Authorization Guideline

Guideline Name	Reblozyl (luspatercept-aamt)

Guideline Note:

Effective Date:	3/1/2023
P&T Approval Date:	3/1/2021
P&T Revision Date:	06/17/2020 ; 01/20/2021 ; 01/19/2022 ; 1/18/2023

1 . Indications

Drug Name: Reblozyl (luspatercept-aamt)
Beta Thalassemia Indicated for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions. Limitations of Use: Reblozyl is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia. **Myelodysplastic Syndromes with Ring Sideroblasts or Myelodysplastic/ Myeloproliferative Neoplasm with Ring Sideroblasts and Thrombocytosis Associated Anemia** Indicated for the treatment of anemia failing an erythropoiesis stimulating agent and requiring 2 or more red blood cell units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T). Limitations of Use: Reblozyl is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia.

2 . Criteria

Product Name: Reblozyl	
Diagnosis	Beta Thalassemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of beta thalassemia major [3]

AND

1.1.2 Patient requires regular red blood cell (RBC) transfusions

OR

1.2 Diagnosis of transfusion-dependent beta thalassemia [3]

AND

2 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

Product Name: Reblozyl	
Diagnosis	Beta Thalassemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy (e.g., reduction in RBC transfusion burden) [1,2]

Product Name: Reblozyl	
Diagnosis	Myelodysplastic Syndromes, Myelodysplastic/Myeloproliferative Neoplasm (MDS-RS, MDS/MPN-RS-T)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

1.1 Very low-to intermediate-risk myelodysplastic syndrome with ring sideroblasts (MDS-RS)

OR

1.2 Myelodysplastic or myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)

AND

2 - Patient has failed an erythropoiesis stimulating agent [e.g., Epogen (epoetin alfa), Aranesp (darbepoetin)]

AND

3 - Patient requires transfusions of 2 or more red blood cell (RBC) units over 8 weeks

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

Product Name: Reblozyl	
Diagnosis	Myelodysplastic Syndromes, Myelodysplastic/Myeloproliferative Neoplasm (MDS-RS, MDS/MPN-RS-T)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy (e.g., RBC transfusion independence, improvement in hemoglobin levels) [1,4]

3 . References

1. Reblozyl Prescribing Information. Celgene Corporation. Summit, NJ. September 2022.
2. Piga A, Perrotta S, Gamberini M, et al. Luspatercept improves hemoglobin levels and blood transfusion requirements in a study of patients with β-thalassemia. Blood 2019; 133 (12): 1279–1289.
3. Per clinical consult with oncologist, December 19, 2019.
4. Fenaux P, Platzbecker U, Ghulam J, et al. Luspatercept in patients with lower-risk myelodysplastic syndromes. N Engl J Med 2020; 382:140-151.

4 . Revision History

Date	Notes

1/4/2023	2023 UM Annual Review. No changes to criteria. Updated references

Prior Authorization Guideline

Guideline Name	Regranex (becaplermin)

Guideline Note:

Effective Date:	9/1/2022
P&T Approval Date:	7/16/2009
P&T Revision Date:	08/13/2020 ; 07/21/2021 ; 7/20/2022

1 . Indications

Drug Name: Regranex Gel (becaplermin)
Diabetic Neuropathic Ulcers Indicated for the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply, when used as an adjunct to, and not a substitute for, good ulcer care practices including initial sharp debridement, pressure relief and infection control. Limitations of Use: The efficacy of Regranex Gel has not been established for the treatment of pressure ulcers and venous stasis ulcers and has not been evaluated for the treatment of diabetic neuropathic ulcers that do not extend through the dermis into subcutaneous tissue (Stage I or II, IAET staging classification) or ischemic diabetic ulcers. The effects of becaplermin on exposed joints, tendons, ligaments, and bone have not been established in humans. Regranex is not intended to be used in wounds that close by primary intention.

2 . Criteria

Product Name: Regranex	
Approval Length	5 Months [1, A]

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a lower extremity diabetic neuropathic ulcer

AND

2 - Treatment will be given in combination with ulcer wound care (e.g., debridement, infection control, and/or pressure relief) [1]

3 . Endnotes

A. Fifty percent of patients will achieve complete healing within 20 weeks with Regranex. Reassessment is required for further therapy. [1] If the ulcer does not decrease in size by approximately 30% after 10 weeks of treatment or complete healing has not occurred in 20 weeks, continued treatment with Regranex should be reassessed. Postmarketing studies have demonstrated an increased risk of mortality secondary to malignancy observed in patients treated with greater than or equal to 3 tubes of Regranex gel. [1]

4 . References

1. Regranex Prescribing Information. Smith & Nephew, Inc. Fort Worth, TX. August 2019.

5 . Revision History

Date	Notes
7/6/2022	2022 Annual Review - no changes to criteria

Prior Authorization Guideline

Guideline Name	Repository Corticotropin Gel Products - PA, NF

Guideline Note:

Effective Date:	10/1/2022
P&T Approval Date:	5/19/2009
P&T Revision Date:	08/15/2019 ; 08/15/2019 ; 08/13/2020 ; 08/19/2021 ; 02/17/2022 ; 8/18/2022

1 . Indications

Drug Name: Acthar Gel (repository corticotropin injection)
Infantile spasms [2, 3] Indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age. **Exacerbations of Multiple Sclerosis [4, 5]** Indicated for the treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease. **All Other Disease States [A]** *Please Note: The request for Acthar for the treatment of a condition other than Infantile Spasms (IS) or Exacerbations of Multiple Sclerosis (MS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the efficacy, safety, or long-term consequences of using repository corticotropin over conventional corticosteroids in these steroid-responsive conditions. **[Non-Approvable Use] Rheumatic Disorders* [6, 7, A]** As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis, Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), Ankylosing spondylitis.

[Non-Approvable Use] Collagen Diseases* [8-10, A] During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis).

[Non-Approvable Use] Dermatologic Diseases* [A] Severe erythema multiforme, Stevens-Johnson syndrome.

[Non-Approvable Use] Allergic States* [A] Serum sickness.

[Non-Approvable Use] Ophthalmic Diseases* [14, A] Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis; optic neuritis; chorioretinitis; anterior segment inflammation.

[Non-Approvable Use] Respiratory Diseases* [11, A] Symptomatic sarcoidosis

[Non-Approvable Use] Edematous State* [12, 13, 15, A] To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

Drug Name: Purified Cortrophin Gel (repository corticotropin injection)

Exacerbations of Multiple Sclerosis [4, 5] Indicated for acute exacerbations of multiple sclerosis.

All Other Disease States [A] *Please Note: The request for Purified Cortrophin Gel for the treatment of a condition other than Infantile Spasms (IS) or Exacerbations of Multiple Sclerosis (MS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the efficacy, safety, or long-term consequences of using repository corticotropin over conventional corticosteroids in these steroid-responsive conditions.

[Non-Approvable Use] Rheumatic Disorders* [6, 7, A] Indicated as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis; Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy); Ankylosing spondylitis; Acute gouty arthritis.

[Non-Approvable Use] Collagen Diseases* [8-10, A] Indicated during an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis).

[Non-Approvable Use] Dermatologic Diseases* [A] Indicated for severe erythema multiforme (Stevens-Johnson syndrome), severe psoriasis.

[Non-Approvable Use] Allergic States* [A] Indicated for atopic dermatitis, serum sickness.

[Non-Approvable Use] Ophthalmic Diseases* [14, A] Indicated for severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: allergic conjunctivitis, keratitis, iritis and iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation.

[Non-Approvable Use] Respiratory Diseases* [11, A] Indicated for symptomatic sarcoidosis.

[Non-Approvable Use] Edematous States* [12, 13, 15, A] Indicated to induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

Off Label Uses: Infantile spasms [2, 3] Indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age.

2 . Criteria

Product Name: Acthar Gel, Purified Cortrophin Gel [off-label]	
Diagnosis	Infantile Spasms (West Syndrome)
Approval Length	4 Week(s)
Guideline Type	Prior Authorization, Non Formulary

Approval Criteria

1 - Diagnosis of infantile spasms (West Syndrome)

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Patient is less than 2 years of age

Product Name: Acthar Gel, Purified Cortrophin Gel	
Diagnosis	Multiple Sclerosis
Approval Length	3 Week(s)
Guideline Type	Prior Authorization, Non Formulary

Approval Criteria

1 - Diagnosis of acute exacerbation of multiple sclerosis

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - One of the following:

3.1 Both of the following:

- Patient is new to therapy with corticotropin
- Trial and failure, contraindication, or intolerance to treatment with two high dose corticosteroid treatments (e.g., prednisone, IV methylprednisolone)

OR

3.2 All of the following:

- Patient's multiple sclerosis exacerbations have been treated in the past with corticotropin
- Patient has benefitted from treatment with corticotropin for acute exacerbations of multiple sclerosis
- Medication is being used to treat a new exacerbation of multiple sclerosis

Product Name: Acthar Gel, Purified Cortrophin Gel	
Diagnosis	All Other Indications [A]
Approval Length	N/A - Requests for non-approvable diagnoses should not be approved
Guideline Type	Prior Authorization, Non Formulary

Approval Criteria

1 - The request for Acthar Gel and Purified Cortrophin Gel for the treatment of a condition other than Infantile Spasms (IS) or Exacerbations of Multiple Sclerosis (MS) is not authorized and will not be approved. There is no consensus in current peer-reviewed medical literature regarding the efficacy, safety, or long-term consequences of using repository corticotropin over conventional corticosteroids in these steroid-responsive conditions:

- Rheumatic Disorders* [6, 7, A] As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis, Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), Ankylosing spondylitis, Acute gouty arthritis.
- Collagen Diseases* [8-10, A] During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis).
- Dermatologic Diseases* [A] Severe erythema multiforme, Stevens-Johnson syndrome, Severe psoriasis.
- Allergic States* [A] Serum sickness, Atopic dermatitis.
- Ophthalmic Diseases* [14, A] Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis; optic neuritis; chorioretinitis; anterior segment inflammation; Allergic conjunctivitis.
- Respiratory Diseases* [11, A] Symptomatic sarcoidosis.
- Edematous State* [12, 13, 15, A] To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.
- Any other disease state not mentioned [A]*

Notes	*Other disease states lack published clinical literature to support the u se of Acthar or Purified Cortrophin Gel [A]

3 . Endnotes

A. Grandfathered indications, although briefly mentioned in the labeling, do not have clinical studies in the prescribing information or medical literature supporting their use of Acthar or Purified Cortrophin Gel.

4 . References

1. Acthar prescribing information. Mallinckrodt ARD LLC. Bedminster, NJ. October 2021.
2. Baram TZ, Mitchell WG, Tournay A, et al. High-dose corticotropin (ACTH) versus prednisone for infantile spasms: a prospective, randomized, blinded study. Pediatrics. 1996 Mar: 97(3):375-379.
3. Hrachovy RA, Frost JD, Glaze DG. High-dose, long-duration versus low-dose, short-duration corticotropin therapy for infantile spasms. J Pediatr. 1994 May; 124(5): 803-806.

4. Thompson, AJ. Relative efficacy of IV methylprednisolone vs ACTH in acute relapse of MS. Neurology. 1989 July;39(7):969.
5. Citterio A, La Mantia L, Ciucci G, et al. Corticosteroids or ACTH for acute exacerbations in multiple sclerosis. Cochrane Database of Systematic Reviews 2000, Issue 4.
6. Gillis T, Crane M, Hinkle C, et al. Repository corticotropin injection as adjunctive therapy in patients with rheumatoid arthritis who have failed previous therapies with at least three different modes of action. Open Access Rheumatol. 2017;9:131-138.
7. Brown, A. Repository corticotropin injection in patients with refractory psoriatic arthritis: a case series. Open Access Rheumatol. 2016;8:97-102.
8. Furie R, Mitrane M, Zhao E, et al. Efficacy and tolerability of repository corticotropin injection in patients with persistently active SLE: results of a phase 4, randomised, controlled pilot study. Lupus Sci Med. 2016;3(1):e000180.
9. Patel A, Seely G, Aggarwal R. Repository corticotropin injection for treatment of idiopathic inflammatory myopathies. Case Rep Rheumatol. 2016;2016:9068061.
10. Aggarwal R, Marder G, Koontz DC, et al. Efficacy and safety of adrenocorticotropic hormone gel in refractory dermatomyositis and polymyositis. Ann Rheum Dis. 2018 May;77(5):720-727.
11. Baughman RP, Sweiss N, Keijsers R, et al. Repository corticotropin for chronic pulmonary sarcoidosis. Lung. 2017;195(3):313-322.
12. Bomback AS, Tumlin JA, Baranski J, et al. Treatment of nephrotic syndrome with adrenocorticotropic hormone (ACTH) gel. Drug Des Devel Ther. 2011;5:147-153.
13. Bomback AS, Canetta PA, Beck Jr LH, et al. Treatment of resistant glomerular diseases with adrenocorticotropic hormone gel: A prospective trial. Am J Nephrol 2012;36:58-67.
14. Sharon Y, Chu DS. Adrenocorticotropic hormone gel for patients with non-infectious uveitis. Am J Ophthalmol Case Rep. 2019;15:100502.
15. Madan A, Mojovic-Das S, Stankovic A, et al. Acthar gel in the treatment of nephrotic syndrome: a multicenter retrospective case series. BMC Nephrol. 2016;17:37.
16. Purified Cortrophin Gel prescribing information. ANI Pharmaceuticals, Inc. Baudette, MN. June 2022.

5 . Revision History

Date	Notes
8/4/2022	Annual Review: No criteria changes. Updated references, indications , and background.

Prior Authorization Guideline

Guideline Name	Restasis (cyclosporine 0.05%)

Guideline Note:

Effective Date:	6/8/2022

1 . Indications

Drug Name: Restasis (cyclosporine 0.05%) ophthalmic emulsion
Keratoconjunctivitis sicca Indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

2 . Criteria

Product Name: Brand Restasis, Generic cyclosporine 0.05% ophthalmic emulsion	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - One of the following:

1.1 Diagnosis of moderate to severe keratoconjunctivitis sicca (dry eye)

OR

1.2 Diagnosis of Sjogren syndrome with suppressed tear production due to ocular inflammation

AND

2 - One of the following [1, B]:

2.1 Patient will not be using concurrent topical ophthalmic anti-inflammatory drugs (e.g., corticosteroids, NSAIDs [nonsteroidal anti-inflammatory drugs])

OR

2.2 Topical ophthalmic anti-inflammatory drugs will only be used concurrently for a short period (up to 8 weeks) while transitioning to monotherapy with the requested drug

Product Name: Brand Restasis, generic cyclosporine 0.05% ophthalmic emulsion	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., increased tear production or improvement in dry eye symptoms)

AND

2 - Patient will not be using concurrent topical ophthalmic anti-inflammatory drugs (e.g., corticosteroids, NSAIDs [nonsteroidal anti-inflammatory drugs])

3 . Endnotes

A. As disease severity increases, aqueous enhancement of the eye using topical agents is appropriate (i.e., emulsions, gels, and ointments can be used). Topical cyclosporine, topical corticosteroids, topical lifitegrast, systemic omega-3 fatty acid supplements, punctual plugs and spectacle side shields/moisture chambers may also be considered in addition to aqueous enhancement therapies in patients who need additional symptom management. [2]
B. The FDA-approved indication states that during clinical trials, increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs. [1]

4 . References

1. Restasis Prescribing Information. Allergan Inc. Irvine, CA. July 2017.
2. American Academy of Ophthalmology Preferred Practice Pattern Cornea/External Disease Committee. Dry Eye Syndrome PPP - 2018. November 2018. https://www.aao.org/preferred-practice-pattern/dry-eye-syndrome-ppp-2018. Accessed May 28, 2021.

5 . Revision History

Date	Notes
6/8/2022	New EHB specific guideline.

Prior Authorization Guideline

Guideline Name	Retevmo (selpercatinib)

Guideline Note:

Effective Date:	2/1/2023
P&T Approval Date:	7/15/2020
P&T Revision Date:	08/19/2021 ; 08/18/2022 ; 12/14/2022

1 . Indications

Drug Name: Retevmo (selpercatinib)
Non-Small Cell Lung Cancer (NSCLC) Indicated for the treatment of adult patients with locally advanced or metastatic RET fusion-positive non-small cell lung cancer, as detected by an FDA-approved test. **Medullary Thyroid Cancer (MTC)** Indicated for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC), as detected by an FDA-approved test, who require systemic therapy. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). **Thyroid Cancer** Indicated for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer, as detected by an FDA-approved test, who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate). This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). **Solid Tumors** Indicated for the treatment of adult patients with locally advanced or metastatic

solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

2 . Criteria

Product Name: Retevmo	
Diagnosis	Non-Small Cell Lung Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Locally Advanced
- Metastatic

AND

3 - Disease has presence of rearranged during transfection (RET) gene fusion-positive tumor(s) as detected by a U.S. Food and Drug Administration (FDA) - approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Retevmo	
Diagnosis	Medullary Thyroid Cancer (MTC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of medullary thyroid cancer (MTC)

AND

2 - Disease is ONE of the following:

- Advanced
- Metastatic

AND

3 - Patient is 12 years of age or older

AND

4 - Disease has presence of rearranged during transfection (RET) gene mutation tumor(s) as detected by a U.S. Food and Drug Administration (FDA) -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

5 - Disease requires treatment with systemic therapy

AND

6 - Prescribed by or in consultation with an oncologist

Product Name: Retevmo	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of thyroid cancer

AND

2 - Disease is ONE of the following:

- Advanced
- Metastatic

AND

3 - Patient is 12 years of age or older

AND

4 - Disease has presence of rearranged during transfection (RET) gene fusion-positive tumor(s) as detected by a U.S. Food and Drug Administration (FDA) -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

5 - Disease requires treatment with systemic therapy

AND

6 - ONE of the following

- Patient is radioactive iodine-refractory
- Radioactive iodine therapy is not appropriate

AND

7 - Prescribed by or in consultation with an endocrinologist or an oncologist

Product Name: Retevmo	
Diagnosis	Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of solid tumors

AND

2 - Disease is ONE of the following:

- Locally Advanced
- Metastatic

AND

3 - Disease has presence of rearranged during transfection (RET) gene fusion-positive tumor(s) [A, 1]

AND

4 - ONE of the following:

- Disease has progressed on or following prior systemic treatment (e.g., chemotherapy)
- There are no satisfactory alternative treatment options

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Retevmo	
Diagnosis	Non-Small Cell Lung Cancer, Medullary Thyroid Cancer (MTC), Thyroid Cancer, Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. An FDA-approved companion diagnostic test for the detection of RET gene fusions and RET gene mutations in plasma or in tumors other than NSCLC and thyroid cancer is not currently available.

4 . References

1. Retevmo Prescribing Information. Lilly USA. Indianapolis, IN. September 2022.

5 . Revision History

Date	Notes
11/21/2022	Update Guideline

Prior Authorization Guideline

Guideline Name	Revcovi (elapegademase-lvlr)

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	1/16/2019
P&T Revision Date:	01/15/2020 ; 02/17/2022 ; 2/16/2023

1 . Indications

Drug Name: Revcovi (elapegademase-lvlr)
Adenosine deaminase severe combined immune deficiency (ADA-SCID) Indicated for the treatment of adenosine deaminase severe combined immune deficiency (ADA-SCID) in pediatric and adult patients.

2 . Criteria

Product Name: Revcovi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of adenosine deaminase deficiency (ADA) with severe combined immunodeficiency (SCID)

Product Name: Revcovi	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient demonstrates positive clinical response to therapy	

3 . References

1. Revcovi Prescribing Information. Leadiant Biosciences, Inc. Gaithersburg, MD. December 2020.
2. Immune Deficiency Foundation Patient & Family Handbook for Primary Immunodeficiency Diseases. Fifth Edition. 2013.

4 . Revision History

Date	Notes
1/25/2023	Update program

Prior Authorization Guideline

Guideline Name	Revlimid (lenalidomide)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	6/6/2006
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 04/20/2022 ; 04/19/2023 ; 5/18/2023

1 . Indications

Drug Name: Revlimid (lenalidomide)
Myelodysplastic Syndromes Indicated for the treatment of adult patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities. Limitations of Use: Not indicated and is not recommended for the treatment of patients with CLL outside of controlled clinical trials. [A] **Multiple Myeloma** Revlimid in combination with dexamethasone is indicated for the treatment of adult patients with multiple myeloma (MM). Also Revlimid is indicated as maintenance therapy in adult patients with MM following autologous hematopoietic stem cell transplantation (auto-HSCT). Limitations of Use: Not indicated and is not recommended for the treatment of patients with CLL outside of controlled clinical trials. [A] **Mantle Cell Lymphoma (MCL)** Indicated for the treatment of adult patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib. Limitations of Use: Not indicated and is not recommended for the treatment of patients with CLL outside of controlled clinical trials. [A] **Follicular Lymphoma (FL)** Revlimid in combination with a rituximab product, is indicated for the treatment of adult patients with previously treated follicular lymphoma (FL). Limitations of Use: Not indicated and is not recommended for the treatment of patients with CLL outside of

controlled clinical trials. [A]

Marginal Zone Lymphoma (MZL) Revlimid in combination with a rituximab product, is indicated for the treatment of adult patients with previously treated marginal zone lymphoma (MZL). Limitations of Use: Not indicated and is not recommended for the treatment of patients with CLL outside of controlled clinical trials. [A]

2 . Criteria

Product Name: Brand Revlimid, Generic lenalidomide	
Diagnosis	Myelodysplastic Syndromes (MDS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of symptomatic or transfusion-dependent anemia due to myelodysplastic syndrome (MDS) associated with a deletion 5q abnormality [2]

AND

2 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Brand Revlimid, Generic lenalidomide	
Diagnosis	Multiple Myeloma (MM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Brand Revlimid, Generic lenalidomide	
Diagnosis	Mantle Cell Lymphoma (MCL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsed or progressed mantle cell lymphoma (MCL)

AND

2 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Brand Revlimid, Generic lenalidomide	
Diagnosis	Follicular Lymphoma (FL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of follicular lymphoma (FL) that has been previously treated

AND

2 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Brand Revlimid, Generic lenalidomide	
Diagnosis	Marginal Zone Lymphoma (MZL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of marginal zone lymphoma (MZL) that has been previously treated

AND

2 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Brand Revlimid, Generic lenalidomide	
Diagnosis	All Indications Listed Above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. Although the prescribing information for Revlimid states that it is not indicated and is not recommended for the treatment of patients with CLL outside of controlled clinical trials due to the increased risk of mortality, current NCCN practice guideline still recommends single agent lenalidomide or in combination with rituximab for relapsed/refractory CLL. [1, 2]

4 . References

1. Revlimid Prescribing Information. Celgene Corporation. Princeton, NJ. December 2022.
2. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium. Available by subscription at: www.nccn.org. Accessed March 8, 2023.

5 . Revision History

Date	Notes
4/28/2023	Program update to remove criteria and only leave the diagnosis and specialist requirements.

Prior Authorization Guideline

Guideline Name	Riluzole Products - PA, NF

Guideline Note:

Effective Date:	9/1/2022
P&T Approval Date:	8/2/2005
P&T Revision Date:	07/15/2020 ; 07/21/2021 ; 10/20/2021 ; 7/20/2022

1 . Indications

Drug Name: Exservan (riluzole film), Rilutek (riluzole tablets), Tiglutik (riluzole suspension)
Amyotrophic Lateral Sclerosis (ALS) Indicated for the treatment of patients with amyotrophic lateral sclerosis (ALS).

2 . Criteria

Product Name: Brand Rilutek, Tiglutik	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of amyotrophic lateral sclerosis (ALS)

AND

2 - Trial and failure or intolerance to generic riluzole tablets

Product Name: Exservan	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of amyotrophic lateral sclerosis (ALS)

AND

2 - Trial and failure or intolerance to generic riluzole tablets and Tiglutik suspension

Product Name: Generic riluzole	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of amyotrophic lateral sclerosis (ALS)

Product Name: Exservan	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of amyotrophic lateral sclerosis (ALS)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to both of the following:

- generic riluzole tablets
- Tiglutik suspension

3 . References

1. Rilutek Prescribing Information. Covis Pharma. Zug, Switzerland. March 2020.
2. Tiglutik Prescribing Information. ITF Pharma, Inc. Berwyn, PA. April 2021.
3. Exservan Prescribing Information. Aquestive Therapeutics. Warren, NJ. April 2020.

4 . Revision History

Date	Notes
7/8/2022	2022 Annual Review- no criteria changes

Prior Authorization Guideline

Guideline Name	Rinvoq (upadacitinib)

Guideline Note:

Effective Date:	2/1/2023
P&T Approval Date:	10/16/2019
P&T Revision Date:	09/16/2020 ; 08/19/2021 ; 03/16/2022 ; 04/20/2022 ; 06/15/2022 ; 08/18/2022 ; 10/19/2022 ; 12/14/2022

1 . Indications

Drug Name: Rinvoq (upadacitinib)
Rheumatoid Arthritis (RA) Indicated for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Rinvoq in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended. **Psoriatic Arthritis (PsA)** Indicated for the treatment of adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Rinvoq in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended. **Ankylosing Spondylitis (AS)** Indicated for the treatment of adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Rinvoq in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended. **Non-radiographic Axial Spondyloarthritis (nr-AxSpA)** Indicated for the treatment of adults

with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy. Limitations of Use: Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine.

Atopic Dermatitis (AD) Indicated for the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable. Limitations of Use: Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

Ulcerative Colitis (UC) Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Rinvoq is not recommended for use in combination with other JAK inhibitors, biological therapies for ulcerative colitis, or with potent immunosuppressants such as azathioprine and cyclosporine.

2 . Criteria

Product Name: Rinvoq	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide
- sulfasalazine

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia, Enbrel, Humira, Amjevita, Simponi)

AND

5 - Not used in combination with other Janus kinase (JAK) inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*	
Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [4]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia, Enbrel, Humira, Amjevita, Simponi)

AND

5 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Ankylosing Spondylitis (AS)

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia, Enbrel, Humira, Amjevita, Simponi)

AND

5 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-AxSpA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active non-radiographic axial spondyloarthritis

AND

2 - Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of

inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) [1, 5]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

AND

5 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia)

AND

6 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-AxSpA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Atopic Dermatitis (AD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe atopic dermatitis

AND

2 - Patient is 12 years of age or older

AND

3 - One of the following:

- Involvement of at least 10% body surface area (BSA)
- SCORing Atopic Dermatitis (SCORAD) index value of at least 25 [A]

AND

4 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist/Immunologist

AND

5 - Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least ONE of the following:

- Medium or higher potency topical corticosteroid
- Pimecrolimus cream
- Tacrolimus ointment
- Eucrisa (crisaborole) ointment

AND

6 - One of the following:

6.1 Trial and failure of a minimum 12-week supply of at least one systemic drug product for the treatment of atopic dermatitis (examples include, but are not limited to, Adbry [tralokinumab-ldrm], Dupixent [dupilumab], etc.)

OR

6.2 Patient has a contraindication, intolerance, or treatment is inadvisable with both of the following FDA-approved atopic dermatitis therapies:

- Adbry (tralokinumab-ldrm)
- Dupixent (dupilumab)

AND

7 - Not used in combination with other JAK inhibitors, biologic immunomodulators (e.g., Dupixent, Adbry), or other immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Atopic Dermatitis (AD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy as evidenced by at least ONE of the following:

- Reduction in body surface area involvement from baseline
- Reduction in SCORing Atopic Dermatitis (SCORAD) index value from baseline [A]

AND

2 - Not used in combination with other JAK inhibitors, biologic immunomodulators (e.g., Dupixent, Adbry), or other immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [6, 7]:

- Greater than 6 stools per day
- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers
- Abnormal lab values (e.g., hemoglobin, ESR, CRP)
- Dependent on, or refractory to, corticosteroids

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [6, 7]:

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine
- Corticosteroids (e.g., prednisone)

AND

5 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Humira, Amjevita, Simponi)

AND

6 - Not used in combination with other JAK inhibitors, biological therapies for UC, or with potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 6, 7]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

AND

2 - Not used in combination with other JAK inhibitors, biological therapies for UC, or with potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

3 . Background

Clinical Practice Guidelines

Table 1. Relative potencies of topical corticosteroids [8]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05

	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2

	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

4 . Endnotes

A. The Scoring Atopic Dermatitis (SCORAD) index is a clinical tool for assessing the severity of atopic dermatitis lesions based on affected body area and intensity of plaque characteristics. [9, 10] The extent and severity of AD over the body area (A) and the severity of 6 specific symptoms (erythema, edema/papulation, excoriations, lichenification, oozing/crusts, and dryness) (B) are assessed and scored by the Investigator. Subjective assessment of itch and sleeplessness is scored by the patient (C). The SCORAD score is a combined score (A/5 + 7B/2 + C) with a maximum of 103. Higher scores indicate greater severity/worsened state. A score of 25 to 50 indicates moderate disease severity and greater than 50 indicates severe disease. [11]

5 . References

1. Rinvoq Prescribing Information. AbbVie Biotechnology Ltd. North Chicago, IL. October 2022.
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8. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014; 71(1):116-32.
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6 . Revision History

Date	Notes
2/1/2023	Addition of new criteria for nr-axSpA; addition of Amjevita as another TNF inhibitor example

Prior Authorization Guideline

Guideline Name	Rituxan Hycela (rituximab and hyaluronidase human)

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	7/26/2017
P&T Revision Date:	03/18/2020 ; 04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Rituxan Hycela (rituximab and hyaluronidase human)
Follicular Lymphoma Indicated for the treatment of adult patients with: 1) Relapsed or refractory, follicular lymphoma as a single agent 2) Previously untreated follicular lymphoma in combination with first line chemotherapy and, in patients achieving a complete or partial response to rituximab in combination with chemotherapy, as single-agent maintenance therapy 3) Non-progressing (including stable disease), follicular lymphoma as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy. Limitations of Use: Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion. Rituxan Hycela is not indicated for the treatment of non-malignant conditions. **Diffuse Large B-cell Lymphoma** Indicated for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens. Limitations of Use: Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion. Rituxan Hycela is not indicated for the treatment of non-malignant conditions. **Chronic Lymphocytic Leukemia (CLL)** Indicated for the treatment of adult patients with previously untreated and previously treated CLL in combination with fludarabine and cyclophosphamide (FC). Limitations of Use: Initiate treatment with Rituxan Hycela only after

patients have received at least one full dose of a rituximab product by intravenous infusion. Rituxan Hycela is not indicated for the treatment of non-malignant conditions.

2 . Criteria

Product Name: Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Follicular Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of follicular lymphoma

AND

2 - One of the following:

2.1 Disease is relapsed or refractory

OR

2.2 Patient exhibited complete or partial response to prior treatment with rituximab in combination with chemotherapy

OR

2.3 Disease is non-progressing or stable following prior treatment with first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy

OR

2.4 Both of the following

2.4.1 Disease is previously untreated

AND

2.4.2 Medication is used in combination with first-line chemotherapy

AND

3 - One of the following:

3.1 Trial and failure, or intolerance to Ruxience

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing treatment regimen

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

Product Name: Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Follicular Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - One of the following:

2.1 Trial and failure, or intolerance to Ruxience

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Diffuse Large B-cell Lymphoma
Approval Length	12 months [A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of diffuse large B-cell lymphoma

AND

2 - Disease is previously untreated

AND

3 - Medication is being used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy

AND

4 - One of the following:

4.1 Trial and failure, or intolerance to Ruxience

OR

4.2 Continuation of therapy for patients currently in the midst of an ongoing treatment regimen

AND

5 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

Product Name: Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Chronic Lymphocytic Leukemia
Approval Length	12 months [B]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia

AND

2 - Medication is being used in combination with fludarabine and cyclophosphamide (FC) therapy

AND

3 - One of the following:

3.1 Trial and failure, or intolerance to Ruxience

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing treatment regimen

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

3 . Endnotes

A. Treatment for DLBCL consists of up to 8 cycles of 21 days each, a total duration of 6 months [1,3]. There is little evidence that use of rituximab as continuation therapy following R-CHOP induction provides additional benefit above induction alone. [2] This is in contrast with follicular lymphoma, where evidence does support maintenance [4] therapy and NCCN recommends consolidation with rituximab monotherapy [3]. However, to account for potential delays in therapy without interrupting treatment, a 12 month authorization is provided.
B. Treatment for CLL consists of up to 6 cycles of 28 days each, a total duration of 6 months [1]. To account for potential delays in therapy without interrupting treatment, a 12 month authorization is provided.
C. An FDA-approved biosimilar is an appropriate substitute for rituximab. [3]
D. The FDA defines biosimilar as a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. [4]

4 . References

1. Rixtuan Hycela Prescribing Information. Genentech, Inc. South San Francisco, CA. June 2021.
2. Habermann TM, Weller EA, Morrison VA, et al. Rituximab-CHOP versus CHOP alone or with maintenance rituximab in older patients with diffuse large B-cell lymphoma. J Clin Oncol. 2006;24(19):3121-3127.

3. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 10, 2023.
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5 . Revision History

Date	Notes
4/4/2023	Annual review - updated references.

Prior Authorization Guideline

Guideline Name	Rituxan Hycela (rituximab and hyaluronidase human) - UM Optimization

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	7/26/2017
P&T Revision Date:	06/15/2022 ; 4/19/2023

1 . Indications

Drug Name: Rituxan Hycela (rituximab and hyaluronidase human)
Follicular Lymphoma Indicated for the treatment of adult patients with: 1) Relapsed or refractory, follicular lymphoma as a single agent 2) Previously untreated follicular lymphoma in combination with first line chemotherapy and, in patients achieving a complete or partial response to rituximab in combination with chemotherapy, as single-agent maintenance therapy 3) Non-progressing (including stable disease), follicular lymphoma as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy. Limitations of Use: Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion. Rituxan Hycela is not indicated for the treatment of non-malignant conditions. **Diffuse Large B-cell Lymphoma** Indicated for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens. Limitations of Use: Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion. Rituxan Hycela is not indicated for the treatment of non-malignant conditions. **Chronic Lymphocytic Leukemia (CLL)** Indicated for the treatment of adult patients with previously untreated and previously treated CLL in combination with fludarabine and

cyclophosphamide (FC). Limitations of Use: Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion. Rituxan Hycela is not indicated for the treatment of non-malignant conditions.

2 . Criteria

Product Name: Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Follicular Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of follicular lymphoma

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

2.1 Disease is relapsed or refractory

OR

2.2 Patient exhibited complete or partial response to prior treatment with rituximab in combination with chemotherapy

OR

2.3 Disease is non-progressing or stable following prior treatment with first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy

OR

2.4 Both of the following:

2.4.1 Disease is previously untreated

AND

2.4.2 Medication is used in combination with first-line chemotherapy

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

3.1 Trial and failure, or intolerance to Ruxience

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing treatment regimen

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

Product Name: Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Follicular Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

2.1 Trial and failure, or intolerance to Ruxience

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Diffuse Large B-cell Lymphoma
Approval Length	12 months [A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of diffuse large B-cell lymphoma

AND

2 - Disease is previously untreated

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming medication is being used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

4.1 Trial and failure, or intolerance to Ruxience

OR

4.2 Continuation of therapy for patients currently in the midst of an ongoing treatment regimen

AND

5 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

Product Name: Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Chronic Lymphocytic Leukemia
Approval Length	12 months [B]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming medication is being used in combination with fludarabine and cyclophosphamide (FC) therapy

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

3.1 Trial and failure, or intolerance to Ruxience

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing treatment regimen

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

3 . Endnotes

A. Treatment for DLBCL consists of up to 8 cycles of 21 days each, a total duration of 6 months [1,3]. There is little evidence that use of rituximab as continuation therapy following R-CHOP induction provides additional benefit above induction alone. [2] This is in contrast with follicular lymphoma, where evidence does support maintenance [4] therapy and NCCN recommends consolidation with rituximab monotherapy [3]. However, to account for potential delays in therapy without interrupting treatment, a 12 month authorization is provided.
B. Treatment for CLL consists of up to 6 cycles of 28 days each, a total duration of 6 months [1]. To account for potential delays in therapy without interrupting treatment, a 12 month authorization is provided.
C. An FDA-approved biosimilar is an appropriate substitute for rituximab. [3]
D. The FDA defines biosimilar as a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. [4]

4 . References

1. Rixtuan Hycela Prescribing Information. Genentech, Inc. South San Francisco, CA. June 2021.
2. Habermann TM, Weller EA, Morrison VA, et al. Rituximab-CHOP versus CHOP alone or with maintenance rituximab in older patients with diffuse large B-cell lymphoma. J Clin Oncol. 2006;24(19):3121-3127.
3. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 10, 2023.
4. U.S. Food and Drug Administration (FDA). Biosimilar and Interchangeable Products. Silver Spring, MD: FDA; October 23, 2017. Available at: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580419.htm#biosimilar. Accessed February 27, 2020.
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5 . Revision History

Date	Notes
4/4/2023	Annual review - updated references.

Prior Authorization Guideline

Guideline Name	Rituximab - PA, NF

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	9/18/2019
P&T Revision Date:	09/18/2019 ; 11/14/2019 ; 10/16/2019 ; 01/15/2020 ; 01/15/2020 ; 02/13/2020 ; 03/18/2020 ; 09/16/2020 ; 02/18/2021 ; 07/21/2021 ; 10/20/2021 ; 12/15/2021 ; 01/19/2022 ; 02/17/2022 ; 07/20/2022 ; 10/19/2022 ; 2/16/2023

1 . Indications

Drug Name: Rituxan (rituximab)
Non-Hodgkin's Lymphoma (NHL) Indicated for the treatment of patients with: a. Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma as a single agent. b. Previously untreated follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with first-line chemotherapy and, in patients achieving a complete or partial response to Rituxan in combination with chemotherapy, as a single-agent maintenance therapy. c. Non-progressing (including stable disease) low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma, as a single agent, after first-line CVP chemotherapy. d. Previously untreated diffuse large B-cell, CD20-positive non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens. **Pediatric Non-Hodgkin's Lymphoma (NHL)** Indicated for previously untreated, advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL) in combination with chemotherapy in pediatric patients aged 6 months and older. **Rheumatoid Arthritis (RA)** In combination with methotrexate, is indicated for the treatment of

adult patients with moderately- to severely-active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies. Limitation of Use: Rituxan is not recommended for use in patients with severe, active infections.

Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with previously untreated and previously treated CD20-positive CLL in combination fludarabine and cyclophosphamide (FC). Limitations of Use: Rituxan is not recommended for use in patients with severe, active infections.

Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) Indicated for the treatment of adult patients with Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in adult and pediatric patients 2 years of age and older in combination with glucocorticoids. Limitations of Use: Rituxan is not recommended for use in patients with severe, active infections.

Pemphigus Vulgaris Indicated for the treatment of moderate to severe Pemphigus Vulgaris (PV) in adult patients.

Off Label Uses: Immune Thrombocytopenic Purpura (ITP) Has been used for the treatment of immune or idiopathic thrombocytopenic purpura. [1, 2] Overall response rates of 35% to 52% in patients with refractory idiopathic thrombocytopenic purpura. [3, 4]

Waldenstrom's Macroglobulinemia Has been used for the treatment of relapsed/refractory Waldenstrom's macroglobulinemia. Rituximab monotherapy (1 to 8 cycles) has shown efficacy in limited studies. [5-8]

Drug Name: Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)

Non-Hodgkin's Lymphoma (NHL) Indicated for the treatment of patients with: a. Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma as a single agent. b. Previously untreated follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with first-line chemotherapy and, in patients achieving a complete or partial response to Rituxan in combination with chemotherapy, as a single-agent maintenance therapy. c. Non-progressing (including stable disease) low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma, as a single agent, after first-line CVP chemotherapy. d. Previously untreated diffuse large B-cell, CD20-positive non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens.

Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC).

Rheumatoid Arthritis (RA) In combination with methotrexate, is indicated for the treatment of adult patients with moderately- to severely-active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.

Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) Indicated for the treatment of adults with Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in combination with

glucocorticoids.

Off Label Uses: **Pediatric Non-Hodgkin's Lymphoma (NHL)** Indicated for previously untreated, advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL) in combination with chemotherapy in pediatric patients aged 6 months and older. [25, C, D]

Drug Name: Riabni (rituximab-arrx)

Non-Hodgkin's Lymphoma (NHL) Indicated for the treatment of patients with: a. Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma as a single agent. b. Previously untreated follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with first-line chemotherapy and, in patients achieving a complete or partial response to Rituxan in combination with chemotherapy, as a single-agent maintenance therapy. c. Non-progressing (including stable disease) low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma, as a single agent, after first-line CVP chemotherapy. d. Previously untreated diffuse large B-cell, CD20-positive non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens.

Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC).

Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) Indicated for the treatment of adults with Granulomatosis with Polyangiitis (GPA) (Wegener’s Granulomatosis) and Microscopic Polyangiitis (MPA) in combination with glucocorticoids.

Rheumatoid Arthritis (RA) Indicated in combination with methotrexate for the treatment of adult patients with moderately- to severely- active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.

Off Label Uses: **Pediatric Non-Hodgkin's Lymphoma (NHL)** Indicated for previously untreated, advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL) in combination with chemotherapy in pediatric patients aged 6 months and older. [25, C, D]

2 . Criteria

Product Name: Rituxan, Truxima, Riabni	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	1 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately- to severely-active rheumatoid arthritis

AND

2 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [26, 27]:

- methotrexate
- leflunomide
- sulfasalazine

AND

3 - Used in combination with methotrexate [A]

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Cimzia (certolizumab)
- Enbrel (etanercept)
- Humira (adalimumab) or Amjevita (adalimumab-atto)
- Simponi (golimumab)
- Rinvoq (upadacitinib)
- Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER)

AND

4.1.2 Trial and failure, contraindication, or intolerance to BOTH of the following:

- Actemra (tocilizumab)
- Orencia (abatacept)

OR

4.2 Continuation of prior rituximab therapy, defined as no more than a 45-day gap in therapy

AND

5 - Trial and failure or intolerance to Ruxience

AND

6 - Prescribed by or in consultation with a rheumatologist

Notes	*Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Ruxience	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	1 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately- to severely-active rheumatoid arthritis

AND

2 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [26, 27]:

- methotrexate
- leflunomide
- sulfasalazine

AND

3 - Used in combination with methotrexate [A]

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Cimzia (certolizumab)
- Enbrel (etanercept)
- Humira (adalimumab) or Amjevita (adalimumab-atto)
- Simponi (golimumab)
- Rinvoq (upadacitinib)
- Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER)

OR

4.2 Continuation of prior rituximab therapy, defined as no more than a 45-day gap in therapy

AND

5 - Prescribed by or in consultation with a rheumatologist

Notes	*Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Rituxan, Ruxience, Truxima, Riabni	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	1 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [10, 26, 27]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - At least 16 weeks have elapsed since last course of therapy [B]

Product Name: Riabni, Truxima	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	1 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of moderately- to severely-active rheumatoid arthritis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [26, 27]:

- methotrexate
- leflunomide
- sulfasalazine

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming that medication is used in combination with methotrexate [A]

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Cimzia (certolizumab)
- Enbrel (etanercept)
- Humira (adalimumab) or Amjevita (adalimumab-atto)
- Simponi (golimumab)
- Rinvoq (upadacitinib)
- Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER)

AND

4.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to BOTH of the following:

- Actemra (tocilizumab)
- Orencia (abatacept)

OR

4.2 Both of the following:

4.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior rituximab therapy, defined as no more than a 45-day gap in therapy

AND

4.2.2 Documentation of positive clinical response to therapy as evidenced by at least one of the following [10, 26, 27]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to Ruxience

AND

6 - Prescribed by or in consultation with a rheumatologist

Notes	*Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.

Product Name: Ruxience	
Diagnosis	Non-Hodgkin's Lymphoma
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following: [10]

- Diagnosis of diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma
- Used as first-line treatment in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens

OR

1.2 Both of the following:

- Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma

- Used as first-line treatment in combination with chemotherapy

OR

1.3 All of the following:

- Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma
- Patient achieved a complete or partial response to a rituximab product in combination with chemotherapy
- Followed by rituximab used as monotherapy for maintenance therapy

OR

1.4 Both of the following: [1]

1.4.1 Diagnosis of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma

AND

1.4.2 One of the following:

- Patient has stable disease following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy
- Patient achieved a partial or complete response following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy

OR

1.5 Diagnosis of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin’s lymphoma.

OR

1.6 All of the following (off-label) [25, C, D]

1.6.1 Diagnosis of one of the following previously untreated, advanced stage indications:

- CD-20-positive diffuse large B-cell lymphoma (DLBCL)
- Burkitt lymphoma (BL)

- Burkitt-like lymphoma (BLL)
- Mature B-cell acute leukemia (B-AL)

AND

1.6.2 Patient is 6 months of age or older

AND

1.6.3 Used in combination with chemotherapy

AND

2 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Riabni, Rituxan, Truxima	
Diagnosis	Non-Hodgkin's Lymphoma
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following: [10]

- Diagnosis of diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma
- Used as first-line treatment in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens

OR

1.2 Both of the following:

- Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma

- Used as first-line treatment in combination with chemotherapy

OR

1.3 All of the following:

- Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma
- Patient achieved a complete or partial response to a rituximab product in combination with chemotherapy
- Followed by rituximab used as monotherapy for maintenance therapy

OR

1.4 Both of the following: [1]

1.4.1 Diagnosis of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma

AND

1.4.2 One of the following:

- Patient has stable disease following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy
- Patient achieved a partial or complete response following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy

OR

1.5 Diagnosis of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin’s lymphoma.

OR

1.6 All of the following (off-label for Riabni, Truxima) [25, C, D]:

1.6.1 Diagnosis of one of the following previously untreated, advanced stage indications:

- CD-20-positive diffuse large B-cell lymphoma (DLBCL)
- Burkitt lymphoma (BL)

- Burkitt-like lymphoma (BLL)
- Mature B-cell acute leukemia (B-AL)

AND

1.6.2 Patient is 6 months of age or older

AND

1.6.3 Used in combination with chemotherapy

AND

2 - One of the following:

2.1 Trial and failure, or intolerance to Ruxience

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

AND

3 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Riabni, Truxima	
Diagnosis	Non-Hodgkin's Lymphoma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following:

1.1 Both of the following: [10]

- Diagnosis of diffuse large B-cell, CD20-positive, non-Hodgkin’s lymphoma
- Used as first-line treatment in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens

OR

1.2 Both of the following:

- Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma
- Used as first-line treatment in combination with chemotherapy

OR

1.3 All of the following:

- Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma
- Patient achieved a complete or partial response to a rituximab product in combination with chemotherapy
- Followed by rituximab used as monotherapy for maintenance therapy

OR

1.4 Both of the following: [1]

1.4.1 Diagnosis of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma

AND

1.4.2 One of the following:

- Patient has stable disease following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy
- Patient achieved a partial or complete response following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy

OR

1.5 Diagnosis of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin's lymphoma.

OR

1.6 All of the following (off-label) [25, C, D]:

1.6.1 Diagnosis of one of the following previously untreated, advanced stage indications:

- CD-20-positive diffuse large B-cell lymphoma (DLBCL)
- Burkitt lymphoma (BL)
- Burkitt-like lymphoma (BLL)
- Mature B-cell acute leukemia (B-AL)

AND

1.6.2 Patient is 6 months of age or older

AND

1.6.3 Used in combination with chemotherapy

AND

2 - One of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Ruxience

OR

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen, defined as no more than a 45-day gap in therapy

AND

3 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Ruxience	
Diagnosis	Chronic Lymphocytic Leukemia
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia [2, 12, 15-19]

AND

2 - Used in combination with fludarabine and cyclophosphamide

AND

3 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Riabni, Rituxan, Truxima	
Diagnosis	Chronic Lymphocytic Leukemia
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia [2, 12, 15-19]

AND

2 - Used in combination with fludarabine and cyclophosphamide

AND

3 - One of the following:

3.1 Trial and failure, or intolerance to Ruxience

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

AND

4 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Riabni, Truxima	
Diagnosis	Chronic Lymphocytic Leukemia
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia [2, 12, 15-19]

AND

2 - Used in combination with fludarabine and cyclophosphamide

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Ruxience

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen, defined as no more than a 45-day gap in therapy

AND

4 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Rituxan	
Diagnosis	Immune or Idiopathic Thrombocytopenic Purpura [1, 2] (Off-Label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of immune or idiopathic thrombocytopenic purpura (off-label) [3, 4, 11]

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Trial and failure, contraindication, or intolerance to at least ONE of the following: [12]

- Glucocorticoids (e.g., prednisone, methylprednisolone)
- Immunoglobulins (e.g., IVIg)
- Splenectomy

AND

4 - Documented platelet count of less than 50 x 10^9 / L [11]

Product Name: Rituxan	
Diagnosis	Pemphigus Vulgaris
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe Pemphigus Vulgaris

AND

2 - Prescribed by or in consultation with a dermatologist

Product Name: Rituxan	
Diagnosis	Pemphigus Vulgaris
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Rituxan therapy

Product Name: Rituxan	
Diagnosis	Waldenstrom's macroglobulinemia
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsed/refractory Waldenstrom's macroglobulinemia (off-label) [1, 2, 5-8]

Product Name: Ruxience	
Diagnosis	Wegener's Granulomatosis and Microscopic Polyangiitis
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis)
- Microscopic Polyangiitis

AND

2 - Used in combination with glucocorticoids (e.g., prednisone)

AND

3 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Pulmonologist
- Rheumatologist

Product Name: Riabni, Rituxan, Truxima	
Diagnosis	Wegener's Granulomatosis and Microscopic Polyangiitis
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis)
- Microscopic Polyangiitis

AND

2 - Used in combination with glucocorticoids (e.g., prednisone)

AND

3 - One of the following:

3.1 Trial and failure, or intolerance to Ruxience

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

AND

4 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Pulmonologist
- Rheumatologist

Product Name: Riabni, Truxima	
Diagnosis	Wegener's Granulomatosis and Microscopic Polyangiitis
Approval Length	3 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following diagnoses:

- Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis)
- Microscopic Polyangiitis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming medication is used in combination with glucocorticoids (e.g., prednisone)

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Ruxience

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen, defined as no more than a 45-day gap in therapy

AND

4 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Pulmonologist

- Rheumatologist

3 . Endnotes

A. Aggressive, continuous and early treatment with DMARDs may slow the destructive processes in RA by preventing or delaying cartilage and bone destruction. [11] Often used in combination, the most commonly prescribed DMARDs include hydroxychloroquine, sulfasalazine, leflunomide and methotrexate, with methotrexate being the gold standard.
B. An open-label extension analysis of RA patients previously treated with Rituxan was conducted. Patients were eligible for the second course if they demonstrated a greater than or equal to 20% reduction in both swollen joint count and the tender joint count at any visit 16 weeks after initial treatment or later and had active disease (swollen joint count greater than or equal to 8 and tender joint count greater than or equal to 8). Repeat courses of treatment were administered at the investigator's discretion, with a minimum interval between treatment courses of 16 weeks. [15]
C. The FDA defines biosimilar as a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. [22]
D. An FDA-approved biosimilar is an appropriate substitute for rituximab. [23, 25]

4 . References

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5 . Revision History

Date	Notes
1/31/2023	Modified criteria to read "used in combination with methotrexate" and "used in combination with glucocorticoids" to align with labeling. Updated references.

Prior Authorization Guideline

Guideline Name	Romidepsin Products

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	5/18/2010
P&T Revision Date:	04/15/2020 ; 06/17/2020 ; 04/21/2021 ; 09/15/2021 ; 04/20/2022 ; 4/15/2023

1 . Indications

Drug Name: Istodax (romidepsin), Romidepsin (romidepsin)
Cutaneous T-cell lymphoma (CTCL) Indicated for the treatment of CTCL in adult patients who have received at least one prior systemic therapy.

2 . Criteria

Product Name: Istodax, Romidepsin	
Diagnosis	Cutaneous T-cell lymphoma (CTCL)
Approval Length	12 Month [2, A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cutaneous T-cell lymphoma (CTCL)

AND

2 - Trial and failure, contraindication, or intolerance to one systemic therapy for the treatment of CTCL [e.g., Trexall (methotrexate), Targretin (bexarotene), cyclophosphamide] [B]

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Istodax, Romidepsin	
Diagnosis	Cutaneous T-cell lymphoma (CTCL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. A 12-month length of authorization is an appropriate amount of time for approval as the minimum is 6 cycles (6 months) and there is no established maximum number of cycles for CTCL. [2]
B. Examples of CTCL systemic therapies include: Campath (alemtuzumab), cyclophosphamide, Doxil (liposomal doxorubicin), Extracorporeal photopheresis, Folotyn (pralatrexate), Gemzar (gemcitabine), Interferon-alpha , Leukeran (chlorambucil), Nipent (pentostatin), Targretin (bexarotene), Temodar (temozolamide), Toposar (etoposide), Trexall (methotrexate), Velcade (bortezomib). [3]

4 . References

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5 . Revision History

Date	Notes
4/6/2023	Annual Review

Prior Authorization Guideline

Guideline Name	Roszet (rosuvastatin/ezetimibe) - ST, NF

Guideline Note:

Effective Date:	8/1/2022
P&T Approval Date:	6/16/2021
P&T Revision Date:	09/15/2021 ; 11/18/2021 ; 6/15/2022

1 . Indications

Drug Name: Roszet (rosuvastatin/ezetimibe)
Non-familial hyperlipidemia Indicated as an adjunct to diet in patients with primary non-familial hyperlipidemia to reduce low-density lipoprotein cholesterol (LDL-C). **Homozygous familial hypercholesterolemia (HoFH)** Indicated alone or as an adjunct to other LDL-C-lowering therapies in patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.

2 . Criteria

Product Name: Roszet, Brand Ezetimibe-Rosuvastatin (ST)	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial of a minimum 30 day supply, contraindication, or intolerance to one of the following generics:

- rosuvastatin
- atorvastatin 40 mg
- atorvastatin 80 mg

Product Name: Roszet, Brand Ezetimibe-Rosuvastatin (NF)	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting one of the following diagnoses:

- Non-familial hyperlipidemia
- Homozygous familial hypercholesterolemia (HoFH)

AND

2 - Submission of medical records (e.g., chart notes) documenting history of a minimum 30 day trial and failure, contraindication, or intolerance to two of the following:

- rosuvastatin
- atorvastatin
- simvastatin

AND

3 - Submission of medical records (e.g., chart notes) documenting history of a minimum 30 day trial and failure, or intolerance to ezetimibe

AND

4 - Physician has provided rationale for needing to use fixed-dose combination therapy with Roszet instead of taking individual products in combination

Product Name: Roszet, Brand Ezetimibe-Rosuvastatin (NF)	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy

3 . References

1. Roszet Prescribing Information. Althera Pharmaceuticals LLC. Morristown, NJ. June 2021.
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4 . Revision History

Date	Notes
5/31/2022	Annual Review - Diagnosis verification added to ST section

Prior Authorization Guideline

Guideline Name	Rozlytrek (entrectinib)

Guideline Note:

Effective Date:	11/1/2022
P&T Approval Date:	10/16/2019
P&T Revision Date:	09/16/2020 ; 09/15/2021 ; 9/21/2022

1 . Indications

Drug Name: Rozlytrek (entrectinib)
Non-small cell lung cancer (NSCLC) Indicated for the treatment of adult patients with ROS1-positive metastatic non-small cell lung cancer (NSCLC), as detected by an FDA-approved test. **Solid Tumors** Indicated for the treatment of adult and pediatric patients 12 years of age and older with solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, as detected by an FDA-approved test without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have either progressed following treatment or have no satisfactory alternative therapy. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

2 . Criteria

Product Name: Rozlytrek	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer (NSCLC)

AND

2 - Patient has ROS1 rearrangement positive tumor(s)

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Rozlytrek	
Diagnosis	Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has solid tumors with a neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, TPR-NTRK1, etc.) [A]

AND

2 - Disease is without a known acquired resistance mutation (e.g., TRKA G595R, TRKA G667C or TRKC G623R substitutions) [2]

AND

3 - Disease is one of the following:

- Metastatic
- Unresectable (including cases where surgical resection is likely to result in severe morbidity)

AND

4 - One of the following:

- Disease has progressed following previous treatment (e.g., surgery, radiation therapy, or systemic therapy) [3]
- Disease has no satisfactory alternative treatments

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Rozlytrek	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. The most common cancers listed in the pivotal trials which evaluated the efficacy of Rozlytrek were: sarcoma, lung, salivary gland tumors, breast, thyroid and colorectal cancer. [1]

4 . References

1. Rozlytrek Prescribing Information. Genentech USA, Inc. South San Francisco, CA. July 2022.
2. Drilon A, Nagasubramanian R, Blake JF, et al. A next-generation TRK kinase inhibitor overcomes acquired resistance to prior TRK kinase inhibition in patients with TRK fusion-positive solid tumors. Cancer Discov. 2017 Sep;7(9):963-972.

5 . Revision History

Date	Notes
9/1/2022	2022 Annual Review - Updated background information

Prior Authorization Guideline

Guideline Name	Rubraca (rucaparib)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	2/16/2017
P&T Revision Date:	08/18/2022 ; 3/15/2023

1 . Indications

Drug Name: Rubraca (rucaparib)
Maintenance Treatment of BRCA-mutated Recurrent Ovarian cancer Indicated for the maintenance treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)- associated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. **Metastatic Castration-Resistant Prostate Cancer with BRCA Mutations** Indicated for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy.

2 . Criteria

Product Name: Rubraca	
Diagnosis	Ovarian Cancer

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Epithelial ovarian cancer
- Fallopian tube cancer
- Primary peritoneal cancer

AND

2 - All of the following:

2.1 Disease is recurrent

AND

2.2 Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin) [3]

AND

2.3 Presence of deleterious BRCA-mutation (germline and/or somatic)

AND

3 - Prescribed by or in consultation with an oncologist

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to Lynparza

OR

4.2 For continuation of prior therapy

Product Name: Rubraca	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic castration-resistant prostate cancer (mCRPC)

AND

2 - Presence of deleterious BRCA mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Patient has received previous treatment with both of the following:

- Androgen receptor-directed therapy [e.g., Erleada (apalutamide), Xtandi (enzalutamide), Zytiga (abiraterone)]
- A taxane-based chemotherapy [e.g., docetaxel, Jevtana (cabazitaxel)]

AND

4 - Prescribed by or in consultation with one of the following:

- Oncologist

- Urologist

AND

5 - One of the following:

5.1 Trial and failure, contraindication, or intolerance to Lynparza

OR

5.2 For continuation of prior therapy

Product Name: Rubraca	
Diagnosis	All Uses
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. In clinical trials for mCRPC, patients received concomitant GnRH analog or had prior bilateral orchiectomy. This PA criterion requirement has been removed from other prostate cancer drugs as part of PA criteria optimization initiative as it was being approved 100% of the time.

4 . References

1. Rubraca Prescribing Information. Clovis Oncology, Inc. Boulder, CO. December 2022.
2. U.S. Food and Drug Administration [website]: List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Available at

https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm301431.htm Accessed July 9, 2021.
3. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Ovarian Cancer - v.1.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed June 15, 2022.
4. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Prostate Cancer v.2.2021. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed July 9, 2021.

5 . Revision History

Date	Notes
3/3/2023	Updated criteria for ovarian cancer

Prior Authorization Guideline

Guideline Name	Rybelsus (semaglutide)

Guideline Note:

Effective Date:	6/17/2022
P&T Approval Date:	8/15/2019
P&T Revision Date:	12/18/2019 ; 01/15/2020 ; 01/20/2021 ; 01/19/2022 ; 5/19/2022

1 . Indications

Drug Name: Rybelsus (semaglutide)
Type 2 diabetes mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: (1) RYBELSUS is not recommended as a first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of rodent C-cell tumor findings to humans. (2) RYBELSUS has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis. (3) RYBELSUS is not indicated for use in patients with type 1 diabetes mellitus.

2 . Criteria

Product Name: Rybelsus	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Drug is not solely being used for weight loss

AND

3 - Trial and failure, contraindication, or intolerance to one of the following generics:

- Metformin
- Metformin ER
- Glipizide-metformin
- Glyburide-metformin
- Pioglitazone-metformin

3 . References

1. American Diabetes Association. Standards of medical care in diabetes. Diabetes Care. 2022; 45 (suppl 1): S125-143.
2. Rybelsus Prescribing Information. Novo Nordisk A/S. Bagsvaerd, Denmark. September 2021.

4 . Revision History

Date	Notes
6/16/2022	Added exclusion criteria for weight loss.

Prior Authorization Guideline

Guideline Name	Rydapt (midostaurin)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	6/28/2017
P&T Revision Date:	02/13/2020 ; 02/18/2021 ; 02/17/2022 ; 3/15/2023

1 . Indications

Drug Name: Rydapt (midostaurin) capsules
Acute Myeloid Leukemia Indicated for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 mutation positive as detected by an FDA-approved test, in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation. Limitations of Use: Rydapt is not indicated as a single-agent induction therapy for the treatment of patients with AML. **Aggressive Systemic Mastocytosis, Systemic Mastocytosis with Associated Hematological Neoplasm, or Mast Cell Leukemia** Indicated for the treatment of adult patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL).

2 . Criteria

Product Name: Rydapt	
Diagnosis	Acute Myeloid Leukemia (AML)

Approval Length	12 Month [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of newly diagnosed acute myeloid leukemia (AML)

AND

2 - FMS-like tyrosine kinase 3 (FLT3) mutation-positive as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [5]

AND

3 - Used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

Product Name: Rydapt	
Diagnosis	Aggressive Systemic Mastocytosis (ASM), Systemic Mastocytosis with Associated Hematological Neoplasm (SM-AHN), and Mast Cell Leukemia (MCL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses: [4]

- Aggressive systemic mastocytosis (ASM)
- Systemic mastocytosis with associated hematological neoplasm (SM-AHN)
- Mast cell leukemia (MCL)

AND

2 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

Product Name: Rydapt	
Diagnosis	All Indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. Although Rydapt (midostaurin) is not FDA-approved for maintenance therapy, the pivotal trial was designed to include induction, re-induction (if indicated), post-remission (consolidation), and maintenance therapy for a total of 12 months. Therapy significantly improved event free survival and overall survival. [1-3]

4 . References

1. Rydapt Prescribing Information. Novartis Pharmaceuticals. East Hanover, NJ. November 2021.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Acute Myeloid Leukemia v.1.2019. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed February 27, 2023.
3. Stone RM, Mandrekar S, Sanford BL, et al. The multi-kinase inhibitor midostaurin (M) prolongs survival compared with placebo (P) in combination with daunorubicin (D)/cytarabine (C) induction (ind), high-dose c consolidation (consol), and as maintenance (maint) therapy in newly diagnosed acute myeloid leukemia (AML) patients (pts) age 18-60 with FLT3 Mutations (muts): an international prospective randomized (rand) p-controlled double-blind trial (CALGB 10603/RATIFY [Alliance]). Blood. 2015 Dec;126:6.
4. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Systemic mastocytosis v.2.2019. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/mastocytosis.pdf. Accessed February 27, 2023.
5. U.S. Food and Drug Administration: List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Available at: https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools. Accessed December13, 2019.

5 . Revision History

Date	Notes
2/27/2023	2023 Annual Review

Prior Authorization Guideline

Guideline Name	Sabril (vigabatrin), Vigadrone

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	11/13/2012
P&T Revision Date:	11/14/2019 ; 03/18/2020 ; 09/16/2020 ; 03/17/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Sabril (vigabatrin), Vigadrone (vigabatrin)
Refractory Complex Partial Seizures Indicated as adjunctive therapy for adults and pediatric patients 2 years of age and older with refractory complex partial seizures (CPS) who have inadequately responded to several alternative treatments and for whom the potential benefits outweigh the risk of vision loss. Sabril/Vigadrone is not indicated as a first line agent for complex partial seizures. **Infantile Spasms (1 Month to 2 Years of Age)** Indicated as monotherapy for pediatric patients with infantile spasms (IS) 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.

2 . Criteria

Product Name: Generic vigabatrin, Vigadrone	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following

1.1 Diagnosis of infantile spasms [A]

AND

1.2 Patient is 1 month to 2 years of age

OR

2 - All of the following:

2.1 Diagnosis of complex partial seizures

AND

2.2 Patient is 2 years of age or older

AND

2.3 Used as adjunctive therapy

AND

2.4 One of the following:

2.4.1 Trial and failure, contraindication, or intolerance to two formulary anticonvulsants [e.g., Lamictal (lamotrigine), Depakene (valproic acid), Dilantin (phenytoin)] [B]

OR

2.4.2 For continuation of prior therapy

Product Name: Brand Sabril	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of infantile spasms [A]

AND

1.1.2 Patient is 1 month to 2 years of age

AND

1.1.3 One of the following:

1.1.3.1 Trial and failure or intolerance to generic vigabatrin tablets or oral suspension

OR

1.1.3.2 For continuation of prior therapy if the patient is established on brand Sabril

OR

1.2 All of the following: [A]

1.2.1 Diagnosis of complex partial seizures

AND

1.2.4 Patient is 2 years of age or older

AND

1.2.2 Used as adjunctive therapy

AND

1.2.3 One of the following:

1.2.3.1 Both of the following:

1.2.3.1.1 Trial and failure, contraindication, or intolerance to two formulary anticonvulsants [e.g., Lamictal (lamotrigine), Depakene (valproic acid), Dilantin (phenytoin)] [B]

AND

1.2.3.1.2 Trial and failure or intolerance to generic vigabatrin tablets or oral suspension

OR

1.2.3.2 For continuation of prior therapy if the patient is established on brand Sabril

Product Name: Generic vigabatrin, Vigadrone, Brand Sabril	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

3 . Endnotes

A. Vigabatrin Risk Evaluation and Mitigation Strategy (REMS) program overview: Vigabatrin Sponsors have created Vigabatrin REMS program to administer the REMS process, which facilitates access to vigabatrin only through select specialty and inpatient pharmacies. The REMS includes the following elements: 1) Patient Guide: outlines the vision loss that can occur with vigabatrin treatment; 2) Elements to Assure Safe Use (ETASU): Vigabatrin Sponsors will maintain a database of certified prescribers (e.g., must counsel regarding the risks associated with vigabatrin, including vission loss; ensure periodic visual monitoring is performed on an ongoing basis, report any adverse event suggestive of vision loss; enrolling patients taking vigabatrin in the REMS program) and will ensure that prescribers comply with the requirements of the REMS and may de-certify noncompliant prescribers. [3] Assessing the effectiveness of vigabatrin should be done within 12 weeks for CPS patients and within 2-4 weeks for IS. Vision monitoring is mandatory in adults and it is required to the extent possible in infants at baseline (no later than 4 weeks after starting vigabatrin) and at least 3 months while on therapy. Vision testing is also required about 3-6 months after the discontinuation of vigabatrin therapy. [1, 2] Under REMS requirement, pharmacies that dispense vigabatrin will be specially certified. Vigabatrin Sponsors will ensure that each patient treated with vigabatrin is enrolled in the Vigabatrin REMS before vigabatrin is dispensed and that vigabatrin will be dispensed to patients with documentation of safe-use conditions. 3) Implementation system: Vigabatrin Sponsors will ensure that vigabatrin is only distributed to certified pharmacies by ensuring that the wholesale/distributors comply with the program requirements, which includes submission of distribution records of all vigabatrin shipments to the REMS program. Vigabatrin Sponsors will maintain a secure database of all certified pharmacies and patients enrolled in the REMS program. A REMS program call center and website will be maintained by Vigabatrin Sponsors in order to provide resources and support for all aspects of the REMS program. [3]
B. To improve patient care and facilitate clinical research, the International League Against Epilepsy (ILAE) appointed a Task Force to formulate a consensus definition of drug resistant epilepsy. The following definition was formulated: Drug resistant epilepsy may be defined as failure of adequate trials of two tolerated and appropriately chosen and used antiepileptic drug (AED) schedules (whether as monotherapies or in combination) to achieve sustained seizure freedom. [4]

4 . References

1. Sabril Prescribing Information. Lundbeck. Deerfield, IL. May 2020.
2. Vigadrone Prescribing Information. Upsher-Smith Laboritories, LLC. Maple Grove, MN. February 2020.
3. REMS@FDA: Vigabatrin Risk Evaluation and Mitigation Strategy (REMS) Program. U.S. Food and Drug Administration; Available at: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=364. Accessed February 15, 2021.
4. Kwan P, Arzimanoglou A, Berg AT, et al. Definition of drug resistant epilepsy: consensus proposal by the ad hoc Task Force of the ILAE Commission on Therapeutic Strategies. Epilepsia. 2010 Jun;51(6):1069-77.

5 . Revision History

Date	Notes
3/1/2023	Annual Review - No criteria changes

Prior Authorization Guideline

Guideline Name	Sapropterin Products

Guideline Note:

Effective Date:	12/1/2022
P&T Approval Date:	2/25/2016
P&T Revision Date:	10/21/2020 ; 03/17/2021 ; 10/20/2021 ; 10/19/2022 ; 11/17/2022

1 . Indications

Drug Name: Kuvan (sapropterin dihydrochloride)
Phenylketonuria Indicated to reduce blood phenylalanine (Phe) levels in adult and pediatric patients one month of age and older with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4-) responsive Phenylketonuria (PKU). It is to be used in conjunction with a Phe-restricted diet.
Drug Name: Javygtor (sapropterin dihydrochloride)
Phenylketonuria Indicated to reduce blood phenylalanine (Phe) levels in adult and pediatric patients one month of age and older with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4-) responsive Phenylketonuria (PKU). It is to be used in conjunction with a Phe-restricted diet.

2 . Criteria

Product Name: Brand Kuvan, Brand Javygtor

Approval Length	2 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of phenylketonuria (PKU)

AND

2 - Used in conjunction with a phenylalanine (Phe)-restricted diet [A]

AND

3 - Patient will have Phe blood levels measured after 1 week of therapy (new starts to therapy only) and periodically for up to 2 months of therapy to determine response [E]

AND

4 - Trial and failure or intolerance to generic sapropterin

Product Name: Brand Kuvan, Brand Javygtor	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has had an objective response to therapy, defined as a 30% or greater reduction in phenylalanine (Phe) blood levels from baseline [B -D]

AND

2 - Used in conjunction with a phenylalanine (Phe)-restricted diet [A]

AND

3 - Patient will continue to have blood Phe levels measured periodically during therapy [E]

Product Name: Generic sapropterin	
Approval Length	2 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of phenylketonuria (PKU)

AND

2 - Used in conjunction with a phenylalanine (Phe)-restricted diet [A]

AND

3 - Patient will have Phe blood levels measured after 1 week of therapy (new starts to therapy only) and periodically for up to 2 months of therapy to determine response [E]

Product Name: Generic sapropterin	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has had an objective response to therapy, defined as a 30% or greater reduction in phenylalanine (Phe) blood levels from baseline [B -D]

AND

2 - Used in conjunction with a phenylalanine (Phe)-restricted diet [A]

AND

3 - Patient will continue to have blood Phe levels measured periodically during therapy [E]

3 . Endnotes

A. All patients who are treating phenylketonuria (PKU) with sapropterin should also be treated with a phenylalanine (Phe) restricted diet [1].
B. Sapropterin was evaluated in a phase III, randomized, placebo-controlled trial to determine its efficacy in reducing blood Phe concentration [2]. The primary endpoint was mean change from baseline in concentration of Phe in blood after 6 weeks. The mean age was 20 years. Results showed that after 6 weeks of therapy, patients who received sapropterin (n=41) had a decrease in mean blood Phe of 236 micromol/L, compared with a 3 micromol/L increase in the placebo group (n=47; p less than 0.0001).
C. Patients should be evaluated for response to therapy after treatment with saproterin at 20mg/kg per day for a period of one month [1]. The 2 month initial authorization duration allows for patients who start on 10mg/kg per day for the first month, to increase their dose to 20mg/kg per day for an additional month prior to evaluation of response.
D. In clinical trials, response to therapy was defined as greater than or equal to 30% decrease in blood Phe from baseline [1]. The American College of Medical Genetics and Genomics guideline notes a significant decline in blood Phe is expected in sapropterin responders once treatment is started [3]. A reduction of 30% is most often cited in the literature as evidence of effective Phe reduction.
E. Phe blood levels should be checked after one week of sapropterin treatment and periodically after that to assess blood Phe control [1].

4 . References

1. Kuvan prescribing information. BioMarin Pharmaceutical Inc. Novato, CA. February 2021.
2. Levy HL, Milanowski A, Chakrapani A, et al. Efficacy of sapropterin dihydrochloride (tetrahydrobiopterin, 6R-BH4) for reduction of phenylalanine concentration in patients

with phenylketonuria: a phase III randomised placebo-controlled study. Lancet. 2007;370(9586):504-10.
3. Vockley J, Andersson HC, Antshel KM, et al. Phenylalanine hydroxylase deficiency: diagnosis and management guideline. Genet Med. 2014 Feb;16(2):188-200.
4. Javygtor prescribing information. Dr. Reddys Laboratories Inc. Princeton, NJ. January 2022.

5 . Revision History

Date	Notes
11/2/2022	Program Update

Prior Authorization Guideline

Guideline Name	Savella

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	11/19/1999
P&T Revision Date:	12/18/2019 ; 03/18/2020 ; 03/17/2021 ; 04/21/2021 ; 10/20/2021 ; 02/17/2022 ; 2/16/2023

1 . Indications

Drug Name: Savella (milnacipran)
Fibromyalgia Indicated for the management of fibromyalgia. Savella is not approved for use in pediatric patients.

2 . Criteria

Product Name: Savella, Savella Titration Pack	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria	

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure, contraindication, or intolerance to one of the following generics: [A]

- amitriptyline*
- cyclobenzaprine*
- duloxetine
- gabapentin
- pregabalin

Notes	*Amitriptyline and cyclobenzaprine are considered to be potentially inappropriate medications for use in patients 65 years of age and older. [2, A]

3 . Endnotes

A. The 2019 Beers Criteria recommends avoiding the use of amitriptyline (independent of diagnosis or condition) and cyclobenzaprine in older adults due to their highly anticholinergic and sedating properties. [2] However, amitriptyline and cyclobenzaprine have strong evidence for efficacy in treating fibromyalgia. [3]

4 . References

1. Savella Prescribing Information. Allergan USA, Inc. Irvine, CA. September 2021.
2. American Geriatrics Society. American Geriatrics Society 2019 updated AGS Beers Criteria for potentially inappropriate medication use in older adults. J Am Geriatr Soc. 2019 Jan 29.
3. Clauw DJ. Fibromyalgia: a clinical review. JAMA. 2014 Apr 16;311(15):1547-55.

5 . Revision History

Date	Notes
2/1/2023	Annual Review - no criteria changes

Prior Authorization Guideline

Guideline Name	Selzentry (maraviroc)

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	11/12/2013
P&T Revision Date:	11/14/2019 ; 11/12/2020 ; 11/18/2021 ; 04/20/2022 ; 11/17/2022

1 . Indications

Drug Name: Selzentry (maraviroc)
CCR5-tropic HIV-1 Indicated in combination with other antiretroviral agents for the treatment of only CCR5-tropic HIV-1 infection in adults and pediatric patients weighing at least 2 kg. Limitations of Use: Selzentry is not recommended in patients with dual/mixed- or CXCR4-tropic HIV-1.

2 . Criteria

Product Name: Brand Selzentry tablets, generic maraviroc 150mg and 300mg tablets, Selzentry solution	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of CCR5-tropic HIV-1 infection as confirmed by a highly sensitive tropism assay

AND

1.1.2 Patient is currently taking or will be prescribed an optimized background antiretroviral therapy regimen

AND

1.1.3 Prescribed by or in consultation with a clinician with HIV expertise

OR

1.2 For continuation of prior therapy

3 . References

1. Selzentry prescribing information. ViiV Healthcare. Research Triangle Park, NC. September 2022.
2. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Dec 2019; 1-378. Available at https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf. Accessed October 24, 2022.

4 . Revision History

Date	Notes
11/18/2022	Annual review - updated references.

Prior Authorization Guideline

Guideline Name	Sensipar (cinacalcet)

Guideline Note:

Effective Date:	9/1/2022
P&T Approval Date:	10/4/2004
P&T Revision Date:	08/15/2019 ; 11/14/2019 ; 07/15/2020 ; 07/21/2021 ; 7/20/2022

1 . Indications

Drug Name: Sensipar (cinacalcet)
Secondary Hyperparathyroidism Indicated for the treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on dialysis. Limitations of Use: Sensipar is not indicated for use in adult patients with CKD who are not on dialysis because of an increased risk of hypocalcemia. **Parathyroid Carcinoma** Indicated for the treatment of hypercalcemia in adult patients with parathyroid carcinoma. **Primary Hyperparathyroidism** Indicated for the treatment of hypercalcemia in adult patients with primary HPT for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy.

2 . Criteria

Product Name: Brand Sensipar, generic cinacalcet

Diagnosis	Secondary hyperparathyroidism [1-3]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older [1, A]

AND

2 - Diagnosis of secondary hyperparathyroidism with chronic kidney disease on dialysis

AND

3 - Trial and failure, contraindication or intolerance to both of the following:

- A phosphate binder (e.g., PhosLo, Fosrenol, Renvela, Renagel, etc.)
- A vitamin D analog (e.g., calcitriol, Hectorol, Zemplar, etc.)

AND

4 - Trial and failure or intolerance to generic cinacalcet (applies to brand Sensipar only)

AND

5 - Prescribed by or in consultation with an oncologist, endocrinologist, or nephrologist

Product Name: Brand Sensipar, generic cinacalcet	
Diagnosis	Hypercalcemia with parathyroid carcinoma
Approval Length	12 Months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older [1, A]

AND

2 - Diagnosis of hypercalcemia with parathyroid carcinoma

AND

3 - Trial and failure or intolerance to generic cinacalcet (applies to brand Sensipar only)

AND

4 - Prescribed by or in consultation with an oncologist, endocrinologist, or nephrologist

Product Name: Brand Sensipar, generic cinacalcet	
Diagnosis	Severe hypercalcemia with primary hyperparathyroidism [4-5]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older [1, A]

AND

2 - Diagnosis of severe hypercalcemia (level greater than 1 mg/dL above the upper limit of normal) with primary hyperparathyroidism [C, D]

AND

3 - Patient is unable to undergo parathyroidectomy

AND

4 - Trial and failure or intolerance to generic cinacalcet (applies to brand Sensipar only)

AND

5 - Prescribed by or in consultation with an oncologist, endocrinologist, or nephrologist

Product Name: Brand Sensipar, generic cinacalcet	
Diagnosis	All diagnoses listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

3 . Endnotes

A. Sensipar is not indicated for use in pediatric patients. In aggregate, pediatric clinical studies did not establish a safe and effective Sensipar dosing regimen for the pediatric population. Dosing with Sensipar in Pediatric Study 1 was stopped because of a fatality in a Sensipar-treated individual. The individual was noted to be severely hypocalcemic at the time of death. [1]
B. In the pivotal study of Sensipar for parathyroid carcinoma, patients were treated with maintenance therapy for up to 48 weeks. [1]
C. As recommended by an endocrinologist consultant, hypercalcemia is defined as serum calcium level greater than or equal to 12.5 mg/dL. [5]

D. In the pivotal study of Sensipar for primary hyperparathyroidism, severe hypercalcemia was defined as a screening serum calcium level of > 12.5 mg/dL. The median exposure to Sensipar was 270 days (range: 32-1,105 days). [1]

4 . References

1. Sensipar prescribing information. Amgen Inc. Thousand Oaks, CA. December 2019.
2. Block GA, Martin KJ, de Francisco AL, et al. Cinacalcet for secondary hyperparathyroidism in patients receiving hemodialysis. N Engl J Med. 2004;350(15):1516-25.
3. Lindberg JS, Culleton B, Wong G, et al. Cinacalcet HCl, an oral calcimimetic agent for the treatment of secondary hyperparathyroidism in hemodialysis and peritoneal dialysis: a randomized, double-blind, multicenter study. J Am Soc Nephrol. 2005;16(3):800-7.
4. Peacock M, Bilezikian JP, Klassen PS, et al. Cinacalcet hydrochloride maintains long-term normocalcemia in patients with primary hyperparathyroidism. J Clin Endocrinol Metab. 2005;90(1):135-41.
5. Per clinical consult with endocrinologist, July 5, 2011.
6. Cinacalcet Prescribing Information. Actavis Pharma, Inc. Parsippany, NJ. August 2018.

5 . Revision History

Date	Notes
7/21/2022	Annual review - no changes.

Prior Authorization Guideline

Guideline Name	SGLT2 Inhibitors

Guideline Note:

Effective Date:	9/1/2022
P&T Approval Date:	7/9/2013
P&T Revision Date:	12/18/2019 ; 05/14/2020 ; 06/16/2021 ; 10/20/2021 ; 12/15/2021 ; 04/20/2022 ; 05/19/2022 ; 7/20/2022

1 . Indications

Drug Name: Jardiance (empagliflozin)
Cardiovascular Disease Indicated to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease. **Type 2 Diabetes** Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: Jardiance is not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. Jardiance is not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR less than 30 mL/min/1.73 m2. Jardiance is likely to be ineffective in this setting based upon its mechanism of action. **Heart Failure** Indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure.
Drug Name: Farxiga (dapagliflozin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Indicated to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and either established cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors. Limitations of Use: Farxiga is not

recommended for patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients. Farxiga is not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR less than 45 mL/min/1.73 m2. Farxiga is likely to be ineffective in this setting based upon its mechanism.

Heart Failure Indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction.

Chronic Kidney Disease Indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression. Limitations of use: Farxiga is not recommended for the treatment of chronic kidney disease in patients with polycystic kidney disease or patients requiring or with a recent history of immunosuppressive therapy for kidney disease. Farxiga is not expected to be effective in these populations.

Drug Name: Xigduo XR (dapagliflozin/metformin XR)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Dapaglilozin is indicated to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors. Limitation of use: XIGDUO XR is not recommended for patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients. Because of the metformin component, the use of XIGDUO XR is limited to adults with type 2 diabetes mellitus for all indications.

Heart Failure Dapagliflozin is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction. Limitations of use: Because of the metformin component, the use of XIGDUO XR is limited to adults with type 2 diabetes mellitus for all indications.

Chronic Kidney Disease Dapagliflozin is indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression. Limitations of use: Xigduo XR is not recommended for the treatment of chronic kidney disease in patients with polycystic kidney disease or patients requiring or with a recent history of immunosuppressive therapy for kidney disease. Xigduo XR is not expected to be effective in these populations. Because of the metformin component, the use of XIGDUO XR is limited to adults with type 2 diabetes mellitus for all indications.

Drug Name: Synjardy (empagliflozin/metformin)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. Limitations of use: Synjardy is not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.

Drug Name: Synjardy XR (empagliflozin and metformin hydrochloride extended-release)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. Limitations of use: Synjardy is not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.

Drug Name: Glyxambi (empagliflozin/linagliptin)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. Limitations of use: Glyxambi is not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients. Glyxambi has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using Glyxambi. Glyxambi is not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR less than 30 mL/min/1.73 m2. Glyxambi is likely to be ineffective in this setting based upon its mechanism of action.

2 . Criteria

Product Name: Glyxambi, Synjardy, Synjardy XR	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure of a minimum 30-day supply, contraindication, or intolerance to one of the following generics:

- Metformin
- Metformin ER
- Glipizide-metformin
- Glyburide-metformin

- Pioglitazone-metformin

Product Name: Farxiga	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of heart failure (NYHA class II-IV) with reduced ejection fraction

AND

1.1.2 Trial and failure of a minimum 30-day supply, contraindication, or intolerance to one of the following [6-8]:

- captopril
- enalapril
- lisinopril
- quinapril
- ramipril
- fosinopril
- trandolapril
- perindopril
- candesartan
- valsartan
- losartan
- bisoprolol
- carvedilol IR/ER
- metoprolol succinate CR/XL
- spironolactone
- eplerenone
- Entresto (sacubitril-valsartan)

OR

1.2 Both of the following:

1.2.1 Diagnosis of type 2 diabetes mellitus

AND

1.2.2 Trial and failure of a minimum 30-day supply, contraindication, or intolerance to one of the following generics:

- metformin
- metformin ER
- glipizide-metformin
- glyburide-metformin
- pioglitazone-metformin

OR

1.3 Diagnosis of chronic kidney disease

Product Name: Jardiance	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of type 2 diabetes mellitus

AND

1.1.2 Trial and failure of a minimum 30-day supply, contraindication, or intolerance to one of the following generics:

- metformin
- metformin ER
- glipizide-metformin

- glyburide-metformin
- pioglitazone-metformin

OR

1.2 One of the following:

1.2.1 Both of the following:

1.2.1.1 Diagnosis of heart failure (NYHA class II-IV) with reduced ejection fraction

AND

1.2.1.2 Trial and failure of a minimum 30-day supply, contraindication, or intolerance to one of the following [6-8]:

- captopril
- enalapril
- lisinopril
- quinapril
- ramipril
- fosinopril
- trandolapril
- perindopril
- candesartan
- valsartan
- losartan
- bisoprolol
- carvedilol IR/ER
- metoprolol succinate CR/XL
- sprinolactone
- eplerenone
- Entresto (sacubitril-valsartan)

OR

1.2.2 One of the following:

- Diagnosis of heart failure with preserved ejection fraction [8]
- Diagnosis of heart failure with mildly reduced ejection fraction

Product Name: Xigduo XR	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of heart failure (NYHA class II-IV) with reduced ejection fraction

AND

1.1.2 Trial and failure of a minimum 30-day supply, contraindication, or intolerance to one of the following [6-8]:

- captopril
- enalapril
- lisinopril
- quinapril
- ramipril
- fosinopril
- trandolapril
- perindopril
- candesartan
- valsartan
- losartan
- bisoprolol
- carvedilol IR/ER
- metoprolol succinate CR/XL
- spironolactone
- eplerenone
- Entresto (sacubitril-valsartan)

OR

1.2 Both of the following:

1.2.1 Diagnosis of type 2 diabetes mellitus

AND

1.2.2 Trial and failure of a minimum 30-day supply, contraindication, or intolerance to one of the following generics:

- metformin
- metformin ER
- glipizide-metformin
- glyburide-metformin
- pioglitazone-metformin

OR

1.3 Diagnosis of chronic kidney disease

3 . References

1. Glyxambi Prescribing Information. Boehringer Ingelheim. Ridgefield, CT. March 2022.
2. Jardiance Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. March 2022.
3. Synjardy/Synjardy XR Prescribing information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. March 2022.
4. Farxiga Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. May 2021.
5. Xigduo XR Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. April 2022.
6. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. Circulation. 2017;136:e137–e161
7. Maddox TM, Januzzi JL, Allen LA, et al. 2021 Update to the 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment: Answers to 10 Pivotal Issues About Heart Failure With Reduced Ejection Fraction. J Am Coll Cardiol. 2021;77:772-810
8. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure. Journal of Cardiac Failure. Published online April 2022.

4 . Revision History

Date	Notes
7/6/2022	Annual review: Updated indications to align with PI, updated referenc es. Updated Jardiance criteria for heart failure section (1.2.2) to allow additional option of heart failure with mildly reduced ejection fraction (new HF type). Background updates.

Prior Authorization Guideline

Guideline Name	Short-Acting Bronchodilators

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	11/13/2007
P&T Revision Date:	11/14/2019 ; 11/14/2019 ; 03/18/2020 ; 08/14/2020 ; 03/17/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Proventil HFA (albuterol sulfate inhalation aerosol)
Bronchospasm Indicated in adults and children 4 years of age and older for the treatment or prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm.
Drug Name: Xopenex HFA (levalbuterol tartrate inhalation aerosol)
Bronchospasm Indicated for the treatment or prevention of bronchospasm in adults, adolescents, and children 4 years of age and older with reversible obstructive airway disease.
Drug Name: Ventolin HFA, Proair HFA (albuterol sulfate inhalation aerosol), Proair Digihaler (albuterol sulfate inhalation powder), Proair Respiclick (albuterol sulfate powder)
Bronchospasm Indicated for the treatment of or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease. **Exercise-Induced Bronchospasm** Indicated for the prevention of exercise-induced bronchospasm in patients 4 years of age and older.

2 . Criteria

Product Name: Proair Digihaler, Proair HFA, Proair Respiclick, Proventil HFA, Xopenex HFA, levalbuterol HFA, Ventolin HFA or Brand Albuterol HFA (Prasco manufacturer only, NDC 66993-0019-68)	
Approval Length	12 Months
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial of generic albuterol HFA

3 . References

1. Proventil HFA [prescribing information]. Whitehouse Station, NJ: Merck & Co. Inc; October 2019.
2. Xopenex HFA [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc; February 2017.
3. Ventolin HFA [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; August 2021.
4. Proair HFA [prescribing information]. Parsippany, NJ: Teva Respiratory, LLC; September 2022.
5. Proair Digihaler [prescribing information]. Parsippany, NJ: Teva Respiratory, LLC; December 2022.
6. Proair Respiclick [prescribing information]. Parsippany, NJ: Teva Respiratory, LLC; September 2022.

4 . Revision History

Date	Notes

2/23/2023	2023 UM Annual Review. No changes to clinical criteria. Updated ba ckground and references.

Prior Authorization Guideline

Guideline Name	Signifor, Signifor LAR (pasireotide) - PA, NF

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	2/19/2013
P&T Revision Date:	11/14/2019 ; 11/12/2020 ; 11/18/2021 ; 01/19/2022 ; 11/17/2022

1 . Indications

Drug Name: Signifor LAR (pasireotide)
Acromegaly Indicated for the treatment of patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option. **Cushing's disease** Indicated for the treatment of patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.
Drug Name: Signifor (pasireotide)
Cushing's disease Indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

2 . Criteria

Product Name: Signifor LAR	
Diagnosis	Acromegaly

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - One of the following:

- Inadequate response to surgery
- Patient is not a candidate for surgery

Product Name: Signifor LAR	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., patient's growth hormone level or insulin-like growth factor 1 level for age and gender has normalized/improved)

Product Name: Signifor, Signifor LAR	
Diagnosis	Cushing's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endogenous Cushing's disease

AND

2 - One of the following:

2.1 Pituitary surgery has not been curative for the patient

OR

2.2 Patient is not a candidate for pituitary surgery

AND

3 - Prescribed by or in consultation with an endocrinologist

Product Name: Signifor, Signifor LAR	
Diagnosis	Cushing's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., a clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs or symptoms of the disease)

Product Name: Signifor	
Diagnosis	Cushing's disease

Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of endogenous Cushing's disease

AND

2 - One of the following:

2.1 Pituitary surgery has not been curative for the patient

OR

2.2 Patient is not a candidate for pituitary surgery

AND

3 - Prescribed by or in consultation with an endocrinologist

3 . Background

Benefit/Coverage/Program Information
Quantity Limit These products are subject to a standard quantity limit. The quantity limit may vary from the standard limit based upon plan-specific benefit design. Please refer to your benefit materials.

4 . References

1. Signifor LAR Prescribing Information. Recordati Rare Diseases Inc. Lebanon, NJ. July 2020.

2. Signifor Prescribing Information. Recordati Rare Diseases Inc. Lebanon, NJ . March 2020.

5 . Revision History

Date	Notes
11/22/2022	Annual review: update initial authorization duration for acromegaly fr om 6 months to 12 months

Prior Authorization Guideline

Guideline Name	Simponi, Simponi Aria (golimumab)

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	6/3/2009
P&T Revision Date:	11/14/2019 ; 12/16/2020 ; 11/18/2021 ; 10/19/2022

1 . Indications

Drug Name: Simponi (golimumab) - for subcutaneous use
Rheumatoid Arthritis (RA) In combination with methotrexate, indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis. **Psoriatic Arthritis (PsA)** Alone or in combination with methotrexate, indicated for the treatment of adult patients with active psoriatic arthritis. **Ankylosing Spondylitis (AS)** Indicated for the treatment of adult patients with active ankylosing spondylitis. **Ulcerative Colitis (UC)** Indicated in adult patients with moderately to severely active ulcerative colitis who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine or 6-mercaptopurine for: (1) inducing and maintaining clinical response, (2) improving endoscopic appearance of the mucosa during induction, (3) inducing clinical remission, and (4) achieving and sustaining clinical remission in induction responders.
Drug Name: Simponi Aria (golimumab) - for intravenous use
Rheumatoid Arthritis (RA) In combination with methotrexate, indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis.

Polyarticular Juvenile Idiopathic Arthritis (PJIA) Indicated for the treatment of active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older.

Psoriatic Arthritis (PsA) Indicated for the treatment of active psoriatic arthritis in patients 2 years of age and older.

Ankylosing Spondylitis (AS) Indicated for the treatment of adult patients with active ankylosing spondylitis.

2 . Criteria

Product Name: Simponi or Simponi Aria	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active RA

AND

2 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [3, 4]:

- methotrexate
- leflunomide
- sulfasalazine

AND

3 - Used in combination with methotrexate

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name: Simponi or Simponi Aria	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Simponi Aria	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severely active PJIA

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [5]:

- leflunomide
- methotrexate

Product Name: Simponi Aria	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [2, 5]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Simponi or Simponi Aria	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active PsA

AND

2 - One of the following [6]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Product Name: Simponi or Simponi Aria	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 2, 6]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name: Simponi or Simponi Aria	
Diagnosis	Ankylosing Spondylitis (AS)

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [7]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Simponi or Simponi Aria	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following [1, 2, 7]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Product Name: Simponi	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [8, 9]:

- Greater than 6 stools per day
- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers
- Abnormal lab values (e.g., hemoglobin, ESR, CRP)
- Dependent on, or refractory to, corticosteroids

AND

3 - One of the following:

3.1 Patient is corticosteroid dependent (i.e., an inability to successfully taper corticosteroids without a return of the symptoms of UC)

OR

3.2 Trial and failure, contraindication, or intolerance to one of the following conventional therapies [1, 8, 9]

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine
- Corticosteroids (e.g., prednisone)

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name: Simponi	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 8, 9]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

3 . References

1. Simponi Prescribing Information. Janssen Biotech Inc. Horsham, PA. September 2019.
2. Simponi Aria Prescribing Information. Janssen Biotech, Inc. Horsham, PA. February 2021.
3. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.
4. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.
5. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Rheumatol. 2019;71(6):846-863.
6. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
7. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and

treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613.
8. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.
9. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterol. 2020;158:1450-1461.

4 . Revision History

Date	Notes
10/24/2022	Further clinical detail and criteria added; annual review - updated ver biage for the methotrexate requirement with RA to match the labeling , and updated UC initial approval duration to 6 months

Prior Authorization Guideline

Guideline Name	Skin Cancer Agents

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	4/10/2012
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: diclofenac sodium gel 3%
Actinic keratosis Indicated for the topical treatment of actinic keratoses. Sun avoidance is indicated during therapy.

2 . Criteria

Product Name: diclofenac sodium 3% gel	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria	

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure, contraindication, or intolerance to one of the following generics:

- imiquimod
- fluorouracil

3 . References

1. American Academy of Dermatology. Actinic Keratosis: diagnosis and treatment. https://www.aad.org/public/diseases/scaly-skin/actinic-keratosis#treatment. Accessed March 17, 2023.
2. Diclofenac sodium gel 3% Prescribing Information. Fort Collins, CO: Tolmar Inc.; June 2021.

4 . Revision History

Date	Notes
4/4/2023	Annual review - picato discontinued and will be obsolete 4/8/2023 - r emoved product. Updated background and references.

Prior Authorization Guideline

Guideline Name	Skyrizi (risankizumab-rzaa)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	6/19/2019
P&T Revision Date:	08/15/2019 ; 06/17/2020 ; 09/16/2020 ; 05/20/2021 ; 07/21/2021 ; 03/16/2022 ; 05/19/2022 ; 08/18/2022 ; 10/19/2022 ; 02/16/2023 ; 5/18/2023

1 . Indications

Drug Name: Skyrizi SC (risankizumab-rzaa)
Plaque Psoriasis (PsO) Indicated for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. **Psoriatic Arthritis (PsA)** Indicated for the treatment of active psoriatic arthritis in adults. **Crohn's Disease (CD)** Indicated for the treatment of moderately to severely active Crohn's disease in adults.
Drug Name: Skyrizi IV (risankizumab-rzaa)
Crohn's Disease (CD) Indicated for the treatment of moderately to severely active Crohn's disease in adults.

2 . Criteria

Product Name: Skyrizi SC 150 mg	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Skyrizi SC 150 mg

Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1-3]:

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Skyrizi SC 150 mg	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis (PsA)

AND

2 - One of the following [4]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Skyrizi SC 150 mg	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Skyrizi IV	
Diagnosis	Crohn's Disease (CD)
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease (CD)

AND

2 - One of the following [5, 6]:

- Frequent diarrhea and abdominal pain
- At least 10% weight loss
- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values (e.g., C-reactive protein [CRP])
- CD Activity Index (CDAI) greater than 220

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies [5, 6]:

- 6-mercaptopurine
- Azathioprine
- Methotrexate
- Corticosteroid (e.g., prednisone)

AND

4 - Will be administered as an intravenous induction dose

AND

5 - Prescribed by or in consultation with a gastroenterologist

Product Name: Skyrizi SC 180 mg, 360 mg	
Diagnosis	Crohn's Disease (CD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease (CD)

AND

2 - Will be used as a maintenance dose following the intravenous induction doses

AND

3 - Prescribed by or in consultation with a gastroenterologist

Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Skyrizi SC 180 mg, 360 mg	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 5, 6]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

Notes	If patient meets criteria above, please approve at GPI-14

3 . References

1. Skyrizi Prescribing Information. AbbVie, Inc. North Chicago, IL. March 2023.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.

3. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
5. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018;113:481-517.
6. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508.

4 . Revision History

Date	Notes
5/3/2023	Annual review - removed 75 mg strength since it has been discontinued; background updates

Prior Authorization Guideline

Guideline Name	Soliqua (insulin glargine/ lixisenatide)

Guideline Note:

Effective Date:	8/1/2022
P&T Approval Date:	2/16/2017
P&T Revision Date:	04/15/2020 ; 06/17/2020 ; 06/16/2021 ; 6/15/2022

1 . Indications

Drug Name: Soliqua 100/33 (insulin glargine and lixisenatide injection)
Type 2 diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: SOLIQUA 100/33 has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis. SOLIQUA 100/33 is not recommended for use in combination with any other product containing a GLP-1 receptor agonist. SOLIQUA 100/33 is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. SOLIQUA 100/33 has not been studied in patients with gastroparesis and is not recommended in patients with gastroparesis. SOLIQUA 100/33 has not been studied in combination with prandial insulin.

2 . Criteria

Product Name: Soliqua 100/33	
Approval Length	12 month(s)

Guideline Type	Step Therapy

Approval Criteria

1 - Trial and failure, contraindication, or intolerance to one of the following generics:

- metformin
- metformin ER
- glipizide-metformin
- glyburide-metformin
- pioglitazone-metformin

3 . References

1. Soliqua Prescribing Information. Sanofi-aventis U.S. LLC. Bridgewater, NJ. July 2021.

4 . Revision History

Date	Notes
6/1/2022	Annual review: No changes to criteria, Updated references.

Prior Authorization Guideline

Guideline Name	Soliris (eculizumab)

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	11/19/2014
P&T Revision Date:	09/18/2019 ; 12/18/2019 ; 02/13/2020 ; 01/20/2021 ; 02/18/2021 ; 02/17/2022 ; 09/21/2022 ; 2/16/2023

1 . Indications

Drug Name: Soliris (eculizumab)
Paroxysmal Nocturnal Hemoglobinuria (PNH) Indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis. **Atypical Hemolytic Uremic Syndrome (aHUS)** Indicated for the treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy. Limitations of Use: Soliris is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS). **Generalized Myasthenia Gravis (gMG)** Indicated for the treatment of adult patients with generalized Myasthenia Gravis (gMG) who are anti-acetylcholine receptor (AchR) antibody positive. **Neuromyelitis Optica Spectrum Disorder (NMOSD)** Indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

2 . Criteria

Product Name: Soliris	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)

AND

2 - Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab)

AND

3 - One of the following:

3.1 Prescribed medication is used for induction therapy and will not exceed 600 mg weekly for the first 4 weeks

OR

3.2 Prescribed medication is used for maintenance therapy and will not exceed 900 mg weekly at week 5, then 900 mg every 2 weeks thereafter

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Soliris	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to therapy

AND

2 - Prescribed medication is used for maintenance therapy and will not exceed 900 mg every 2 weeks

Product Name: Soliris	
Diagnosis	Atypical Hemolytic Uremic Syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of atypical hemolytic uremic syndrome (aHUS)

AND

2 - Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab)

AND

3 - One of the following:

3.1 For patients 18 years of age and older:

3.1.1 Prescribed medication is used for induction therapy and will not exceed 900 mg weekly for the first 4 weeks

OR

3.1.2 Prescribed medication is used for maintenance therapy and will not exceed 1200 mg weekly at week 5, then 1200 mg every 2 weeks thereafter

OR

3.2 For patients less than 18 years of age, dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for aHUS (refer to Table 1 in Background Section for dosing schedule)

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Nephrologist

Product Name: Soliris	
Diagnosis	Atypical Hemolytic Uremic Syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response (e.g., increase in mean platelet counts, hematologic normalization) to therapy

AND

2 - One of the following:

2.1 For patients 18 years of age and older, prescribed medication is used for maintenance therapy and will not exceed 1200 mg every 2 weeks

OR

2.2 For patients less than 18 years of age, dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for aHUS (refer to Table 1 in Background Section for MAINTENANCE dosing schedule)

Product Name: Soliris	
Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis (gMG)

AND

2 - Patient is anti-acetylcholine receptor (AChR) antibody positive

AND

3 - One of the following: [2, 3]

3.1 Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

OR

3.2 Both of the following:

3.2.1 Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

AND

3.2.2 Trial and failure, contraindication, or intolerance to one of the following:

- Chronic plasmapheresis or plasma exchange (PE)
- Intravenous immunoglobulin (IVIG)

AND

4 - Trial and failure, contraindication, or intolerance to one of the following:

- Ultomiris (ravulizumab)
- Vyvgart (efgartigimod)

AND

5 - One of the following:

5.1 Prescribed medication is used for induction therapy and will not exceed 900 mg weekly for the first 4 weeks

OR

5.2 Prescribed medication is used for maintenance therapy and will not exceed 1200 mg at week 5, then 1200 mg every 2 weeks thereafter

AND

6 - Prescribed by or in consultation with a neurologist

Product Name: Soliris	
Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Prescribed medication is used for maintenance therapy and will not exceed 1200 mg every 2 weeks

Product Name: Soliris	
Diagnosis	Neuromyelitis Optica Spectrum Disorder (NMOSD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neuromyelitis optica spectrum disorder (NMOSD)

AND

2 - Patient is anti-aquaporin-4 (AQP4) antibody positive

AND

3 - One of the following:

3.1 Prescribed medication is used for induction therapy and will not exceed 900 mg weekly for the first 4 weeks

OR

3.2 Prescribed medication is used for maintenance therapy and will not exceed 1200 mg at week 5, then 1200 mg every 2 weeks thereafter

AND

4 - Prescribed by or in consultation with one of the following:

- Neurologist
- Ophthalmologist

Product Name: Soliris	
Diagnosis	Neuromyelitis Optica Spectrum Disorder (NMOSD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Prescribed medication is used for maintenance therapy and will not exceed 1200 mg every 2 weeks

3 . Background

Benefit/Coverage/Program Information

Table 1. Dosing Recommendations for Atypical Hemolytic Uremic Syndrome (aHUS) in Patients Less Than 18 Years of Age

Patient Body Weight	Induction Therapy	Maintenance Therapy
40 kg and over	900 mg weekly for 4 dose	1200 mg at week 5; Then 1200 mg every 2 weeks
30 kg to less than 40 kg	600 mg weekly for 2 doses	900 mg at week 3; Then 900 mg every 2 weeks
20 kg to less than 30 kg	600 mg weekly for 2 doses	600 mg at week 3; Then 600 mg every 2 weeks
10 kg to less than 20 kg	600 mg weekly for 1 dose	300 mg at week 2; Then 300 mg every 2 weeks
5 kg to less than 10 kg	300 mg weekly for 1 dose	300 mg at week 2; Then 300 mg every 3 weeks

4 . References

1. Soliris Prescribing Information. Alexion Pharmaceuticals, Inc. Boston, MA. November 2020.
2. Howard JF Jr, Utsugisawa K, Benatar M, et al. Safety and efficacy of eculizumab in anti-acetylcholine receptor antibody-positive refractory generalised myasthenia gravis (REGAIN): a phase 3, randomised, double-blind, placebo-controlled, multicentre study. Lancet Neurol. 2017;16(12):976-986.
3. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis. Neurology. 2016;87(4):419-25.

5 . Revision History

Date	Notes
1/25/2023	2023 UM Annual Review. No changes.

Prior Authorization Guideline

Guideline Name	Somatuline Depot (lanreotide) - PA, NF

Guideline Note:

Effective Date:	12/1/2022
P&T Approval Date:	11/13/2007
P&T Revision Date:	11/14/2019 ; 10/21/2020 ; 10/20/2021 ; 03/16/2022 ; 07/20/2022 ; 10/19/2022

1 . Indications

Drug Name: Somatuline Depot (lanreotide)
Acromegaly Indicated for the long-term treatment of acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option. The goal of treatment in acromegaly is to reduce growth hormone (GH) and insulin growth factor-1 (IGF-1) levels to normal. **Gastroenteropancreatic Neuroendocrine Tumors (GEP-NET)** Indicated for the treatment of adult patients with unresectable, well or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival. **Carcinoid Syndrome** Indicated for the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.
Drug Name: Lanreotide Injection
Acromegaly Indicated for the long-term treatment of acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option. The goal of treatment in acromegaly is to reduce growth hormone (GH) and insulin growth factor-1 (IGF-1) levels to normal.

Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs) Indicated for the treatment of adult patients with unresectable, well or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival.

Off Label Uses: Carcinoid Syndrome [3] Indicated for the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.

2 . Criteria

Product Name: Somatuline Depot, Brand Lanreotide	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - One of the following:

2.1 Inadequate response to one of the following:

- Surgery
- Radiotherapy

OR

2.2 Not a candidate for one of the following:

- Surgery

- Radiotherapy

AND

3 - Trial and failure or intolerance to Somatuline Depot (Applies to Brand Lanreotide only)

AND

4 - Prescribed by or in consultation with an endocrinologist

Product Name: Somatuline Depot, Brand Lanreotide	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy, such as a reduction or normalization of IGF-1/GH level for same age and sex

Product Name: Brand Lanreotide	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - One of the following:

2.1 Inadequate response to one of the following:

- Surgery
- Radiotherapy

OR

2.2 Not a candidate for one of the following:

- Surgery
- Radiotherapy

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to Somatuline Depot

AND

4 - Prescribed by or in consultation with an endocrinologist

Product Name: Somatuline Depot 120mg/0.5mL, Brand Lanreotide 120mg/0.5ml	
Diagnosis	Advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NET)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastroenteropancreatic neuroendocrine tumor (GEP-NET)

AND

2 - Disease is one of the following:

- Unresectable, locally advanced
- Metastatic

AND

3 - Trial and failure or intolerance to Somatuline Depot (Applies to Brand Lanreotide only)

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Somatuline Depot 120mg/0.5mL, Brand Lanreotide 120mg/0.5ml	
Diagnosis	Advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NET)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Brand Lanreotide 120mg/0.5ml	
Diagnosis	Advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NET)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of gastroenteropancreatic neuroendocrine tumor (GEP-NET)

AND

2 - Disease is one of the following:

- Unresectable, locally advanced
- Metastatic

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to Somatuline Depot

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Somatuline Depot 120mg/0.5mL, Brand Lanreotide 120mg/0.5ml [off-label]	
Diagnosis	Carcinoid Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of carcinoid syndrome

AND

2 - Used to reduce the frequency of short-acting somatostatin analog rescue therapy

AND

3 - Trial and failure or intolerance to Somatuline Depot (Applies to Brand Lanreotide only)

AND

4 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Oncologist

Product Name: Somatuline Depot 120mg/0.5mL, Brand Lanreotide 120mg/0.5ml [off-label]	
Diagnosis	Carcinoid Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Brand Lanreotide 120mg/0.5ml [off-label]	
Diagnosis	Carcinoid Syndrome
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of carcinoid syndrome

AND

2 - Used to reduce the frequency of short-acting somatostatin analog rescue therapy

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to Somatuline Depot

AND

4 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Oncologist

3 . References

1. Somatuline Depot Prescribing Information. Ipsen Biopharmaceuticals, Inc. Cambridge, MA. June 2019.
2. Lanreotide Injection Prescribing Information. Exelan Pharmaceuticals, Inc. Boca Raton, FL. February 2022.
3. Lanreotide Acetate. In: IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com/. Accessed September 19, 2022.

4 . Revision History

Date	Notes
10/20/2022	Annual review: no criteria changes.

Prior Authorization Guideline

Guideline Name	Somavert (pegvisomant)

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	7/14/2006
P&T Revision Date:	12/18/2019 ; 11/12/2020 ; 11/18/2021 ; 11/17/2022

1 . Indications

Drug Name: Somavert (pegvisomant)
Acromegaly Indicated for the treatment of acromegaly in patients who have had an inadequate response to surgery or radiation therapy, or for whom these therapies are not appropriate. The goal of treatment is to normalize serum insulin-like growth factor-I (IGF-I) levels.

2 . Criteria

Product Name: Somavert	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - One of the following: [2]

2.1 Inadequate response to one of the following:

- Surgery
- Radiation therapy
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

OR

2.2 Not a candidate for all of the following:

- Surgery
- Radiation therapy
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

AND

3 - Trial and failure, contraindication, or intolerance to generic octreotide (a somatostatin analogue) [2]

AND

4 - Prescribed by or in consultation with an endocrinologist

Product Name: Somavert	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (such as biochemical control; decrease or normalization of IGF-1 levels)

3 . References

1. Somavert Prescribing Information. Pharmacia & Upjohn Company LLC. New York, NY. August 2021.
2. Katznelson L, Laws ER, Melmed S, et al. Acromegaly: An endocrine society clinical practice guideline, J Clin Endocrinol Metab, 2014 Nov;99(11):3933-51. doi: 10.1210/jc.2014-2700. Epub 2014 Oct 30.

4 . Revision History

Date	Notes
11/22/2022	Annual review - update initial authorization duration from 12 weeks to 12 months.

Prior Authorization Guideline

Guideline Name	Sovaldi (sofosbuvir)

Guideline Note:

Effective Date:	7/1/2022

1 . Indications

Drug Name: Sovaldi (sofosbuvir)
Chronic Hepatitis C (CHC) ADULT PATIENTS: Indicated for the treatment of adult patients with chronic hepatitis C virus (HCV) infection as a component of a combination antiviral treatment regimen. - Genotype 1 or 4 infection without cirrhosis or with compensated cirrhosis for use in combination with pegylated interferon and ribavirin. - Genotype 2 or 3 infection without cirrhosis or with compensated cirrhosis for use in combination with ribavirin. PEDIATRIC PATIENTS: Indicated for the treatment of chronic HCV genotype 2 or 3 infection in pediatric patients 3 years of age and older without cirrhosis or with compensated cirrhosis for use in combination with ribavirin

2 . Criteria

Product Name: Sovaldi	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 1 or 4 - Sovaldi Plus Peginterferon Plus Ribavirin
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1 or 4

AND

2 - Used in combination with peginterferon alfa and ribavirin

AND

3 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

AND

6 - One of the following:

6.1 Both of the following:

6.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

- Epclusa (sofosbuvir/velpatasvir)

- Harvoni (ledipasvir/sofosbuvir)

AND

6.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

6.2 For continuation of prior Sovaldi (sofosbuvir) therapy

Product Name: Sovaldi	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 2 - Sovaldi Plus Ribavirin
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 2 infection

AND

2 - Used in combination with ribavirin

AND

3 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

AND

6 - One of the following:

6.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to BOTH of the following:

- Epclusa (sofosbuvir/velpatasvir)
- Mavyret (glecaprevir/pibrentasvir)

OR

6.2 For continuation of prior Sovaldi (sofosbuvir) therapy

Product Name: Sovaldi	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 3 - Sovaldi Plus Ribavirin
Approval Length	24 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 3 infection

AND

2 - Used in combination with ribavirin

AND

3 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

AND

6 - One of the following:

6.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to BOTH of the following:

- Epclusa (sofosbuvir/velpatasvir)
- Mavyret (glecaprevir/pibrentasvir)

OR

6.2 For continuation of prior Sovaldi (sofosbuvir) therapy

Product Name: Sovaldi

Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 1, 2, 3, 4, 5, or 6; Treatment-Experienced (Prior failure of Mavyret)
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with Mavyret (glecaprevir/pibrentasvir) [2]

AND

3 - Used in combination with Mavyret (glecaprevir/pibrentasvir) and ribavirin [2]

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

Product Name: Sovaldi	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 1, 2, 3, 4, 5, or 6; Treatment-Experienced (Prior failure of Vosevi)
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with Vosevi (sofosbuvir/velpatasvir/voxilaprevir)

AND

3 - Used in combination with Mavyret (glecaprevir/pibrentasvir) and ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

3 . References

1. Sovaldi Prescribing Information. Gilead Sciences, Inc. Foster City, CA. March 2020.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. September 2021. http://www.hcvguidelines.org/full-report-view. Accessed May 16, 2022.

4 . Revision History

Date	Notes
6/22/2022	Updated guideline effective date to 7/1/22 to align with UM optimizati on updates. No other updates made to guideline.

Prior Authorization Guideline

Guideline Name	Sprycel (dasatinib)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	10/3/2006
P&T Revision Date:	02/13/2020 ; 02/18/2021 ; 02/17/2022 ; 02/16/2023 ; 5/18/2023

1 . Indications

Drug Name: Sprycel (dasatinib)
Newly diagnosed Chronic Myeloid Leukemia Indicated for the treatment of adults with newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. **Resistant or intolerant Chronic Myeloid Leukemia** Indicated for the treatment of adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib. **Acute Lymphoblastic Leukemia (ALL)** Indicated for the treatment of adults with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy. **Pediatric ALL** Indicated for the treatment of pediatric patients 1 year of age and older with newly diagnosed Ph+ ALL in combination with chemotherapy. **Pediatric Patients with Ph+ CML** Indicated for the treatment of pediatric patients 1 year of age and older with Ph+ CML in chronic phase.

2 . Criteria

Product Name: Sprycel	
Diagnosis	Philadelphia chromosome-positive/BCR ABL positive (Ph+/BCR ABL) Acute Lymphoblastic Leukemia/Acute Lymphoblastic Lymphoma (ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Ph+/BCR ABL acute lymphoblastic leukemia (ALL)

AND

2 - Prescribed by or in consultation with an oncologist and/or hematologist

Product Name: Sprycel	
Diagnosis	Ph+/BCR ABL Acute Lymphoblastic Leukemia/Acute Lymphoblastic Lymphoma (ALL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Sprycel	
Diagnosis	Ph+/BCR ABL Chronic Myelogenous/Myeloid Leukemia (CML)
Approval Length	12
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Ph+/BCR ABL chronic myelogenous/myeloid leukemia (CML)

AND

2 - Prescribed by or in consultation with an oncologist and/or hematologist

Product Name: Sprycel	
Diagnosis	Ph+/BCR ABL Chronic Myelogenous/Myeloid Leukemia (CML)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. According to National Comprehensive Cancer Network (NCCN) recommendations, imatinib, dasatinib, bosutinib, and nilotinib are first-line therapies for chronic myelogenous/myeloid leukemia. In settings where all 4 agents are appropriate as a first-line option, a step through any of the 4 products is inappropriate. [2]

B. According to NCCN recommendations, patients with disease that is resistant to first-line imatinib should be treated with nilotinib, dasatinib, or bosutinib in the second-line setting, taking into account BCR::ABL1 kinase domain mutation status. Patients with disease that is resistant to first-line treatment with bosutinib, nilotinib, or dasatinib could be treated with an alternate TKI (other than imatinib) in the second-line setting, taking into account BCR::ABL1 kinase domain mutation status. Dasatinib and nilotinib are effective against a majority of mutations resistant to imatinib, except for the T315I mutation. Consider clinical trial, asciminib, ponatinib, omacetaxine, or hematopoietic cell transplantation (HCT) for patients with a T315I mutation. [2]

4 . References

1. Sprycel [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; June 2021.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Chronic Myeloid Leukemia v.1.2023. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf. Accessed January 9, 2023.

5 . Revision History

Date	Notes
4/28/2023	Program update to remove criteria and just leave the diagnosis and s pecialist requirements.

Prior Authorization Guideline

Guideline Name	State Mandate Reference Document

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	10/25/2017
P&T Revision Date:	10/16/2019 ; 01/15/2020 ; 08/13/2020 ; 10/21/2020 ; 10/21/2020 ; 01/20/2021 ; 03/17/2021 ; 08/19/2021 ; 10/20/2021 ; 11/18/2021 ; 12/15/2021 ; 06/15/2022 ; 07/20/2022 ; 10/19/2022 ; 11/17/2022 ; 5/18/2023

1 . Criteria

Guideline Type	Administrative

Approval Criteria

1 - For Arizona, (effective 12/31/2022), when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of

action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity. Note: Samples may not count as sufficient experience with the prescribed medication to be considered stable on the medication.

OR

2 - The following mandates apply to Arkansas:

2.1 Effective 7/22/2015, all clinical criteria are deemed met when the medication is being used for pain control in someone who is terminally ill (defined as no expectation of recovery and death as a result of the illness or disease is reasonably expected within six [6] months).

OR

2.2 Effective 1/1/2022, when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity.

OR

3 - The following mandates apply to California:

3.1 Effective 1/1/2017, step therapy requirements are deemed met if the provider submits medical records confirming the patient has been on the medication, it is appropriately

prescribed, and that the medication is considered safe and effective in treating the patient's condition.

OR

3.2 Effective 7/1/1999 (applies to small group only), all clinical criteria are deemed met when the patient has previously been approved for coverage of the medication and the patient has had no reasonable break in therapy (i.e., last dose was within the last 60 days per claims history). The medication should be approved for the quantity the patient was previously taking as long as it is considered safe and effective for treating the medical condition.

OR

3.3 Effective 1/1/2022, step therapy requirements are deemed met if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is not in the best interest of the patient, based on medical necessity.

OR

4 - The following mandates apply to Colorado:

4.1 Effective 1/1/2019, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

4.2 Effective 1/1/2023, when the provider confirms that a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as a documented step one prescription drug, and the prescription drug is ineffective or was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs

are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration.

OR

5 - The following mandates apply to Connecticut:

5.1 Effective 1/1/2012, step therapy may not be required for pain medications when a non AB rated alternative is required as first line.

OR

5.2 Effective 1/1/2015, only a 30 day trial of first step drugs will be required.

OR

5.3 Effective 1/1/2015, step therapy requirements are deemed met if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity.

OR

5.4 Effective 1/1/2018, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

6 - The following mandates apply to Delaware:

6.1 Effective 9/1/2017, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer and treatment is consistent with the U.S. Food and Drug Administration-

approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

6.2 Effective 1/1/2020, when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity.

OR

7 - The following mandates apply to Georgia:

7.1 Effective 7/1/2015, all clinical criteria are deemed met when a patient is diagnosed as terminally ill and the medication requested is FDA-approved or meets off-label criteria for use directly related to the terminal illness. Terminal illness is defined as any disease, illness, or health condition that a physician has diagnosed and expected to result in death in 24 months or less.

OR

7.2 Effective 7/1/2019, when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional

criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective.

OR

8 - The following mandates apply to Illinois:

8.1 Effective 1/1/2018, step therapy requirements are deemed met if the provider submits medical records confirming the patient is currently stabilized on the requested medication for the medical condition under consideration.

OR

8.2 Effective 1/1/2019, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

9 - For Indiana, (effective 7/1/2016), when the provider submits medical records confirming a patient has previously received either a documented step one prescription drug or another prescription drug that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria.

OR

10 - For Iowa, (effective 1/1/2018), when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will

not be required to try any other alternatives with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration. Note: Samples and drugs obtained through coupon cards may not count as sufficient experience with the prescribed medication to be considered stable on the medication.

OR

11 - The following mandates apply to Kentucky:

11.1 Effective 7/12/2012, only a 30 day trial of first step drugs will be required.

OR

11.2 Effective 1/1/2023, when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity.

OR

12 - The following mandates apply to Louisiana:

12.1 Effective 8/1/2019, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer and treatment is consistent with the U.S. Food and Drug Administration-approved indication, or the National Comprehensive Cancer Network Drugs & Biologics

Compendium indication for the treatment of stage four advanced metastatic cancer, or the prescribed drug or drug regimen is supported by peer-reviewed, evidenced-based medical literature.

OR

12.2 Effective 1/1/2021, step therapy and non-formulary requirements are deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is not in the best interest of the patient or expected to be ineffective based on medical necessity.

OR

13 - The following mandates apply to Maine:

13.1 Effective 1/1/2020, when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, the required step one prescription drug is not in the best interest of the patient based on medical necessity, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective.

OR

13.2 Effective 1/1/2022, all clinical criteria are deemed met when the medication is being prescribed to assess or treat the patient’s serious mental illness, defined in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders published by the American Psychiatric Association, as a mental disorder that results in serious functional impairment that substantially interferes with or limits one or more major life activities.

OR

14 - The following mandates apply to Maryland:

14.1 Effective 7/1/2015, step therapy requirements are deemed met if the provider submits medical records confirming the patient has been on the medication in the past 180 days and that the medication is effective in treating the patient's condition.

OR

14.2 Effective 7/1/2015, step therapy requirements may not require trial of a drug that has not been approved by the U.S. Food and Drug Administration for the medical condition being treated.

OR

14.3 Effective 10/1/2017, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

14.4 Effective 1/1/2023, all clinical criteria are deemed met for rituximab and/or intravenous immunoglobulin (IVIg) therapy when the medication is being used for a diagnosis of pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) or pediatric acute onset neuropsychiatric syndrome (PANS).

OR

15 - For Minnesota, (effective 1/1/2020), any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer, or an associated condition, and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

16 - For Nebraska, (effective 1/1/2022), step therapy requirements are deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is not in the best interest of the patient or expected to be ineffective based on medical necessity.

OR

17 - For Nevada, (effective 1/1/2022), any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage three or four cancer, or an associated condition, AND; the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity.

OR

18 - The following mandates apply to New Mexico:

18.1 Effective 1/1/2019, when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be

tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria.

OR

18.2 Effective 7/1/2019, step therapy requirements are deemed met if the prescription drug requested is generic AND the required step one prescription drug is a therapeutically equivalent generic.

OR

19 - For New York, (effective 1/1/2017), when the provider submits medical records confirming a patient has previously received either a documented step one prescription drug or another prescription drug that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration. Note: Samples and drugs obtained through coupon cards may not count as sufficient experience with the prescribed medication to be considered stable on the medication.

OR

20 - For North Dakota, (effective 8/5/2019), any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

21 - For Ohio, (effective 3/24/2021), any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer, or an associated condition, and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive

Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer, or consistent with best practices for the treatment of stage four advanced metastatic cancer, as supported by peer-reviewed medical literature.

OR

22 - For Oklahoma, (effective 11/1/2019), step therapy and non-formulary requirements are deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is not in the best interest of the patient based or expected to be ineffective based on medical necessity.

OR

23 - For Oregon, (effective 1/1/2022), when the provider confirms that a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as a documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for a period of at least 90 days for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity. Note: Samples and drugs obtained through coupon cards may not count as sufficient experience with the prescribed medication to be considered stable on the medication.

OR

24 - For Pennsylvania, (effective 10/12/2020), any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer, or a severe adverse health condition experienced as a result of stage four metastatic cancer, and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

25 - For South Dakota, (effective 1/1/2021), step therapy and non-formulary requirements are deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is not in the best interest of the patient based or expected to be ineffective based on medical necessity.

OR

26 - For Tennessee, (effective 1/1/2023), step therapy requirements are deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity. Note: Samples and drugs obtained through coupon cards may not count as sufficient experience with the prescribed medication to be considered stable on the medication.

OR

27 - The following mandates apply to Texas:

27.1 Effective 1/1/2018, when the provider confirms that a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as a documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, and if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or cause harm to the patient, based on medical necessity.

OR

27.2 Effective 1/1/2020, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer, or an associated condition, and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

28 - For Virginia, (effective 1/1/2020), step therapy requirements are deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective.

OR

29 - For Washington, (effective 1/1/2021), when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity.

OR

30 - For West Virginia, (effective 1/1/2017), when the provider submits medical records confirming that a patient has previously received either a documented step one prescription drug or another prescription drug that has the same mechanism of action as a the

documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration.

OR

31 - For Wisconsin, (effective 11/1/2019), any clinical criteria component involving a trial/failure requirement are deemed met when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Any clinical criteria component involving a trial/failure requirement are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective.

2 . Background

Benefit/Coverage/Program Information

Background:

This document serves as a reference for changes requested to pharmacy utilization management programs based on state mandates. This includes but is not limited to step therapy, prior authorization regulations, supply limits, first line trial duration limitations, and pain therapy/end of life regulations.

Additional Clinical Rules:

- Applicable clinical programs will apply.

3 . Revision History

Date	Notes
5/4/2023	update guideline

Prior Authorization Guideline

Guideline Name	Stelara (ustekinumab)

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	2/16/2010
P&T Revision Date:	08/15/2019 ; 11/14/2019 ; 09/16/2020 ; 09/15/2021 ; 09/21/2022 ; 10/19/2022 ; 12/14/2022

1 . Indications

Drug Name: Stelara SC (ustekinumab)
Plaque Psoriasis (PsO) Indicated for the treatment of patients 6 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. **Psoriatic Arthritis (PsA)** Indicated for the treatment of patients 6 years or older with active psoriatic arthritis. **Crohn's Disease (CD)** Indicated for the treatment of adult patients with moderately to severely active Crohn's disease. **Ulcerative Colitis (UC)** Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.
Drug Name: Stelara IV (ustekinumab)
Crohn's Disease (CD) Indicated for the treatment of adult patients with moderately to severely active Crohn's disease.

Ulcerative Colitis (UC) Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.

2 . Criteria

Product Name: Stelara SC 45 mg/0.5 mL	
Diagnosis	Plaque Psoriasis
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Patient is 6 years of age or older

AND

4 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene

- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

5 - Prescribed by or in consultation with a dermatologist

Notes	*Approval Duration: 6 months. **QL Override (For new starts only): For psoriasis, please enter 2 PAs as follows: First PA: Approve one syringe or vial per 28 days for the two months with a fill count of 2; Second PA: Approve one syringe or vial per 56 days (no overrides needed) for the remaining 4 months. (Stelara is hard-coded with a quantity of one prefilled syringe/vial per 56 days; 0.5 mL per 45 mg vial or syringe and 1 mL per 90 mg syringe)

Product Name: Stelara SC 90 mg/1 mL	
Diagnosis	Plaque Psoriasis
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Patient's weight is greater than 100 kg (220 lbs)

AND

4 - Patient is 6 years of age or older

AND

5 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

6 - Prescribed by or in consultation with a dermatologist

Notes	*Approval Duration: 6 months. **QL Override (For new starts only): For psoriasis, please enter 2 PAs as follows: First PA: Approve one syringe or vial per 28 days for the two months with a fill count of 2; Second PA: Approve one syringe or vial per 56 days (no overrides needed) for the remaining 4 months. (Stelara is hard-coded with a quantity of one prefilled syringe/vial per 56 days; 0.5 mL per 45 mg vial or syringe and 1 mL per 90 mg syringe)

Product Name: Stelara SC	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1-3]:

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name: Stelara SC 45 mg/0.5 mL	
Diagnosis	Psoriatic arthritis
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [4]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Patient is 6 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Dermatologist

• Rheumatologist	
Notes	*Approval Duration: 6 months. **QL Override (For new starts only): For psoriatic arthritis, please enter 2 PAs as follows: First PA: Approve one syringe or vial per 28 days for the two months with a fill count of 2; Second PA: Approve one syringe or vial per 56 days (no overrides needed) for the remaining 4 months. (Stelara is hard-coded with a quantity of one prefilled syringe/vial per 56 days; 0.5 mL per 45 mg vial or syringe and 1 mL per 90 mg syringe)

Product Name: Stelara SC 90 mg/1 mL	
Diagnosis	Psoriatic arthritis
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [4]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Diagnosis of co-existent moderate to severe psoriasis [1, 4]

AND

4 - Patient’s weight is greater than 100 kg (220 lbs)

AND

5 - Patient is 6 years of age or older

AND

6 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Notes	*Approval Duration: 6 months. **QL Override (For new starts only): For psoriatic arthritis, please enter 2 PAs as follows: First PA: Approve one syringe or vial per 28 days for the two months with a fill count of 2; Second PA: Approve one syringe or vial per 56 days (no overrides needed) for the remaining 4 months. (Stelara is hard-coded with a quantity of one prefilled syringe/vial per 56 days; 0.5 mL per 45 mg vial or syringe and 1 mL per 90 mg syringe)

Product Name: Stelara SC	
Diagnosis	Psoriatic arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name: Stelara IV

Diagnosis	Crohn's Disease
Approval Length	1 Time(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - One of the following [5, 6]:

- Frequent diarrhea and abdominal pain
- At least 10% weight loss
- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values (e.g., C-reactive protein [CRP])
- CD Activity Index (CDAI) greater than 220

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [5, 6]:

- 6-mercaptopurine
- azathioprine
- corticosteroids (e.g., prednisone)
- methotrexate

AND

4 - Stelara is to be administered as an intravenous induction dose

AND

5 - Stelara induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for Crohn's disease:

- 260 mg for patients weighing 55 kg or less
- 390 mg for patients weighing more than 55 kg to 85 kg
- 520 mg for patients weighing more than 85 kg

AND

6 - Prescribed by or in consultation with a gastroenterologist

Product Name: Stelara SC	
Diagnosis	Crohn's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - Will be used as a maintenance dose following the intravenous induction dose

AND

3 - Prescribed by or in consultation with a gastroenterologist

Product Name: Stelara IV	
Diagnosis	Ulcerative Colitis
Approval Length	1 Time(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [7, 8]:

- Greater than 6 stools per day
- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers
- Abnormal lab values (e.g., hemoglobin, ESR, CRP)
- Dependent on, or refractory to, corticosteroids

AND

3 - Trial and failure, contraindication, or intolerance to treatment with at least ONE of the following [7, 8]:

- Corticosteroid (e.g., prednisone)
- 6-mercaptopurine
- Azathioprine
- Aminosalicylates (e.g., mesalamine, olsalazine, sulfasalazine)

AND

4 - Stelara is to be administered as an intravenous induction dose

AND

5 - Stelara induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for ulcerative colitis:

- 260 mg for patients weighing 55 kg or less
- 390 mg for patients weighing more than 55 kg to 85 kg
- 520 mg for patients weighing more than 85 kg

AND

6 - Prescribed by or in consultation with a gastroenterologist

Product Name: Stelara SC	
Diagnosis	Ulcerative Colitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - Will be used as a maintenance dose following the intravenous induction dose

AND

3 - Prescribed by or in consultation with a gastroenterologist

Product Name: Stelara SC	
Diagnosis	Crohn's Disease and Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 5-8]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

3 . References

1. Stelara prescribing information. Janssen Biotech, Inc. Horsham PA. August 2022.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
3. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
5. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn’s disease in adults. Am J Gastroenterol. 2018;113:481-517.
6. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508.
7. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.
8. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterol. 2020;158:1450-1461.

4 . Revision History

Date	Notes
12/7/2022	Further clinical detail and criteria added; removal of conventional ste p from SC UC and CD criteria.

Prior Authorization Guideline

Guideline Name	Stivarga (regorafenib)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	2/19/2013
P&T Revision Date:	12/18/2019 ; 06/17/2020 ; 06/16/2021 ; 06/15/2022 ; 5/18/2023

1 . Indications

Drug Name: Stivarga (regorafenib)
Metastatic Colorectal Cancer (mCRC) Indicated for the treatment of patients with metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild- type, an anti-EGFR therapy. **Gastrointestinal Stromal Tumor (GIST)** Indicated for the treatment of patients with locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate. **Hepatocellular Carcinoma (HCC)** Indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.

2 . Criteria

Product Name: Stivarga

Diagnosis	Metastatic Colorectal Cancer (mCRC) [1,2]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic colorectal cancer (mCRC)

AND

2 - Prescribed by or in consultation with an oncologist

Product Name: Stivarga	
Diagnosis	Gastrointestinal Stromal Tumor (GIST) [1,2]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Gastrointestinal Stromal Tumor (GIST)

AND

2 - Disease is one of the following:

- Locally advanced
- Unresectable
- Metastatic

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Stivarga	
Diagnosis	Hepatocellular Carcinoma (HCC) [1,2]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hepatocellular carcinoma (HCC)

AND

2 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hepatologist
- Gastroenterologist

Product Name: Stivarga	
Diagnosis	All Indications Listed Above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Stivarga Prescribing Information. Bayer HealthCare Pharmaceuticals Inc., December 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed April 19, 2022.

4 . Revision History

Date	Notes
5/4/2023	Program update to remove t/f criterion.

Prior Authorization Guideline

Guideline Name	Strensiq (asfotase alfa)

Guideline Note:

Effective Date:	3/29/2023

1 . Indications

Drug Name: Strensiq (asfotase alfa)
Perinatal/infantile- and juvenile-onset hypophosphatasia (HPP) Indicated for the treatment of patients with perinatal/infantile- and juvenile-onset hypophosphatasia (HPP).

2 . Criteria

Product Name: Strensiq*	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Submission of medical records (e.g., chart notes) documenting all of the following:	

1.1 One of the following diagnoses:

- Perinatal/infantile-onset hypophosphatasia (HPP)
- Juvenile-onset hypophosphatasia (HPP)

AND

1.2 Onset of clinical signs and symptoms of hypophosphatasia prior to age 18 years (e.g., respiratory insufficiency, vitamin B6 responsive seizures, hypotonia, failure to thrive, delayed walking, waddling gait, dental abnormalities, low trauma fractures) [A-D; 1, 7-9]

AND

1.3 Radiographic evidence supporting the diagnosis of hypophosphatasia at the age of onset prior to age 18 (e.g., infantile rickets, craniosynostosis, non-traumatic fractures, osteoporosis or low bone mineral content for age [as detected by DEXA]) [A-D; 1, 7-9]

AND

1.4 One of the following: [F-G; 2-6, 8]

1.4.1 Both of the following:

1.4.1.1 Patient has low level activity of serum alkaline phosphatase (ALP) evidenced by an ALP level below the age and gender-adjusted normal range

AND

1.4.1.2 Patient has an elevated level of tissue non-specific alkaline phosphatase (TNSALP) substrate (e.g., serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPi level])

OR

1.4.2 Confirmation of tissue-nonspecific alkaline phosphatase (TNSALP) gene mutation by ALPL genomic DNA testing

AND

2 - Prescribed by a specialist experienced in the treatment of inborn errors of metabolism (e.g., endocrinologist, rheumatologist, geneticist, orthopedist) [H; 2-6]

AND

3 - Requested dose will not exceed the following: [H,1] (Note to prescriber: Three times a week dosing leads to less waste and may lead to less injection site reactions compared to six times a week dosing)

- 9 mg/kg per week for perinatal/infantile-onset HPP
- 6 mg/kg per week for juvenile-onset HPP

AND

4 - If patient weighs less than 40 kg, the 80 mg/0.8mL vial will not be approved (patient's weight must be provided)

Notes	*If criteria above are met and the 80mg strength is requested, see table in the Background Section for auth approval instructions. For all other strengths, approve auth at GPI-14 level if criteria above are met.

Product Name: Strensiq*	
Approval Length	9 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has responded to treatment with Strensiq as evidenced by one of the following: [1, 7-9]

- Improvement and/or stabilization of clinical signs and/or symptoms of hypophosphatasia (e.g., respiratory status [ventilator free survival], growth) or radiographic findings (e.g., skeletal manifestations)

- Clinically relevant decrease from baseline in tissue non-specific alkaline phosphatase (TNSALP) substrate (e.g., serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPi level])

AND

2 - Prescribed by a specialist experienced in the treatment of inborn errors of metabolism (e.g., endocrinologist, rheumatologist, geneticist, orthopedist) [H, 2-6]

AND

3 - Requested dose will not exceed the following: [H, 1] (Note to prescriber: Three times a week dosing leads to less waste and may lead to less injection site reactions compared to six times a week dosing)

- 9 mg/kg per week for perinatal/infantile-onset HPP
- 6 mg/kg per week for juvenile-onset HPP

AND

4 - If patient weighs less than 40 kg, the 80 mg/0.8mL vial will not be approved (patient's weight must be provided)

Notes	*If criteria above are met and the 80mg strength is requested, see table in the Background Section for auth approval instructions. For all other strengths, approve auth at GPI-14 level if criteria above are met.

Product Name: Strensiq	
Guideline Type	Quantity Limit*
Approval Criteria **1** - For the 80mg/0.8mL vial, requests for additional quantity will not be approved	
Notes	*Note: Requests will be denied as medical necessity.

3 . Background

Benefit/Coverage/Program Information
80 mg/0.8 mL Vial Approval Instructions: **Please enter 2 PAs as follows with the same start date:**

Member Weight	First PA	Second PA
40 to 74 kg	Approve 12 vials (9.6 mL) per 28 days at GPI-14.	Approve at GPI-12 (no overrides needed).
75 to 119 kg	Approve 24 vials (19.2 mL) per 28 days at GPI-14.	Approve at GPI-12 (no overrides needed).
Greater than or equal to 120 kg	Approve 36 vials (28.8 mL) per 28 days at GPI-14.	Approve at GPI-12 (no overrides needed).

4 . Endnotes

A. Study 1 was a 24-week prospective single-arm trial in 11 patients, 7/11(64%) were female and 10/11(91%) were white, aged 3 weeks to 39.5 months with severe perinatal/infantile-onset HPP. Severe perinatal/infantile onset HPP was defined as biochemical, medical history and radiographic evidence of HPP as well as the presence of any of the following: rachitic chest deformity, vitamin B6 dependent seizures, or failure to thrive.[1]
B. HPP is diagnosed by identifying its symptoms and complications beginning with a detailed patient history. HPP signs are revealed by a thorough clinical examination, and supported by routine x-rays and various laboratory tests including biochemical studies. [8]
C. The clinical review team concluded that the totality of evidence, including growth, radiographic, and histomorphometric data collected in both populations and survival data collected in the perinatal/infantile-onset population, were sufficient to make a favorable medical risk benefit determination for approval for the juvenile-onset indication. [7]
D. Clinical course Perinatal-onset HPP typically is diagnosed on prenatal ultrasound examination which demonstrates unmineralized or hypomineralized bone. As noted earlier, the lethal perinatal form results in stillbirth or early neonatal death secondary to pulmonary insufficiency caused by chest wall deformities (flail chest). Other clinical features may include fever, anemia, failure to thrive, irritability, apnea and bradycardia, intracranial hemorrhage and pyridoxine-dependent seizures. The benign perinatal form clinically resembles other milder forms of HPP. Infantile-onset HPP presents before age six months of age, with infants developing clinical signs and symptoms of rickets, including growth failure, hypotonia, bowing of long bones, and rachitic changes of the ribs. Other clinical hallmarks are wide fontanels (actually hypomineralized skull bone) and craniosynostosis. Other skull deformities may include hypertelorism and

brachycephaly. Infantile-onset HPP patients are at increased risk of pneumonia due to flail chest In juvenile-onset HPP (also termed as childhood HPP), premature loss of the primary teeth (prior to age 5 years) is a major clinical hallmark of disease. Radiographic evidence of dental hypoplasia may precede radiographic evidence of skeletal disease. Patients who develop rickets may have delayed walking, gait abnormalities (waddling gait) and short stature. Other complications include pathologic fractures, most commonly involving the metaphysis, and static myopathy. Patient may also experience bone pain and stiffness. Some patients may improve spontaneously during puberty, with recurrence of skeletal symptoms during adulthood. As in infantile-onset HPP, patients with juvenile-onset HPP may develop nephrocalcinosis. Dental involvement of secondary dentition is generally less severe Adult-onset HPP usually presents during middle age, with about 50% of patients having a history of rickets and or premature dental loss during childhood. The chief clinical features of adult-onset HPP are recurrent stress fractures and femoral pseudofractures (areas of osteomalacia). Patients also may experience hip or thigh pain (secondary to femoral pseudofractures) and may develop chondrocalcinosis [7, 9]

E. HPP is a rare metabolic disease characterized by low serum alkaline-phosphatase activity which results in bone mineralization defects and various systemic complications [2, 6] The disease arises from a genetic mutation within the tissue-nonspecific isozyme of alkaline phosphatase (TNSALP). The mutation results in a loss of function which leads to an accumulation of TNSALP substrates (e.g., inorganic pyrophosphate and pyridoxal 5′-phosphate (PLP). Given the complexities and rarity of the condition, the criteria requires the medication to be prescribed by or in consultation with a specialist experienced in the treatment of inborn errors of metabolism, this aims to ensure proper diagnosis.
F. HPP is caused by mutations in the ALPL gene. This is the only gene that causes HPP. The ALPL gene creates (encodes) a type of protein called an enzyme named TNSALP. Enzymes are specialized proteins that break down specific chemicals in the body. TNSALP is essential for the proper development and health of bones and teeth, and is abundant in the skeleton, liver, and kidneys. Mutations in the ALPL gene lower the activity of TNSALP, in turn leading to accumulation of phosphoethanolamine (PEA), pyridoxal 5’-phosphate (PLP), and inorganic pyrophosphate (PPi). [8]
G. HPP is a rare metabolic disease characterized by low serum alkaline-phosphatase activity which results in bone mineralization defects and various systemic complications [2, 6] The disease arises from a genetic mutation within the tissue-nonspecific isozyme of alkaline phosphatase (TNSALP). The mutation results in a loss of function which leads to an accumulation of TNSALP substrates (e.g., inorganic pyrophosphate and pyridoxal 5′-phosphate (PLP). Given the complexities and rarity of the condition, the criteria requires the medication to be prescribed by or in consultation with a specialist experienced in the treatment of inborn errors of metabolism, this aims to ensure proper diagnosis.
H. The 80 mg/0.8 mL vial should not be used in patients weighing less than 40 kg, as the systemic exposure of the drug is lower than that achieved within the lower strengths. Use in these patients could result in inadequate exposure and poor treatment outcomes. [1]

5 . References

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6. Whyte MP, Greenberg CR, Salman N, et al. Enzyme-replacement therapy in life-threatening hypophosphatasia. N Engl J Med. 2012; 366(10):904-913.
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8. Whyte, M. Hypophosphatasia. NORD- National Organization for Rare Disorders.Available at https://rarediseases.org/rare-diseases/hypophosphatasia/. Accessed october 4, 2021.
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6 . Revision History

Date	Notes
3/28/2023	Update to operational note.

Prior Authorization Guideline

Guideline Name	Sunosi (solriamfetol)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	6/19/2019
P&T Revision Date:	01/15/2020 ; 05/14/2020 ; 05/19/2022 ; 11/17/2022 ; 5/18/2023

1 . Indications

Drug Name: Sunosi (solriamfetol)
Narcolepsy Indicated to improve wakefulness in adults patients with excessive daytime sleepiness associated with narcolepsy. **Obstructive sleep apnea (OSA)** Indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with obstructive sleep apnea (OSA). Limitations of use: Sunosi is not indicated to treat the underlying airway obstruction in OSA. Ensure that the underlying airway obstruction is treated (e.g., with continuous positive airway pressure (CPAP)) for at least one month prior to initiating Sunosi for excessive daytime sleepiness. Modalities to treat the underlying airway obstruction should be continued during treatment with Sunosi. Sunosi is not a substitute for these modalities.

2 . Criteria

Product Name: Sunosi	
Diagnosis	Narcolepsy

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [A, B]

AND

2 - BOTH of the following;

2.1 Trial and failure, contraindication, or intolerance to ONE of the following:

- generic modafinil
- generic armodafinil

AND

2.2 ONE of the following:

2.2.1 Trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant

OR

2.2.2 History of or potential for a substance use disorder

Product Name: Sunosi	
Diagnosis	Narcolepsy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy.

Product Name: Sunosi	
Diagnosis	Obstructive Sleep Apnea (OSA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of obstructive sleep apnea defined by one of the following: [4]

1.1 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [C]

OR

1.2 Both of the following:

1.2.1 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [C]

AND

1.2.2 One of the following signs/symptoms are present:

- Daytime sleepiness
- Nonrestorative sleep
- Fatigue
- Insomnia
- Waking up with breath holding, gasping, or choking
- Habitual snoring noted by a bed partner or other observer

- Observed apnea

AND

2 - Both of the following:

2.1 Standard treatment(s) for the underlying obstruction (e.g., with continuous positive airway pressure [CPAP], bi-level positive airway pressure [BiPAP]) have been used for one month or longer

AND

2.2 Patient is fully compliant with ongoing treatment(s) for the underlying airway obstruction

AND

3 - Trial and failure, contraindication or intolerance to ONE of the following:

- generic modafinil
- generic armodafinil

Product Name: Sunosi	
Diagnosis	Obstructive Sleep Apnea (OSA)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy.

AND

2 - Patient continues to be fully compliant with ongoing treatment(s) for the underlying airway obstruction (e.g., CPAP, BiPAP)

3 . Endnotes

A. International Classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy type 1 (narcolepsy with cataplexy) require: 1) Daily periods of irrepressible need to sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) occurring for at least 3 months. 2) The presence of one or both of the following: cataplexy and a mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT; or cerebrospinal fluid (CSF) hypocretin-1 concentration is low (less than or equal to 110 pg/mL or less than one-third of mean values obtained in normal subjects with the same standardized assay) [2,3].
B. International Classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy type 2 (narcolepsy without cataplexy) include: 1) Daily periods of irrepressible need to sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) occurring for at least 3 months. 2) Cataplexy is absent. 3) CSF hypocretin-1 levels, if measured, is either greater than 100 pg/mL or greater than one-third of mean values obtained in normal subjects with the same standardized assay. 4) A mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT. 5) Hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, obstructive sleep apnea, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal [2,3].
C. Examples of obstructive respiratory events include: obstructive and mixed apneas, hypopneas, or respiratory effort related arousals (RERA) [2].

4 . References

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5 . Revision History

Date	Notes
4/13/2023	2023 Annual Review.

Prior Authorization Guideline

Guideline Name	Sutent (sunitinib) - PA, NF

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	4/1/2006
P&T Revision Date:	03/18/2020 ; 03/17/2021 ; 10/20/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Sutent (sunitinib)
Gastrointestinal stromal tumor (GIST) Indicated for the treatment of adult patients gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate. **Advanced pancreatic neuroendocrine tumors (pNET)** Indicated for the treatment of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in patients with unresectable locally advanced or metastatic disease. **Advanced renal cell carcinoma** Indicated for the treatment of adult patients with advanced renal cell carcinoma. **Adjuvant treatment of renal cell carcinoma** Indicated for the adjuvant treatment of adult patients at high risk of recurrent renal cell carcinoma following nephrectomy.

2 . Criteria

Product Name: Brand Sutent, Generic sunitinib	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2 - History of disease progression, contraindication, or intolerance to Gleevec (imatinib)

AND

3 - Trial and failure or intolerance to generic sunitinib (applies to Brand Sutent only)

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Brand Sutent, Generic sunitinib	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Brand Sutent	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming history of disease progression, contraindication, or intolerance to Gleevec (imatinib)

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic sunitinib

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Brand Sutent, Generic sunitinib	
Diagnosis	Pancreatic Neuroendocrine Tumors (pNET)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET)

AND

2 - One of the following:

- unresectable locally advanced disease
- metastatic disease

AND

3 - Trial and failure or intolerance to generic sunitinib (applies to Brand Sutent only)

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Brand Sutent, Generic sunitinib	
Diagnosis	Pancreatic Neuroendocrine Tumors (pNET)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Brand Sutent	
Diagnosis	Pancreatic Neuroendocrine Tumors (pNET)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET)

AND

2 - One of the following:

- unresectable locally advanced disease
- metastatic disease

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic sunitinib

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Brand Sutent, Generic sunitinib	
Diagnosis	Advanced Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced/metastatic renal cell carcinoma

AND

2 - Trial and failure or intolerance to generic sunitinib (applies to Brand Sutent only)

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Brand Sutent, Generic sunitinib	
Diagnosis	Advanced Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Brand Sutent	
Diagnosis	Advanced Renal Cell Carcinoma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of advanced/metastatic renal cell carcinoma

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic sunitinib

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Brand Sutent, Generic sunitinib	
Diagnosis	Adjuvant Treatment of Renal Cell Carcinoma
Approval Length	12 Months [A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of renal cell carcinoma (RCC)

AND

2 - Used as adjuvant therapy

AND

3 - Patient is at high risk of recurrent RCC following nephrectomy

AND

4 - Trial and failure or intolerance to generic sunitinib (applies to Brand Sutent only)

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Brand Sutent	
Diagnosis	Adjuvant Treatment of Renal Cell Carcinoma
Approval Length	12 Months [A]
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of renal cell carcinoma (RCC)

AND

2 - Used as adjuvant therapy

AND

3 - Patient is at high risk of recurrent RCC following nephrectomy

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic sunitinib

AND

5 - Prescribed by or in consultation with an oncologist

3 . Endnotes

A. The recommended dose of Sutent for the adjuvant treatment of RCC is 50mg taken orally once daily, on a schedule of 4 weeks on treatment followed by 2 weeks off (Schedule 4/2), for nine 6-week cycles (approximately 1 year). [1, 2]

4 . References

1. Sutent Prescribing Information. Pfizer Labs. New York, NY. August 2021.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Kidney Cancer. v.2.2021. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed February 15, 2021.

5 . Revision History

Date	Notes
3/2/2023	Annual review: No criteria changes. Updated indications section to ali gn with PI verbiage.

Prior Authorization Guideline

Guideline Name	Synagis (palivizumab)

Guideline Note:

Effective Date:	4/1/2022
P&T Approval Date:	3/17/2000
P&T Revision Date:	10/21/2020 ; 10/20/2021 ; 3/16/2022

1 . Indications

Drug Name: Synagis (palivizumab)
Prophylaxis of respiratory syncytial virus (RSV) Indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients: with a history of premature birth (less than or equal to 35 weeks gestational age) and who are 6 months of age or younger at the beginning of respiratory syncytial virus (RSV) season; with bronchopulmonary dysplasia (BPD) that required medical treatment within the previous 6 months and who are 24 months of age or younger at the beginning of respiratory syncytial virus (RSV) season; with hemodynamically significant congenital heart disease (CHD) and who are 24 months of age or younger at the beginning of respiratory syncytial virus (RSV) season. Limitations of use: The safety and efficacy of Synagis have not been established for treatment of RSV disease.

2 . Criteria

Product Name: Synagis	
Diagnosis	Premature Infants (without other indications)

Approval Length	5 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Born prematurely at or before 29 weeks, 0 days gestation [2, B]

AND

2 - Age < 12 months at the start of the respiratory syncytial virus (RSV) season [A].

AND

3 - Used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region.

Notes	Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. [A] Typical RSV season is from November through March; however, RSV season can fall outsid e this time frame. If outside this time frame, refer to the CDC surveilla nce reports (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) to confirm the start of RSV season based on region.

Product Name: Synagis	
Diagnosis	Chronic Lung Disease of Prematurity
Approval Length	5 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Chronic lung disease (CLD) of prematurity [2]

AND

2 - Born before 32 weeks, 0 days gestation [2]

AND

3 - Received greater than 21% oxygen supplementation for at least the first 28 days after birth

AND

4 - One of the following:

4.1 Age < 12 months at the start of the respiratory syncytial virus (RSV) season.

OR

4.2 Both of the following:

- Age at least 12 to < 24 months at the start of the RSV season
- Received medical support (i.e., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) within 6 months before the start of the second RSV season

AND

5 - Prescribed by or in consultation with one of the following:

- Pediatric pulmonologist
- Neonatologist
- Pediatric intensivist
- Infectious disease specialist

AND

6 - Used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region.

Notes	Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. [A] Typical RSV season is from November through March; however, RSV season can fall outsid e this time frame. If outside this time frame, refer to the CDC surveilla nce reports (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) to confirm the start of RSV season based on region.

Product Name: Synagis	
Diagnosis	Hemodynamically Significant Congenital Heart Disease
Approval Length	5 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Age < 12 months at the start of the respiratory syncytial virus (RSV) season, with one of the following: [C] (persons of all ages).

1.1.1 All of the following:

- Acyanotic heart failure
- Receiving medication to control congestive heart failure
- Patient will require a cardiac surgical procedure

OR

1.1.2 Moderate to severe pulmonary hypertension

OR

1.1.3 Cyanotic heart defect

OR

1.2 Both of the following*: [D]

- Age < 24 months
- Patient will or has undergone a cardiac transplantation during the respiratory syncytial virus (RSV)season

AND

2 - Prescribed by or in consultation with a pediatric cardiologist

AND

3 - Used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region

Notes	Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. *ONE additional postoper ative dose allowed for patients undergoing cardiac transplantation, car diac bypass or extracorporeal membrane oxygenation. [A, D] Typical RSV season is from November through March; however, RSV season can fall outside this time frame. If outside this time frame, refer to the CDC surveillance reports (http://www.cdc.gov/surveillance/nrevss/rsv/i ndex.html) to confirm the start of RSV season based on region.

Product Name: Synagis	
Diagnosis	Pulmonary Abnormality or Neuromuscular Disorder
Approval Length	5 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Pulmonary abnormalities (e.g., pulmonary malformations, tracheoesophageal fistula, conditions requiring tracheostomy) or neuromuscular disease (e.g., cerebral palsy) [2]

AND

2 - Age < 12 months at the start of the respiratory syncytial virus (RSV) season.

AND

3 - Impaired ability to clear secretions from the upper airway due to an ineffective cough

AND

4 - Prescribed by or in consultation with one of the following:

- Pediatric pulmonologist
- Neurologist

AND

5 - Used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region

Notes	Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. [A] Typical RSV season is from November through March; however, RSV season can fall outsid e this time frame. If outside this time frame, refer to the CDC surveilla nce reports (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) to confirm the start of RSV season based on region.

Product Name: Synagis	
Diagnosis	Immunocompromised Children
Approval Length	5 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Received or will receive a solid organ transplant, hematopoietic stem cell transplant, or chemotherapy during the respiratory syncytial virus (RSV) season.

AND

2 - Age < 24 months

AND

3 - Lymphocyte count is below the normal range for patient's age

AND

4 - Prescribed by or in consultation with one of the following:

- Pediatric pulmonologist
- Infectious disease specialist
- Pediatric intensivist

AND

5 - Used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region

Notes	Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. [A] Typical RSV season is from November through March; however, RSV season can fall outsid e this time frame. If outside this time frame, refer to the CDC surveilla nce reports (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) to confirm the start of RSV season based on region.

Product Name: Synagis	
Diagnosis	Children with Cystic Fibrosis
Approval Length	5 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis [2]

AND

2 - One of the following:

2.1 Both of the following:

- Age < 12 months
- Clinical evidence of chronic lung disease (CLD) and/or nutritional compromise (i.e., failure to thrive)

OR

2.2 Both of the following:

- Age at least 12 to < 24 months
- Severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life, abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length < 10th percentile on pediatric growth chart [E]

Notes	Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. [A] Typical RSV season is from November through March; however, RSV season can fall outsid e this time frame. If outside this time frame, refer to the CDC surveilla nce reports (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) to confirm the start of RSV season based on region.

3 . Endnotes

A. Five monthly doses of palivizumab will provide more than 6 months of prophylactic serum palivizumab concentrations. Administration of more than five monthly doses is not recommended. If RSV season onset is in November, the first dose should be administered in November, and the fifth and final dose should be administered in March. If RSV season onset is in November and the first dose is given in January, the third and

final dose should be administered in March. In most of North America, peak RSV activity typically occurs between November and March, usually beginning in November or December, peaking in January or February, and ending by the end of March or sometime in April. Communities in the southern United States, particularly some communities in the state of Florida, tend to experience the earliest onset of RSV. Data from the Centers for Disease Control and Prevention (CDC) have identified variations in the onset and offset of the RSV "season" in the state of Florida that could affect the timing of palivizumab administration. [2] For analysis of National Respiratory and Enteric Virus Surveillance System (NREVSS) reports in the CDC Morbidity and Mortality Weekly Report (MMWR), season onset is defined as the first of 2 consecutive weeks during which the mean percentage of specimens testing positive for RSV antigen is at least 10% and RSV season offset is defined as the last of 2 consecutive weeks during which the mean percentage of positive specimens is at least 10%. [3] NREVSS surveillance data can be viewed here (http://www.cdc.gov/surveillance/nrevss/rsv/)

B. Palivizumab prophylaxis is not recommended for otherwise healthy infants born at or after 29 weeks, 0 days' gestation. [2]
C. The following conditions are NOT considered hemodynamically significant congenital heart disease: secundum atrial septal defect, small ventricular septal defect, pulmonary stenosis, uncomplicated aortic stenosis, mild coaractation of the aorta, and patent ductus arteriosus; lesions adequately corrected by surgery, unless continuing required medication for congestive heart failure; mild cardiomyopathy and not receiving medical therapy for the condition; children in the second year of life. [2]
D. Pediatric growth charts can be viewed here (http://www.cdc.gov/growthcharts/who_charts.htm)
E. Children undergoing these procedures should receive an additional dose of palivizumab as soon as possible after the procedure. Thereafter, doses should be administered monthly as scheduled. [2]
F. Monthly prophylaxis should be discontinued in any infant or child who experiences a breakthrough RSV hospitalization. [2]
G. Palivizumab prophylaxis is not recommended for prevention of health care-associated RSV disease. [2]
H. The burden of RSV disease and costs associated with transport from remote locations may result in a broader use of palivizumab for RSV prevention in Alaska Native populations and possibly in selected other American Indian populations. [2]

4 . References

1. Synagis Prescribing Information. Swedish Orphan Biovitrum AB (publ). Stockholm, Sweden September 2021.
2. Commitee on Infectious Diseases and Bronchiolitis Guidelines Committee. Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalizations for respiratory syncytial virus infection. Pediatrics. 2014 Aug;134(2):415-20. doi: 10.1542/peds.2014-1665.
3. Panozzo CA, Stockman LJ, et al. Use of respiratory syncytial virus surveillance data to optimize the timing of immunoprophylaxis. Pediatrics. 2010 Jul;126(1):e116-23.

5 . Revision History

Date	Notes
3/3/2022	Updated notes to add guidance on RSV season variance

Prior Authorization Guideline

Guideline Name	Synribo (omacetaxine mepesuccinate)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	2/19/2013
P&T Revision Date:	06/17/2020 ; 06/16/2021 ; 06/15/2022 ; 5/18/2023

1 . Indications

Drug Name: Synribo (omacetaxine mepesuccinate)
Chronic Myeloid Leukemia (CML) Indicated for the treatment of adult patients with chronic or accelerated phase chronic myeloid leukemia (CML) with resistance and/or intolerance to two or more tyrosine kinase inhibitors (TKIs).

2 . Criteria

Product Name: Synribo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of chronic myelogenous leukemia **AND** **2** - Prescribed by or in consultation with a hematologist/oncologist [A]

Product Name: Synribo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on therapy	

3 . Endnotes

A. Synribo should be prepared in a healthcare facility and administered by a healthcare professional. As omacetaxine mepesuccinate is an antineoplastic product, special handling and disposal procedures should be followed. [1]

4 . References

1. Synribo Prescribing Information. Cephalon, Inc. North Wales, PA. November 2020.

5 . Revision History

Date	Notes
4/28/2023	Program update to remove trial requirement of 2 TKI's.

Prior Authorization Guideline

Guideline Name	Tabrecta (capmatinib) - PA, NF

Guideline Note:

Effective Date:	8/1/2022
P&T Approval Date:	7/15/2020
P&T Revision Date:	11/12/2020 ; 11/12/2020 ; 06/16/2021 ; 6/15/2022

1 . Indications

Drug Name: Tabrecta (capmatinib)
Non-Small Cell Lung Cancer (NSCLC) Indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.

2 . Criteria

Product Name: Tabrecta	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is metastatic

AND

3 - Presence of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Tabrecta	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Tabrecta	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of non-small cell lung cancer (NSCLC)

AND

1.1.2 Disease is metastatic

AND

1.1.3 Presence of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

1.1.4 Prescribed by or in consultation with an oncologist

OR

1.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

3 . References

1. Tabrecta Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. January 2022.

4 . Revision History

Date	Notes
6/17/2022	Annual review: Updated GL name to include PA, NF guideline types. Updated NF section to require paid claims or submission of medical r ecords to confirm COT.

Prior Authorization Guideline

Guideline Name	Tadalafil

Guideline Note:

Effective Date:	9/1/2022
P&T Approval Date:	7/18/2018
P&T Revision Date:	07/15/2020 ; 07/21/2021 ; 7/20/2022

1 . Indications

Drug Name: Generic tadalafil
Benign Prostatic Hyperplasia (BPH) and Erectile Dysfunction (ED) Indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) and for the treatment of erectile dysfunction (ED) and the signs and symptoms of BPH (ED/BPH). Limitation of use: If Cialis is used with finasteride to initiate BPH treatment, such use is recommended for up to 26 weeks because the incremental benefit of Cialis decreases from 4 weeks until 26 weeks, and the incremental benefit of Cialis beyond 26 weeks is unknown.

2 . Criteria

Product Name: Generic tadalafil 2.5 mg or generic tadalafil 5 mg	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of benign prostatic hyperplasia (BPH)

Notes	Quantity limit: Cialis (tadalafil) 2.5 mg and 5 mg tablets will be subject to a quantity limit of 1 tablet per day.

3 . References

1. Tadalafil Prescribing Information. Teva Pharmaceuticals USA, Inc. North Wales, PA. May 2020.

4 . Revision History

Date	Notes
8/12/2022	Annual review - no changes.

Prior Authorization Guideline

Guideline Name	Tafinlar (dabrafenib)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	7/9/2013
P&T Revision Date:	03/18/2020 ; 03/17/2021 ; 03/16/2022 ; 08/18/2022 ; 3/15/2023

1 . Indications

Drug Name: Tafinlar (dabrafenib)
BRAF V600E mutation-positive unresectable or metastatic melanoma Indicated as a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test. Limitation of use: Tafinlar is not indicated for treatment of patients with wild-type BRAF melanoma. **BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma** Indicated in combination with trametinib for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test. Limitation of use: Tafinlar is not indicated for treatment of patients with wild-type BRAF melanoma. **BRAF V600E mutation-positive metastatic non-small cell lung cancer** Indicated in combination with trametinib for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test. Limitation of use: Tafinlar is not indicated for treatment of patients with wild-type BRAF NSCLC. **BRAF V600E or V600K mutation-positive adjunctive treatment for melanoma** Indicated for adjuvant treatment in combination with trametinib for patients with melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection. Limitation of use: Tafinlar is not indicated for treatment

of patients with wild-type BRAF melanoma

Anaplastic thyroid cancer (ATC) with BRAF V600E mutation Indicated in combination with trametinib for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options. Limitation of use: Tafinlar is not indicated for treatment of patients with wild-type BRAF melanoma.

BRAF V600E mutation-positive unresectable or metastatic solid tumors Indicated, in combination with trametinib, for the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options.

2 . Criteria

Product Name: Tafinlar	
Diagnosis	Unresectable or metastatic melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses: [2]

- Unresectable melanoma
- Metastatic melanoma

AND

2 - One of the following:

2.1 Cancer is BRAFV600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

OR

2.2 Both of the following:

2.2.1 Cancer is BRAFV600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

AND

2.2.2 Medication is used in combination with Mekinist (trametinib)

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Tafinlar	
Diagnosis	Unresectable or metastatic melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Tafinlar	
Diagnosis	Non-small cell lung cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer

AND

2 - Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

AND

3 - Medication is used in combination with Mekinist (trametinib)

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Tafinlar	
Diagnosis	Non-small cell lung cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Tafinlar	
Diagnosis	Adjunctive treatment for melanoma
Approval Length	12 Month [A]

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of melanoma

AND

2 - Cancer is BRAF V600E mutation or V600K mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Involvement of lymph nodes following complete resection [2]

AND

4 - Used as adjunctive therapy

AND

5 - Medication is used in combination with Mekinist (trametinib)

AND

6 - Prescribed by or in consultation with an oncologist

Product Name: Tafinlar	
Diagnosis	Anaplastic thyroid cancer (ATC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC) [2]

AND

2 - Cancer is BRAF V600E mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Cancer may not be treated with standard locoregional treatment options

AND

4 - Medication is used in combination with Mekinist (trametinib)

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Tafinlar	
Diagnosis	Anaplastic thyroid cancer (ATC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Tafinlar	
Diagnosis	Unresectable or metastatic solid tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of solid tumors

AND

2 - Patient is 6 years of age or older

AND

3 - Disease is one of the following:

- unresectable
- metastatic

AND

4 - Patient has progressed on or following prior treatment and have no satisfactory alternative treatment options

AND

5 - Cancer is BRAF V600E mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

6 - Medication is used in combination with Mekinist (trametinib)

AND

7 - Prescribed by or in consultation with an oncologist

Product Name: Tafinlar	
Diagnosis	Unresectable or metastatic solid tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. The recommended dosage of TAFINLAR is 150 mg orally taken twice daily in combination with trametinib until disease recurrence or unacceptable toxicity for up to 1 year for the adjuvant treatment of melanoma [1].

4 . References

1. Tafinlar Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. June 2022.
2. National Comprehensive Cancer (NCCN) Drugs & Biologics Compendium [internet database]. Updated periodically. Available at: http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed February 14, 2023.

5 . Revision History

Date	Notes
3/15/2023	Annual review - updated references.

Prior Authorization Guideline

Guideline Name	Tagrisso (osimertinib)

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	1/27/2016
P&T Revision Date:	04/15/2020 ; 02/18/2021 ; 04/21/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Tagrisso (osimertinib)
First-line Treatment of EGFR Mutation-Positive Metastatic Non-Small Cell Lung Cancer (NSCLC) Indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test. **Previously Treated EGFR T790M Mutation-Positive Metastatic NSCLC** Indicated for the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC), as detected by an FDA-approved test, whose disease has progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy. **Adjuvant Treatment of EGFR Mutation-Positive Non-Small Cell Lung Cancer (NSCLC)** Indicated as adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.

2 . Criteria

Product Name: Tagrisso	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following

1.1 All of the following:

1.1.1 Diagnosis of metastatic non-small cell lung cancer (NSCLC)

AND

1.1.2 One of the following:

1.1.2.1 Both of the following:

1.1.2.1.1 Patient has a known active epidermal growth factor receptor (EGFR) T790M mutation as detected by a U.S. Food and Drug Administration (FDA) -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

1.1.2.1.2 Patient has experienced disease progression on or after one of the following EGFR Tyrosine Kinase Inhibitors (TKIs): [1-3]

- Gilotrif (afatinib)*
- Iressa (gefitinib)*
- Tarceva (erlotinib)*
- Vizimpro (dacomitinib)*

OR

1.1.2.2 Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by an U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

1.1.3 Prescribed by or in consultation with an oncologist

OR

1.2 All of the following:

1.2.1 Diagnosis of non-small cell lung cancer (NSCLC)

AND

1.2.2 Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by an U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

1.2.3 Both of the following:

- Patient is receiving as adjuvant therapy
- Patient has had a complete surgical resection of the primary non-small cell lung cancer (NSCLC) tumor

AND

1.2.4 Prescribed by or in consultation with an oncologist

Notes	*This product may require prior authorization.

Product Name: Tagrisso	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Tagrisso prescribing information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. October 2022.
2. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium [internet database]. National Comprehensive Cancer Network, Inc.; 2014. Updated periodically. Available by subscription at: www.nccn.org. Accessed March 27, 2023.
3. National comprehensive cancer network (NCCN). Clinical practice guidelines in oncology. Non-small cell lung cancer. v.3.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed March 27, 2023.

4 . Revision History

Date	Notes
4/10/2023	2023 Annual Review

Prior Authorization Guideline

Guideline Name	Taltz (ixekizumab)

Guideline Note:

Effective Date:	2/1/2023
P&T Approval Date:	5/19/2016
P&T Revision Date:	09/18/2019 ; 10/16/2019 ; 11/14/2019 ; 05/14/2020 ; 08/13/2020 ; 09/16/2020 ; 07/21/2021 ; 03/16/2022 ; 06/15/2022 ; 07/20/2022 ; 10/19/2022 ; 12/14/2022 ; 1/18/2023

1 . Indications

Drug Name: Taltz (ixekizumab)
Plaque Psoriasis (PsO) Indicated for the treatment of patients 6 years of age and older with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. **Psoriatic Arthritis (PsA)** Indicated for the treatment of adult patients with active psoriatic arthritis. **Ankylosing Spondylitis (AS)** Indicated for the treatment of adult patients with active ankylosing spondylitis. **Non-radiographic Axial Spondyloarthritis (nr-axSpA)** Indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

2 . Criteria

Product Name: Taltz	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Patient is 6 years of age or older

AND

4 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

5 - Prescribed by or in consultation with a dermatologist

AND

6 - One of the following:

6.1 Trial and failure, contraindication, or intolerance to ONE of the following:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab) or Amjevita (adalimumab-atto)
- Skyrizi (risankizumab)
- Stelara (ustekinumab)
- Tremfya (guselkumab)

OR

6.2 For continuation of prior Taltz therapy, defined as no more than a 45-day gap in therapy

Product Name: Taltz	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1-3]:

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name: Taltz	
Diagnosis	Psoriatic Arthritis

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [4]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to ONE of the following:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab) or Amjevita (adalimumab-atto)
- Simponi (golimumab)
- Stelara (ustekinumab)
- Tremfya (guselkumab)
- Skyrizi (risankizumab-rzaa)
- Rinvoq (upadacitinib)

- Xeljanz/XR (tofacitinib/ER)

OR

4.2 For continuation of prior Taltz therapy, defined as no more than a 45-day gap in therapy

Product Name: Taltz	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name: Taltz	
Diagnosis	Ankylosing Spondylitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab) or Amjevita (adalimumab-atto)
- Simponi (golimumab)
- Rinvoq (upadacitinib)
- Xeljanz/XR (tofacitinib/ER)

OR

4.2 For continuation of prior Taltz therapy, defined as no more than a 45-day gap in therapy

Notes	* Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Taltz	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Product Name: Taltz	
Diagnosis	Non-radiographic Axial Spondyloarthritis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active non-radiographic axial spondyloarthritis

AND

2 - Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) [1, 3]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

AND

5 - One of the following:

5.1 Trial and failure, contraindication, or intolerance to ONE of the following:

- Cimzia (certolizumab pegol)
- Rinvoq (upadacitinib)

OR

5.2 For continuation of prior Taltz therapy, defined as no more than a 45-day gap in therapy

Product Name: Taltz	
Diagnosis	Non-radiographic Axial Spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

3 . References

1. Taltz prescribing information. Eli Lilly and Company. Indianapolis, IN. May 2022.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.

3. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
5. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613.

4 . Revision History

Date	Notes
2/1/2023	Addition of Amjevita as another preferred step option for PsO, PsA, a nd AS; addition of an age criterion to the PsO criteria to align with the labeling

Prior Authorization Guideline

Guideline Name	Tarceva (erlotinib)

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	7/14/2003
P&T Revision Date:	06/19/2019 ; 04/15/2020 ; 04/21/2021 ; 04/21/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Tarceva (erlotinib)
Non-Small Cell Lung Cancer (NSCLC) Indicated for metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen. **Pancreatic Cancer** Indicated for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer in combination with gemcitabine.

2 . Criteria

Product Name: Brand Tarceva, Generic erlotinib	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of locally advanced or metastatic (stage III or IV) non-small cell lung cancer (NSCLC) [2]

AND

2 - Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions, exon 21 (L858R) substitution, exon 18 (G719X, G719) or exon 20 (S7681) mutation as detected by an U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Brand Tarceva, Generic erlotinib	
Diagnosis	Pancreatic Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Locally advanced pancreatic cancer
- Unresectable pancreatic cancer
- Metastatic pancreatic cancer

AND

2 - Used in combination with Gemzar (gemcitabine)

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Brand Tarceva, Generic erlotinib	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Tarceva Prescribing Information. Genentech USA, Inc. South San Francisco, CA. October 2016.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Non-small cell lung cancer. v.3.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed March 27, 2023.
3. Erlotinib Prescribing Information. Mylan Pharmaceuticals. Morgantown, WV. January 2019.

4 . Revision History

Date	Notes
4/10/2023	2023 Annual Review - references updated

Prior Authorization Guideline

Guideline Name	Targretin (bexarotene)

Guideline Note:

Effective Date:	10/1/2022
P&T Approval Date:	11/17/2009
P&T Revision Date:	08/15/2019 ; 11/14/2019 ; 08/13/2020 ; 08/19/2021 ; 07/20/2022 ; 8/18/2022

1 . Indications

Drug Name: Targretin (bexarotene) capsules
Cutaneous T-Cell Lymphoma Indicated for the treatment of cutaneous manifestations of cutaneous T-cell lymphoma in patients who are refractory to at least one prior systemic therapy.
Drug Name: Targretin (bexarotene) gel 1%
Cutaneous T-Cell Lymphoma Indicated for the topical treatment of cutaneous lesions in patients with cutaneous T-cell lymphoma (Stage 1A and 1B) who have refractory or persistent disease after other therapies or who have not tolerated other therapies.

2 . Criteria

Product Name: Brand Targretin capsules, Generic bexarotene capsules, Brand Targretin gel, Generic bexarotene Gel

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cutaneous T-cell lymphoma (CTCL) [A]

AND

2 - Trial and failure, contraindication, or intolerance to at least one prior therapy (including skin-directed therapies [e.g., corticosteroids {i.e., clobetasol, diflorasone, halobetasol, augmented betamethasone dipropionate}, topical mechlorethamine, phototherapy, etc] or systemic therapies [e.g., brentuximab vedotin, methotrexate, etc])

AND

3 - Trial and failure, contraindication, or intolerance to generic Targretin (Applies to brand Targretin only)

AND

4 - Prescribed by or in consultation with one of the following:

- Oncologist
- Dermatologist

Product Name: Brand Targretin capsules, Generic bexarotene capsules, Brand Targretin gel, Generic bexarotene Gel	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria
1 - Patient does not show evidence of disease progression while on therapy

3 . Endnotes

A. Cutaneous T-cell lymphomas (CTCLs) are a group of non-Hodgkin's lymphomas (NHLs) primarily developing in the skin and at times progress to involve lymph nodes, blood, and visceral organs. Mycosis fungoides (MF) is the most common subtype and is usually associated with an indolent clinical course with intermittent, stable, or slow progression of the lesions. Extracutaneous involvement (lymph nodes, blood, or less commonly, other organs) or large cell transformation (LCT) may be seen in advanced-stage disease. Sezary Syndrome (SS) is a rare erythrodermic, leukemic variant of CTCL and is characterized by significant blood involvement, erythroderma, and often lymphadenopathy. Primary cutaneous CD30+ T cell lymphoproliferative disorders are also included as a subtype of CTCL. [3]

4 . References

1. Targretin prescribing information. Bausch Health US, LLC. Bridgewater, NJ. April 2020.
2. Targretin gel 1% prescribing information. Bausch Health US, LLC. Bridgewater, NJ. February 2020.
3. National Comprehensive Cancer Network (NCCN). Primary Cutaneous Lymphomas v.2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf. Accessed on July 26, 2022.
4. Bexarotene gel 1% prescribing information. Amneal Pharmaceuticals, Inc. Bridgewater, NJ. April 2022.

5 . Revision History

Date	Notes
7/26/2022	Annual Review

Prior Authorization Guideline

Guideline Name	Tasigna (nilotinib)

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	10/3/2006
P&T Revision Date:	12/18/2019 ; 04/15/2020 ; 04/21/2021 ; 11/18/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Tasigna (nilotinib)
Newly diagnosed Ph+ Chronic Myeloid Leukemia Indicated for the treatment of adult and pediatric patients greater than or equal to 1 year of age with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase. **Resistant or intolerant CML in chronic phase (CP) and accelerated phase (AP)** Indicated for the treatment of chronic phase and accelerated phase Ph+ CML in adult patients resistant to or intolerant to prior therapy that included imatinib. **Resistant or intolerant CML in chronic phase (CP) and accelerated phase (AP), Pediatric** Indicated for pediatric patients greater than or equal to 1 year of age with chronic phase and accelerated phase Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) with resistance or intolerance to prior tyrosine-kinase inhibitor (TKI) therapy.

2 . Criteria

Product Name: Tasigna	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome-positive/BCR ABL positive (Ph+/BCR ABL) chronic myelogenous/myeloid leukemia (CML) (A)

AND

2 - Prescribed by or in consultation with one of the following:

- oncologist
- hematologist

AND

3 - Patient is 1 year of age or older

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to generic imatinib

OR

4.2 Continuation of prior therapy

Product Name: Tasigna	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on therapy	

3 . Endnotes

A. BCR-ABL1 refers to a gene sequence found in an abnormal chromosome 22. The cause of chronic myelogenous leukemia (CML) can be traced to a single, specific genetic abnormality in one chromosome. The presence of the gene sequence known as BCR-ABL1 confirms the diagnosis of CML.

4 . References

1. Tasigna Prescribing Information. Novartis Pharmaceutical Corporation. East Hanover, NJ. September 2021.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Chronic Myelogenous Leukemia v.1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf. Accessed March 27, 2023.

5 . Revision History

Date	Notes
4/10/2023	2023 Annual Review

Prior Authorization Guideline

Guideline Name	Tavneos (avacopan) - PA, NF

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	12/15/2021
P&T Revision Date:	04/20/2022 ; 11/17/2022

1 . Indications

Drug Name: Tavneos (avacopan)
Anti-Neutrophil Cytoplasmic Autoantibody (ANCA)-Associated Vasculitis Indicated as an adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids. Tavneos does not eliminate glucocorticoid use.

2 . Criteria

Product Name: Tavneos	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following types of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis:

- Granulomatosis with polyangiitis (GPA)
- Microscopic polyangiitis (MPA)

AND

2 - Diagnosis is confirmed by one of the following: [4]

- ANCA test positive for proteinase 3 (PR3) antigen
- ANCA test positive for myeloperoxidase (MPO) antigen
- Tissue biopsy

AND

3 - Patient is receiving concurrent immunosuppressant therapy with one of the following: [1-3]

- cyclophosphamide
- rituximab

AND

4 - One of the following:

4.1 Patient is concurrently on glucocorticoids (e.g., prednisone)

OR

4.2 History of contraindication or intolerance to glucocorticoids (e.g., prednisone)

AND

5 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Pulmonologist
- Rheumatologist

Product Name: Tavneos	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Patient is receiving concurrent immunosuppressant therapy (e.g., azathioprine, cyclophosphamide, methotrexate, rituximab)

AND

3 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Pulmonologist
- Rheumatologist

Product Name: Tavneos	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of one of the following types of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis:

- Granulomatosis with polyangiitis (GPA)
- Microscopic polyangiitis (MPA)

AND

2 - Diagnosis is confirmed by one of the following: [4]

- ANCA test positive for proteinase 3 (PR3) antigen
- ANCA test positive for myeloperoxidase (MPO) antigen
- Tissue biopsy

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming patient is receiving concurrent immunosuppressant therapy with one of the following: [1-3]

- cyclophosphamide
- rituximab

AND

4 - One of the following:

4.1 Paid claims or submission of medical records (e.g., chart notes) confirming patient is concurrently on glucocorticoids (e.g., prednisone)

OR

4.2 Paid claims or submission of medical records (e.g., chart notes) confirming contraindication or intolerance to glucocorticoids (e.g., prednisone)

AND

5 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Pulmonologist
- Rheumatologist

3 . References

1. Tavneos Prescribing Information. ChemoCentryx, Inc. San Carlos, CA. October 2021.
2. Jayne DRW, Merkel PA, Schall TJ, Bekker P; ADVOCATE Study Group. Avacopan for the Treatment of ANCA-Associated Vasculitis. N Engl J Med. 2021;384(7):599-609. doi:10.1056/NEJMoa2023386
3. Per clinical consult with rheumatologist November 17, 2021.
4. Falk RJ, Merkel PA, King TE. Granulomatosis with polyangiitis and microscopic polyangiitis: clinical manifestations and diagnosis. In: Post T, ed. UpToDate 2022. Accessed October 9, 2022.
5. Merkel PA, Kaplan AA. Granulomatosis with polyangiitis and microscopic polyangiitis: Induction and maintenance therapy. UpToDate 2022. Accessed October 9, 2022.

4 . Revision History

Date	Notes
10/14/2022	2022 Annual Review

Prior Authorization Guideline

Guideline Name	Tecfidera (dimethyl fumarate) - PA, NF

Guideline Note:

Effective Date:	7/1/2022
P&T Approval Date:	6/16/2021
P&T Revision Date:	5/19/2022

1 . Indications

Drug Name: Tecfidera (dimethyl fumarate)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

2 . Criteria

Product Name: Brand Tecfidera	
Approval Length	12 month(s)
Guideline Type	Non Formulary
Approval Criteria	

1 - Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [3]

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting failure after a trial of at least 4 weeks, or intolerance to both of the following:

- generic dimethyl fumarate
- Bafiertam (monomethyl fumarate) [A, 5]

AND

3 - Not used in combination with another disease-modifying therapy for MS [B, 6, 7]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Generic dimethyl fumarate	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [4]

AND

2 - Not used in combination with another disease-modifying therapy for MS [B, 6, 7]

AND

3 - Prescribed by or in consultation with a neurologist

Product Name: Brand Tecfidera	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [3]

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting failure after a trial of at least 4 weeks, or intolerance to both of the following:

- generic dimethyl fumarate
- Bafiertam (monomethyl fumarate)

AND

3 - Not used in combination with another disease-modifying therapy for MS [B, 6, 7]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Brand Tecfidera, generic dimethyl fumarate	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS [B, 6, 7]

AND

3 - Prescribed by or in consultation with a neurologist

3 . Endnotes

A. Although the trial results of Bafiertam was based off of Tecfidera, the consultant thinks that the two drugs should have the same efficacy and safety profile since Bafiertam was approved via the FDA 505(b)(2) pathway. [5]
B. The advantage of using combination disease-modifying therapy (DMT) compared to monotherapy DMT use has not been demonstrated, but there are safety concerns, such as reduced efficacy or disease aggravation, with combination use. [6, 7]

4 . References

1. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline: Disease-modifying therapies for adults with multiple sclerosis. Neurology 2018;90:777-788.
2. National Multiple Sclerosis Society. Types of MS. Available at: https://www.nationalmssociety.org/What-is-MS/Types-of-MS. Accessed March 29, 2019.
3. Tecfidera Prescribing Information. Biogen Idec Inc. Cambridge, MA. February 2022.
4. Dimethyl Fumarate Prescribing Information. Mylan Pharmaceuticals Inc. Morgantown, WV. May 2020.
5. Per clinical consultation with MS specialist, July 22, 2020.
6. Wingerchuk, D., & Carter, J. (2014). Multiple Sclerosis: Current and Emerging Disease-Modifying Therapies and Treatment Strategies. Mayo Clinic Proceedings, 89(2), 225-240.

7. Sorensen, P., Lycke, J., Erälinna, J., Edland, A., Wu, X., & Frederiksen, J. et al. (2011). Simvastatin as add-on therapy to interferon beta-1a for relapsing-remitting multiple sclerosis (SIMCOMBIN study): a placebo-controlled randomised phase 4 trial. The Lancet Neurology, 10(8), 691-701.

5 . Revision History

Date	Notes
5/11/2022	2022 Annual Review. Updated criteria

Prior Authorization Guideline

Guideline Name	Temodar (temozolomide)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	7/9/2013
P&T Revision Date:	08/15/2019 ; 07/15/2020 ; 07/21/2021 ; 07/20/2022 ; 5/18/2023

1 . Indications

Drug Name: Temodar (temozolomide)
Newly Diagnosed Glioblastoma Indicated for the treatment of adult patients with newly diagnosed glioblastoma concomitantly with radiotherapy and then as maintenance treatment. **Refractory Anaplastic Astrocytoma** Indicated for the treatment of adult patients with refractory anaplastic astrocytoma, who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine.

2 . Criteria

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Glioblastoma, Anaplastic Astrocytoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Glioblastoma
- Anaplastic Astrocytoma

AND

2 - Prescribed by or in consultation with an oncologist

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Glioblastoma, Anaplastic Astrocytoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Temodar Prescribing Information, Merck & Co, Inc. Whitehouse Station, NJ. November 2019.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Central Nervous System Cancers v.2.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf. Accessed on July 6, 2022.

4 . Revision History

Date	Notes
5/4/2023	Program update to remove criterion related to concomitant use or previous therapeutic use

Prior Authorization Guideline

Guideline Name	Tepmetko (tepotinib) - PA, NF

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	4/21/2021
P&T Revision Date:	07/21/2021 ; 12/15/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Tepmetko (tepotinib)
Non-small cell lung cancer (NSCLC) Indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (MET) exon 14 skipping alterations.

2 . Criteria

Product Name: Tepmetko	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is metastatic

AND

3 - Presence of mesenchymal-epithelial transition (MET) exon 14 skipping alterations [A]

AND

4 - Prescribed by or in consultation with an oncologist

AND

5 - One of the following:

5.1 Trial and failure, contraindication, or intolerance to Tabrecta

OR

5.2 For continuation of prior therapy

Product Name: Tepmetko	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Tepmetko	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is metastatic

AND

3 - Presence of mesenchymal-epithelial transition (MET) exon 14 skipping alterations [A]

AND

4 - Prescribed by or in consultation with an oncologist

AND

5 - One of the following:

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Tabrecta

OR

5.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

3 . Endnotes

A. An FDA-approved test for detection of MET exon 14 skipping alterations in NSCLC for selecting patients for treatment with Tepmetko is not available. Testing for the presence of MET exon 14 skipping alterations in plasma specimens is recommended only in patients for whom a tumor biopsy cannot be obtained. [1]

4 . References

1. Tepmetko Prescribing Information. EMD Serono, Inc. Rockland, MA. February 2021.

5 . Revision History

Date	Notes
4/22/2023	Annual review: no criteria changes.

Prior Authorization Guideline

Guideline Name	Teriparatide Products

Guideline Note:

Effective Date:	5/1/2022
P&T Approval Date:	
P&T Revision Date:	1/19/2022

1 . Indications

Drug Name: Forteo (teriparatide injection), Teriparatide (teriparatide injection)
Postmenopausal women with osteoporosis at high risk of fracture Indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, teriparatide reduces the risk of vertebral and nonvertebral fractures. **Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture** Indicated to increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. **Men and women with glucocorticoid-induced osteoporosis at high risk for fracture** Indicated for the treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

2 . Criteria

Product Name: Forteo	
Diagnosis	Postmenopausal osteoporosis or osteopenia at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of postmenopausal osteoporosis or osteopenia

AND

2 - One of the following: [2,4,8,10,D]

2.1 Both of the following:

2.1.1 Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.1.2 One of the following:

2.1.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.1.2.2 Trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

OR

2.2 Both of the following:

2.2.1 BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following:

2.2.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.2.2.2 Both of the following:

2.2.2.2.1 Trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

AND

2.2.2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities: [F]

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

AND

3 - Trial and failure or intolerance to Brand Teriparatide

AND

4 - One of the following: [7,B]

4.1 Treatment duration of parathyroid hormones (e.g., teriparatide) has not exceeded a total of 24 months during the patient's lifetime

OR

4.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide)

Product Name: Brand Teriparatide	
Diagnosis	Postmenopausal osteoporosis or osteopenia at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of postmenopausal osteoporosis or osteopenia

AND

2 - One of the following: [2,4,8,10,D]

2.1 Both of the following:

2.1.1 Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.1.2 One of the following:

2.1.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.1.2.2 Trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

OR

2.2 Both of the following:

2.2.1 BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following:

2.2.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.2.2.2 Both of the following:

2.2.2.2.1 Trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

AND

2.2.2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities: [F]

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

AND

3 - One of the following: [7,B]

3.1 Treatment duration of parathyroid hormones (e.g., teriparatide) has not exceeded a total of 24 months during the patient's lifetime

OR

3.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide)

Product Name: Forteo, Brand Teriparatide	
Diagnosis	Postmenopausal osteoporosis or osteopenia at high risk for fracture
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following: [7,B]

1.1 Treatment duration of parathyroid hormones (e.g., teriparatide) has not exceeded a total of 24 months during the patient's lifetime

OR

1.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide)

Product Name: Forteo	
Diagnosis	Primary or hypogonadal osteoporosis or osteopenia at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary or hypogonadal osteoporosis or osteopenia

AND

2 - One of the following: [2,4,8,10,D]

2.1 Both of the following:

2.1.1 Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.1.2 One of the following:

2.1.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.1.2.2 Trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

OR

2.2 Both of the following:

2.2.1 BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following:

2.2.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.2.2.2 Both of the following:

2.2.2.2.1 Trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

AND

2.2.2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities: [F]

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

AND

3 - Trial and failure or intolerance to Brand Teriparatide

AND

4 - One of the following: [7,B]

4.1 Treatment duration of parathyroid hormones (e.g., teriparatide) has not exceeded a total of 24 months during the patient's lifetime

OR

4.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide)

Product Name: Brand Teriparatide	
Diagnosis	Primary or hypogonadal osteoporosis or osteopenia at high risk for fracture

Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary or hypogonadal osteoporosis or osteopenia

AND

2 - One of the following: [2,4,8,10,D]

2.1 Both of the following:

2.1.1 Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.1.2 One of the following:

2.1.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.1.2.2 Trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

OR

2.2 Both of the following:

2.2.1 BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following:

2.2.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.2.2.2 Both of the following:

2.2.2.2.1 Trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

AND

2.2.2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities: [F]

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

AND

3 - One of the following: [7,B]

3.1 Treatment duration of parathyroid hormones (e.g., teriparatide) has not exceeded a total of 24 months during the patient's lifetime

OR

3.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide)

Diagnosis	Primary or hypogonadal osteoporosis or osteopenia at high risk for fracture
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following: [7,B]

1.1 Treatment duration of parathyroid hormones (e.g., teriparatide) has not exceeded a total of 24 months during the patient's lifetime

OR

1.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide)

Product Name: Forteo	
Diagnosis	Glucocorticoid-induced osteoporosis at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of glucocorticoid-induced osteoporosis

AND

2 - History of prednisone or its equivalent at a dose greater than or equal to 5 mg/day for greater than or equal to 3 months [C]

AND

3 - One of the following: [8,A]

3.1 BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site)

OR

3.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

OR

3.3 History of one of the following fractures resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

AND

4 - Trial and failure, contraindication, or intolerance to one bisphosphonate (e.g., alendronate) [E]

AND

5 - Trial and failure or intolerance to Brand Teriparatide

AND

6 - One of the following: [7,B]

6.1 Treatment duration of parathyroid hormones (e.g., teriparatide) has not exceeded a total of 24 months during the patient's lifetime

OR

6.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide)

Product Name: Brand Teriparatide	
Diagnosis	Glucocorticoid-induced osteoporosis at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of glucocorticoid-induced osteoporosis

AND

2 - History of prednisone or its equivalent at a dose greater than or equal to 5 mg/day for greater than or equal to 3 months [C]

AND

3 - One of the following: [8,A]

3.1 BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site)

OR

3.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

OR

3.3 History of one of the following fractures resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

AND

4 - Trial and failure, contraindication, or intolerance to one bisphosphonate (e.g., alendronate) [E]

AND

5 - One of the following: [7,B]

5.1 Treatment duration of parathyroid hormones (e.g., teriparatide) has not exceeded a total of 24 months during the patient's lifetime

OR

5.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide)

Product Name: Forteo, Brand Teriparatide	
Diagnosis	Glucocorticoid-induced osteoporosis at high risk for fracture
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following: [7,B]

1.1 Treatment duration of parathyroid hormones (e.g., teriparatide) has not exceeded a total of 24 months during the patient's lifetime

OR

1.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide)

3 . Definitions

Definition	Description
Dual x-ray absorptiometry (DXA) [3]	A diagnostic test used to assess bone density in the spine, hip, or wrist using radiation exposure about one tenth that of a standard chest x-ray. Central DXA (spine, hip) is the preferred measurement for definitive diagnosis and for monitoring the effects of therapy.
Osteopenia [3]	The designation for bone density between 1.0 and 2.5 standard deviations below the mean for young normal adults (T-score between -1 and -2.5).
Osteoporosis [3]	A chronic, progressive disease characterized by low bone mass, microarchitectural deterioration and decreased bone strength, bone fragility and a consequent increase in fracture risk; bone density 2.5 or more standard deviations below the young normal mean (T-score at or below -2.5).
Quantitative computed tomography (QCT) [3]	A diagnostic test used to assess bone density; reflects three-dimensional bone mineral density. Usually used to assess the lumbar spine, but has been adapted for other skeletal sites. It is also possible to measure trabecular and cortical bone density in the periphery by peripheral QCT (pQCT).

T-score [3]	In describing bone mineral density, the number of standard deviations above or below the mean for young normal adults of the same sex.
Z-score [3]	In describing bone mineral density, the number of standard deviations above or below the mean for persons of the same age and sex.

4 . Endnotes

A. According to the American College of Rheumatology (ACR) guidelines for the prevention and treatment of glucocorticoid-induced osteoporosis, patients considered at high risk of fractures are as follows: (a) prior osteoporotic fracture, (b) a hip or spine BMD T-score less than or equal to -2.5, or (c) FRAX 10-year risk of hip or major osteoporotic fracture at 3 percent or more and 20 percent or more, respectively. [9]
B. Use for more than 2 years during a patient's lifetime should only be considered if a patient remains at or has returned to having a high risk for fracture. [1]
C. Most of the evidence supporting the efficacy of Forteo is based on studies evaluating its use in the treatment of glucocorticoid-induced osteoporosis (GIOP). To identify high risk patients, the GIOP studies (Saag et al, 2009) included patients with a history of prednisone or its equivalent at a dose greater than or equal to 5 mg/day for greater than or equal to 3 months. [5, 6]
D. According to AACE, alendronate, risedronate, zoledronic acid, or denosumab have evidence for broad spectrum anti-fracture efficacy (spine, hip, nonvertebral fracture risk reduction) and are appropriate as initial therapy for most patients at high risk of fracture. Raloxifene or ibandronate may be appropriate initial therapy in some cases where patients requiring drugs with spine-specific efficacy. Teriparatide has been shown to reduce the risk of vertebral and nonvertebral fractures. It is recommended for patients with very high fracture risk or those in whom bisphosphonate therapy has been ineffective. [2]
E. According to ACR, oral bisphosphonates are considered first-line for patients with glucocorticoid-induced osteoporosis at high risk for fractures. For patients in whom oral bisphosphonates are not appropriate, IV bisphosphonates should be considered. If bisphosphonate therapy is not appropriate, teriparatide should be considered. [9]
F. The WHO FRAX tool is available at www.shef.ac.uk/FRAX and incorporates multiple clinical factors that predict fracture risk, largely independent of BMD. [2]

5 . References

1. Forteo prescribing information. Eli Lilly and Company. Indianapolis, IN. April 2021.
2. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the prevention and treatment of postmenopausal osteoporosis: 2020 update. Available at: https://pro.aace.com/disease-state-resources/bone-and-parathyroid/clinical-practice-guidelines/clinical-practice. Accessed May 6, 2021.

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4. North American Menopause Society. Management of postmenopausal osteoporosis in postmenopausal women: 2010 position statement of the North American Menopause Society. Menopause 2010;17(1):25-54.
5. Per clinical consult with bone disease specialist, September 26, 2011.
6. Saag KG, Zanchetta JR, Devogelaer JP, et al. Effects of teriparatide versus alendronate for treating glucocorticoid-induced osteoporosis: thirty-six-month results of a randomized, double-blind, controlled trial. Arthritis Rheum. 2009;60(11):3346-55.
7. Per clinical consultation with endocrinologists. January 23 & 30, 2018.
8. American College of Rheumatology guideline for the prevention and treatment of glucocorticoid-induced osteoporosis: 2017 edition. Available at: https://www.rheumatology.org/Portals/0/Files/Guideline-for-the-Prevention-and-Treatment-of-GIOP.pdf. Accessed January 23, 2018.
9. Eastell R, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: An endocrine society clinical practice guideline. J Clin Endocrin Metab. 2019; 104(5):1595-1622.
10. Teriparatide prescribing information. Alvogen, Inc. Morristown, NJ. November 2019.

6 . Revision History

Date	Notes
9/13/2022	EHB guideline

Prior Authorization Guideline

Guideline Name	Testosterone

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	
P&T Revision Date:	11/14/2019 ; 02/13/2020 ; 02/13/2020 ; 04/15/2020 ; 04/21/2021 ; 03/16/2022 ; 05/19/2022 ; 09/21/2022 ; 08/18/2022 ; 09/21/2022 ; 11/17/2022 ; 01/18/2023 ; 02/16/2023 ; 03/15/2023 ; 4/19/2023

1 . Indications

Drug Name: Androderm (testosterone [T] patch), Androgel (T gel and pump), Fortesta (T gel), Natesto (T nasal gel), Testim (T gel), and Vogelxo (T gel and pump)
Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy or toxic damage from alcohol or heavy metals. These men usually have low testosterone serum levels and gonadotropins (FSH, LH) above the normal range. Important limitations of use: Safety and efficacy in men with "age-related hypogonadism (also referred to as "late-onset hypogonadism") have not been established. Safety and efficacy in males less than 18 years old have not been established. Topical testosterone products may have different doses, strengths, or application instructions that may result in different systemic exposure. **Hypogonadotropic hypogonadism (congenital or acquired)** Indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

Important limitations of use: Safety and efficacy in men with "age-related hypogonadism (also referred to as "late-onset hypogonadism") have not been established. Safety and efficacy in males less than 18 years old have not been established. Topical testosterone products may have different doses, strengths, or application instructions that may result in different systemic exposure.

Drug Name: Methitest (methyltestosterone) tablet

Delayed puberty in males Indicated for stimulation of puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be obtained every six months to assess the effect of treatment on the epiphyseal centers.

Metastatic mammary cancer in females Indicated for secondary use in women with advancing inoperable metastatic (skeletal) mammary cancer who are 1 to 5 years postmenopausal. Primary goals of therapy in these women include ablation of the ovaries. Other methods of counteracting estrogen activity are adrenalectomy, hypophysectomy, and/or antiestrogen therapy. This treatment has also been used in premenopausal women with breast cancer who have benefited from oophorectomy and are considered to have a hormone-responsive tumor. Judgment concerning androgen therapy should be made by an oncologist with expertise in this field.

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome, or orchidectomy.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired) is idiopathic gonadotropin or LHRH deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation. If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty.

Drug Name: Depo-Testosterone (testosterone cypionate) injection

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchiectomy. Safety and efficacy of Depo-Testosterone (testosterone cypionate) in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement

therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired) - Gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. Safety and efficacy of Depo-Testosterone (testosterone cypionate) in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

Drug Name: Testopel (testosterone) pellet

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchiectomy. If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sex characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty. Safety and efficacy of Testopel in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism" have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired)- idiopathic gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty. If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sex characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty. Safety and efficacy of Testopel in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism" have not been established.

Delayed puberty in males Indicated for stimulation of puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be obtained every six months to assess the effect of treatment on the epiphyseal centers.

Drug Name: Aveed (testosterone undecanoate) injection

Primary hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually

have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Aveed should only be used in patients who require testosterone replacement therapy and in whom the benefits of the product outweigh the serious risks of pulmonary oil microembolism and anaphylaxis. Limitations of use: Safety and efficacy of Aveed in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established. Safety and efficacy of Aveed in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired): idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Aveed should only be used in patients who require testosterone replacement therapy and in whom the benefits of the product outweigh the serious risks of pulmonary oil microembolism and anaphylaxis. Limitations of use: Safety and efficacy of Aveed in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established. Safety and efficacy of Aveed in males less than 18 years old have not been established.

Drug Name: Testone CIK (testosterone cypionate) injection

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome; or orchidectomy. Limitations of Use: Safety and efficacy of testosterone cypionate in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired) - idiopathic gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. Limitations of Use: Safety and efficacy of testosterone cypionate in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.

Drug Name: Xyosted (testosterone enanthate) injection

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) - Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter’s syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (FSH, LH) above the normal range. Safety and efficacy of Xyosted in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired) - Gonadotropin or

LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Safety and efficacy of Xyosted in males less than 18 years old have not been established.

Drug Name: Jatenzo (testosterone undecanoate) capsule

Primary hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Limitations of Use: Safety and efficacy of Jatenzo in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Hypogonadotropic hypogonadism (congenital or acquired) is gonadotropin or luteinizing hormone releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Limitations of Use: Safety and efficacy of Jatenzo in males less than 18 years old have not been established.

Drug Name: Tlando (testosterone undecanoate) capsule

Primary hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Limitations of Use: Safety and efficacy of Tlando in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Hypogonadotropic hypogonadism (congenital or acquired) is gonadotropin or luteinizing hormone releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Limitations of Use: Safety and efficacy of Tlando in males less than 18 years old have not been established.

Drug Name: Kyzatrex (testosterone undecanoate) capsule

Primary hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually

have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Limitations of Use: Safety and efficacy of Kyzatrex in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Hypogonadotropic hypogonadism (congenital or acquired) is gonadotropin or luteinizing hormone releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Limitations of Use: Safety and efficacy of Kyzatrex in males less than 18 years old have not been established.

Drug Name: Androderm, Androgel, Aveed, Depo-Testosterone, Fortesta, Methitest, Natesto, Testone CIK, Testim, Testopel, Vogelxo, Xyosted

Off Label Uses: Transgender male (female-to-male) - Gender Dysphoria/Gender Incongruence [11-12, 17, 28-29] Testosterone in 3 different formulations, including transdermal gel, significantly increased testosterone levels from the physiological range for women to the normal male range by week 30 of treatment in an observational study in transgender male (female-to-male) individuals. Hormonal sex reassignment therapy was associated with significantly fewer symptoms related to social distress, anxiety, and depression compared with those not receiving hormonal therapy in 1 cross-sectional study. Gender transition treatment can be initiated in adults and adolescents with confirmed persistent gender dysphoria/gender incongruence who have the capacity to make fully informed decisions and consent, usually by age 16 years, and have well-controlled, if any, mental health concerns. The goals of therapy are to suppress endogenous sex hormones of the designated gender and to replace these with endogenous sex hormones of the affirmed gender. Either parenteral or transdermal testosterone may be used to achieve and maintain testosterone levels in the normal male range. Avoid sustained supraphysiologic levels to reduce risk of adverse reactions. Compelling reasons may exist to initiate therapy at younger than 16 years; although, studies in this population are minimal. Initial therapy to undergo suppression of pubertal development at Tanner stages G2/B2 is suggested. Neither puberty suppression nor gender-affirming hormone therapies are recommended in pre-pubertal children.

2 . Criteria

Product Name: Androderm, Brand Androgel gel and pump (1%), Brand Androgel gel and pump (1.62%), Generic testosterone gel and pump 20.25 mg/1.25 g, 40.5 mg/2.5 g (1.62%), Natesto, Generic testosterone gel 25 mg/2.5 g (1%), Generic testosterone gel 50 mg/5 g (1%), Generic testosterone gel pump (1%), Generic testosterone topical solution 30 mg/act, Generic testosterone gel 10 mg/act (2%), Aveed, Generic testosterone enanthate, Brand Depo-Testosterone, Brand Fortesta, Brand Testim, Brand Testosterone Cypionate, Testone CIK, Testopel, Testosterone implant pellets, Brand Testosterone Propionate, Xyosted, Brand Vogelxo

Diagnosis	Male hypogonadism
Approval Length	6 months for patients new to testosterone therapy; or 12 months for patients continuing testosterone therapy but without a current authorization on file. [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hypogonadism (e.g., testicular hypofunction, male hypogonadism)

AND

2 - Male patient at birth [C]

AND

3 - Patient is 18 years of age or older

AND

4 - One of the following:

4.1 Two pre-treatment serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L) or less than the reference range for the lab** [7, 9]

OR

4.2 Both of the following:

4.2.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

4.2.2 One pre-treatment calculated free or bioavailable testosterone level less than 5 ng/dL (< 0.17 nmol/L) or less than the reference range for the lab**

OR

4.3 Patient has a history of one of the following:

- Bilateral orchiectomy
- Panhypopituitarism
- A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

OR

4.4 Both of the following:

4.4.1 Patient is continuing testosterone therapy

AND

4.4.2 One of the following:

4.4.2.1 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is within or below the normal limits of the reporting lab

OR

4.4.2.2 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted

AND

5 - Trial and failure or intolerance to both of the following (applies to Aveed, Testopel, Testosterone implant pellets, Testone CIK, Brand Depo-Testosterone, Brand Testosterone Cypionate and Brand Testosterone Propionate only):

- Generic testosterone cypionate
- Generic testosterone enanthate

AND

6 - Trial and failure or intolerance to generic testosterone gel (applies to Brand Androgel, Brand Fortesta, Brand Testim, Brand Vogelxo, and Brand Natesto only)

Notes	**This may require treatment to be temporarily held.

Product Name: Generic testosterone cypionate	
Diagnosis	Male hypogonadism
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hypogonadism (e.g., testicular hypofunction, male hypogonadism)

AND

2 - Male patient at birth [C]

AND

3 - Patient is 18 years of age or older

AND

4 - One of the following:

4.1 Two pre-treatment serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L) or less than the reference range for the lab** [7, 8]

OR

4.2 Both of the following:

4.2.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

4.2.2 One pre-treatment calculated free or bioavailable testosterone level less than 5 ng/dL (< 0.17 nmol/L) or less than the reference range for the lab**

OR

4.3 Patient has a history of one of the following:

- Bilateral orchiectomy
- Panhypopituitarism
- A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

OR

4.4 Both of the following:

4.4.1 Patient is continuing testosterone therapy

AND

4.4.2 One of the following:

4.4.2.1 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is within or below the normal limits of the reporting lab

OR

4.4.2.2 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted

Notes	**This may require treatment to be temporarily held.

Product Name: Methitest, Generic methyltestosterone, Jatenzo, Kyzatrex, Tlando	
Diagnosis	Male hypogonadism
Approval Length	6 months for patients new to testosterone therapy; or 12 months for patients continuing testosterone therapy but without a current authorization on file. [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hypogonadism (e.g., testicular hypofunction, male hypogonadism)

AND

2 - Male patient at birth [C]

AND

3 - Patient is 18 years of age or older

AND

4 - One of the following:

4.1 Two pre-treatment serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L) or less than the reference range for the lab*** [7, 8]

OR

4.2 Both of the following:

4.2.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

4.2.2 One pre-treatment calculated free or bioavailable testosterone level less than 5 ng/dL (< 0.17 nmol/L) or less than the reference range for the lab***

OR

4.3 Patient has a history of one of the following:

- Bilateral orchiectomy
- Panhypopituitarism
- A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

OR

4.4 Both of the following:

4.4.1 Patient is continuing testosterone therapy

AND

4.4.2 One of the following:

4.4.2.1 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is within or below the normal limits of the reporting lab

OR

4.4.2.2 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted

AND

5 - Trial and failure or intolerance to both of the following:

- Androderm (testosterone patch)
- Generic testosterone gel

Notes	***This may require treatment to be temporarily held.

Product Name: Androderm, Brand Androgel gel and pump (1%), Generic testosterone gel 25 mg/2.5 g (1%), Brand Androgel gel and pump (1.62%), Generic testosterone gel and pump 20.25 mg/1.25 g, 40.5 mg/2.5 g (1.62%), Generic testosterone topical solution 30 mg/act, Brand Fortesta, Generic testosterone gel 10 mg/act (2)%, Jatenzo, Kyzatrex, Methitest, Natesto, Brand Testim, Generic methyltestosterone, Brand Vogelxo gel and pump (1%), Generic testosterone gel 50 mg/5 g (1%), Generic testosterone pump (1%), Aveed, Generic testosterone enanthate, Brand Depo-Testosterone, Brand Testosterone Cypionate, Testone CIK, Testopel, Testosterone implant pellets, Brand Testosterone Propionate, Tlando, Xyosted	
Diagnosis	Gender Dysphoria/Gender Incongruence (off-label) [11-12, 17, 26 D]
Approval Length	6 months for patients new to testosterone therapy; or 12 months for patients continuing testosterone therapy but without a current authorization on file [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gender dysphoria/gender incongruence [11-12, 17, 26]

AND

2 - Using hormones to change characteristics to align with gender expression [11, 17, 28-29]

AND

3 - Trial and failure or intolerance to both of the following (applies to Aveed, Testopel,

Testosterone implant pellets, Testone CIK, Brand Depo-Testosterone, Brand Testosterone Cypionate, Brand Testosterone Propionate):

- Generic testosterone cypionate
- Generic testosterone enanthate

AND

4 - Trial and failure or intolerance to generic testosterone (applies to Brand Androgel, Brand Fortesta, Brand Testim, Brand Vogelxo, Brand Natesto only)

Product Name: Generic testosterone cypionate	
Diagnosis	Gender Dysphoria/Gender Incongruence (off-label) [11-12, 17, 26 D]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gender dysphoria/gender incongruence [11-12, 17, 26]

AND

2 - Using hormones to change characteristics to align with gender expression [11, 17, 28-29]

Product Name: Androderm, Brand Androgel gel and pump (1%), Generic testosterone gel 25 mg/2.5 g (1%), Brand Androgel gel and pump (1.62%), Generic testosterone gel and pump 20.25 mg/1.25 g, 40.5 mg/2.5 g (1.62%), Generic testosterone topical solution 30 mg/act, Brand Fortesta, Generic testosterone gel 10 mg/act (2)%, Jatenzo, Kyzatrex, Methitest, Natesto, Brand Testim, Generic methyltestosterone, Brand Vogelxo gel and pump (1%), Generic testosterone gel 50 mg/5 g (1%), Generic testosterone pump (1%), Aveed, Generic testosterone enanthate, Brand Depo-Testosterone, Brand Testosterone Cypionate, Generic testosterone cypionate, Testone CIK, Testopel, Testosterone implant pellets, Brand Testosterone Propionate, Tlando, Xyosted	
Diagnosis	Male hypogonadism, Gender dysphoria/Gender incongruence
Approval Length	12 Month [B]
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Follow-up total serum testosterone level drawn within the past 6 months for patients new to testosterone therapy, or 12 months for patients continuing testosterone therapy, is within or below the normal limits of the reporting lab

OR

1.2 Follow-up total serum testosterone level drawn within the past 6 months for patients new to testosterone therapy, or 12 months for patients continuing testosterone therapy, is outside of upper limits of normal for the reporting lab and the dose is adjusted

OR

1.3 Both of the following:

1.3.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

1.3.2 One of the following:

1.3.2.1 Follow-up calculated free or bioavailable testosterone level drawn within the past 6 months for patients new to testosterone therapy, or 12 months for patients continuing testosterone therapy, is within or below the normal limits of the reporting lab

OR

1.3.2.2 Follow-up calculated free or bioavailable testosterone level drawn within the past 6 months for patients new to testosterone therapy, or 12 months for patients continuing testosterone therapy, is outside of upper limits of normal for the reporting lab and the dose is adjusted

Product Name: Methitest, Generic testosterone enanthate, Testopel, Testosterone implant pellets, Generic methyltestosterone, Brand Testosterone Cypionate [off-label]	
Diagnosis	Delayed puberty [E]
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of delayed puberty [A]

AND

2 - Male patient at birth [C]

AND

3 - Trial and failure or intolerance to both of the following (applies to Testopel and Testosterone implant pellets only):

- Generic testosterone cypionate [F]
- Generic testosterone enanthate

Product Name: Generic testosterone cypionate [off-label]	
Diagnosis	Delayed puberty [E]
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of delayed puberty [A]

AND

2 - Male patient at birth [C]

Product Name: Methitest, Generic methyltestosterone, Generic testosterone enanthate	
Diagnosis	Inoperable breast cancer in women
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Breast cancer is inoperable

AND

3 - Used for palliative treatment

AND

4 - Female patient at birth [C]

3 . Endnotes

A. Delayed puberty is defined as the lack of the initial signs of sexual maturation by an age that is more than 2-2.5 standard deviations above the mean for the population (traditionally, the age of 14 years in boys and 13 years in girls). In most cases, delayed puberty is not due to an underlying pathology, but instead represents an extreme end of the normal spectrum of pubertal timing, a developmental pattern referred to as constitutional delay of growth and puberty (CDGP). CDGP is the most common cause of delayed puberty in both sexes, but it can be diagnosed only after underlying conditions have been ruled out. Management of CDGP may involve expectant observation or therapy with low-dose sex steroids. [9]

B. Initial authorization of 6 months, and reauthorization of 12 months is based on the Endocrine Society's Clinical Practice Guideline's recommendation to monitor testosterone level 3 to 6 months after initiation of testosterone therapy, and then annually to assess whether symptoms have responded to treatment and whether the patient is suffering from any adverse effects. [8]
C. The gender criteria in place for male hypogonadism, delayed puberty, and inoperable breast cancer are to ensure safe and effective medication utilization due to FDA-approved labeling supporting the gender restriction [refer to individual Package Inserts]. Age and/or gender criteria will remain in the guideline, consistent with the following direction approved by Legal & Regulatory: “Age and gender edits in place due to FDA safety guidance, labeling or supported by medical literature to satisfy medical necessity criteria would not be inconsistent with the [Section 1557 HCR non-discrimination] regulation."
D. According to DRUGDEX, for the treatment of transgender male (female-to-male) patients with gender dysphoria, various forms and dosages of testosterone have been used. [12] Clinical studies have also demonstrated the efficacy of several different androgen preparations to induce masculinization in female-to-male transgender persons. Regimens to change secondary sex characteristics follow the general principle of hormone replacement treatment of male hypogonadism. Either parenteral or transdermal preparations can be used to achieve testosterone values in the normal male range. [11]
E. An X-ray of the hand and wrist to determine bone age should be taken every 6 months to assess the effect of treatment on epiphyseal center [19-20].
F. Per consult with specialist, the pharmacokinetics of T. cypionate and T. enanthate are quite similar and physiologically produce similar results. The two agents are very close in efficacy and behavioral effects. Although T. cypionate isn't FDA-approved for delayed puberty, it is used in practice due to its similarity to T. enanthate. [25]

4 . References

1. Androderm Prescribing Information. Allergan Inc. Madison, NJ. May 2020.
2. Androgel Prescribing Information. Abbvie, Inc. North Chicago, IL. May 2019.
3. Androgel 1.62% Prescribing Information. AbbVie Inc. North Chicago, IL. February 2019.
4. Fortesta Prescribing Information. Endo Pharmaceuticals. Malvern, PA. June 2020.
5. Methitest Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. October 2018.
6. Testim Prescribing Information. Endo Pharmaceuticals Inc. Malvern, PA. August 2021.
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11. Hembree, Wylie C, et al. "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline." J Clin Endocrinol Metab. November 2017, 102(11):3869-3903.

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13. Natesto Prescribing Information. Trimel BioPharma SRL. Eaglewood, CO. September 2017.
14. Testosterone Prescribing Information. Upsher-Smith Laboratories, Inc. Maple Grove, MN. July 2017.
15. Testosterone Pump Prescribing Information. Upsher-Smith Laboratories, Inc. Maple Grove, MN. July 2017.
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19. Testosterone Enanthate Prescribing Information. Actavis Pharma, Inc. Corona, CA. December 2017.
20. Testopel Prescribing Information. Slate Pharma. Rye, NY. August 2018.
21. Aveed Prescribing Information. Endo Pharmaceuticals Solutions Inc. August 2021.
22. Testone CIK Prescribing Information. Asclemed USA, Inc. Torrance, CA. November 2018.
23. Xyosted Prescribing Information. Antares Pharma, Inc. Ewing, NJ. November 2019.
24. Jatenzo Prescribing Information. Clarus Therapeutics, Inc. Northbrook, IL. June 2019.
25. Per clinical consultation with endocrinology specialist, March 02, 2020.
26. World Health Organization. ICD-11: International classification of diseases (11th revision).
27. Tlando Prescribing Information. Antares Pharma, Inc. Ewing, NJ. March 2022.
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29. Health Care for Transgender and Gender Diverse Individuals: ACOG Committee Opinion, Number 823. American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice.137(3):e75-e88, 2021
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5 . Revision History

Date	Notes
4/5/2023	Updated the step through both Generic testosterone cypionate and G eneric testosterone enanthate as drug shortage has been resolved

Prior Authorization Guideline

Guideline Name	Thalomid (thalidomide)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	5/22/2007
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 05/19/2022 ; 5/18/2023

1 . Indications

Drug Name: Thalomid (thalidomide)
Erythema Nodosum Leprosum (ENL) Indicated for the acute treatment of the cutaneous manifestations of moderate to severe ENL. Not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis. Also indicated as a maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence. **Newly Diagnosed Multiple Myeloma** Indicated in combination with dexamethasone for the treatment of patients with newly diagnosed multiple myeloma.

2 . Criteria

Product Name: Thalomid	
Diagnosis	Erythema Nodosum Leprosum (ENL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe erythema nodosum leprosum (ENL) with cutaneous manifestations

AND

2 - Thalomid is not used as monotherapy if moderate to severe neuritis is present

Product Name: Thalomid	
Diagnosis	Erythema Nodosum Leprosum (ENL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Thalomid	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - Used in combination with dexamethasone, unless the patient has an intolerance to steroids

AND

3 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Thalomid	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Thalomid Prescribing Information. Celgene Corporation. Summit, NJ. December 2022.

4 . Revision History

Date	Notes
5/3/2023	Annual review - updated references.

Prior Authorization Guideline

Guideline Name	Thyrogen (thyrotropin alfa for injection)

Guideline Note:

Effective Date:	6/1/2022
P&T Approval Date:	1/19/2001
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 4/20/2022

1 . Indications

Drug Name: Thyrogen (thyrotropin alfa for injection)
Adjunctive Diagnostic Tool for Serum Thyroglobulin Testing in Well Differentiated Thyroid Cancer Indicated for use as an adjunctive diagnostic tool for serum thyroglobulin (Tg) testing with or without radioiodine imaging in the follow-up of patients with well-differentiated thyroid cancer who have previously undergone thyroidectomy. Limitations of Use: Thyrogen-stimulated Tg levels are generally lower than, and do not correlate with, Tg levels after thyroid hormone withdrawal. Even when Thyrogen-stimulated Tg testing is performed in combination with radioiodine imaging, there remains a risk of missing a diagnosis of thyroid cancer or of underestimating the extent of disease. Anti-Tg antibodies may confound the Tg assay and render Tg levels uninterpretable. Therefore, in such cases, even with a negative or low-stage Thyrogen radioiodine scan, consideration should be given to further evaluating patients. **Adjunct to Treatment for Ablation in Well Differentiated Thyroid Cancer** Indicated for use as an adjunctive treatment for radioiodine ablation of thyroid tissue remnants in patients who have undergone a near-total or total thyroidectomy for well-differentiated thyroid cancer and who do not have evidence of distant metastatic thyroid cancer. Limitations of Use: The effect of Thyrogen on long-term thyroid cancer outcomes has not been determined. Due to the relatively small clinical experience with Thyrogen in remnant ablation, it is not possible to

conclude whether long-term thyroid cancer outcomes would be equivalent after use of Thyrogen or use of thyroid hormone withholding for TSH elevation prior to remnant ablation.

2 . Criteria

Product Name: Thyrogen	
Approval Length	1 course of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Thyrogen is being used as a diagnostic tool for serum thyroglobulin testing in well differentiated thyroid cancer

OR

1.2 All of the following:

1.2.1 Thyrogen is being used as an adjunctive treatment for radioiodine ablation of thyroid tissue remnants

AND

1.2.2 Patient has undergone a near-total or total thyroidectomy for well-differentiated thyroid cancer

AND

1.2.3 Patient does not have evidence of distant metastatic thyroid cancer

AND

2 - One of the following:

2.1 Patient is unable to tolerate thyroid hormone withdrawal (ie, intolerable hypothyroid symptoms) [1,2]

OR

2.2 Thyroid hormone withdrawal is medically contraindicated (ie, exacerbation of comorbid conditions) [1,2]

OR

2.3 Patient has inadequate thyroid stimulating hormone (TSH) response to thyroid hormone withdrawal [1]

OR

2.4 Patient has an undetectable Tg on thyroid hormone suppressive therapy, to exclude the diagnosis of residual or recurrent thyroid cancer [1]

3 . References

1. Thyrogen Package Insert. Genzyme Corporation. Cambridge, MA. March 2020.
2. Cooper DS, Doherty GM, Haugen BR, et al. Revised American Thyroid Association Management Guidelines. For Patients with Thyroid Nodules and Differentiated Thyroid Cancer. Thyroid. 2009;19 (11):1167-1214.

4 . Revision History

Date	Notes
3/28/2022	2022 Annual Review - No changes to criteria, updated background in formation

Prior Authorization Guideline

Guideline Name	Tier Lowering Exceptions Process

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	5/28/2014
P&T Revision Date:	11/14/2019 ; 11/12/2020 ; 11/18/2021 ; 11/17/2022

Note:

The intent of this policy is to serve as guidance for clients who would like to implement a Tier Lowering program.

1 . Criteria

Product Name: Tier Lowering Exceptions Process	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - A prescribed drug will be considered for coverage under the prescribed drug's lower tier when one of the following are met:

1.1 All lower-tiered medication alternatives would be less effective or have been

demonstrated to be ineffective for treating the patient's condition when used at optimized dose and frequency

OR

1.2 All lower-tiered medication alternatives would have adverse effects (intolerance or contraindication) in the treatment of the patient's condition.

2 . Revision History

Date	Notes
11/2/2022	Annual review: No updates required.

Prior Authorization Guideline

Guideline Name	Tobramycin Inhaled Products - ST, NF

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	5/21/2013
P&T Revision Date:	04/15/2020 ; 12/16/2020 ; 01/20/2021 ; 04/21/2021 ; 01/19/2022 ; 04/20/2022 ; 5/18/2023

1 . Indications

Drug Name: Bethkis (tobramycin) Inhalation Solution
Cystic Fibrosis Indicated for the management of cystic fibrosis patients with Pseudomonas aeruginosa. Safety and efficacy have not been demonstrated in patients under the age of six years, patients with FEV 1 less than 40% or greater than 80% predicted, or patients colonized with Burkholderia cepacia.
Drug Name: Kitabis Pak (co-packaged tobramycin inhalation solution PARI LC PLUS reusable nebulizer)
Cystic fibrosis Indicated for the management of cystic fibrosis in adults and pediatric patients 6 years of age and older with P. aeruginosa. Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with FEV1 less than 25% or greater than 75% predicted, or patients colonized with Burkholderia cepacia.
Drug Name: TOBI (tobramycin) Inhalation Solution
Cystic fibrosis Indicated for the management of cystic fibrosis in adults and pediatric patients 6 years of age and older with Pseudomonas aeruginosa. Safety and efficacy have not been

demonstrated in patients under the age of 6 years, patients with forced expiratory volume in 1 second (FEV1) <25% or >75% predicted, or patients colonized with Burkholderia cepacia.

2 . Criteria

Product Name: Brand Bethkis Inhalation Solution, Kitabis Pak, Brand TOBI Inhalation Solution	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication.

AND

2 - Trial and failure of a minimum 30 day supply, or intolerance to both of the following:

generic tobramycin 300 mg/4 ml nebulized solution

generic tobramycin 300 mg/5 ml nebulized solution

Product Name: Brand Bethkis Inhalation Solution, Kitabis Pak, Brand TOBI Inhalation Solution	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication.

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure of a minimum 30 day supply, or intolerance to both of the following:

generic tobramycin 300 mg/4 ml nebulized solution

generic tobramycin 300 mg/5 ml nebulized solution

3 . References

Kitabis Pak Prescribing Information. Catalent Pharma Solutions, LLC. Woodstock, IL. April 2023.

TOBI Prescribing Information. Novartis Pharmaceuticals. East Hanover, NJ. February 2023.

Bethkis Prescribing Information. Chiesi USA, Inc. Woodstock, IL. February 2023.

4 . Revision History

Date	Notes
5/5/2023	Annual review: No criteria changes. Updated indications and references. Attached EHB formulary.

Prior Authorization Guideline

Guideline Name	Tolvaptan Products

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	4/21/2021
P&T Revision Date:	02/17/2022 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Samsca (tolvaptan)
Hyponatremia, hypervolemic and euvolemic Indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia (serum sodium < 125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure and Syndrome of Inappropriate Antidiuretic Hormone (SIADH). Important limitations: Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms should not be treated with Samsca. It has not been established that raising serum sodium with Samsca provides a symptomatic benefit to patients.
Drug Name: Jynarque (tolvaptan)
Autosomal Dominant Polycystic Kidney Disease Indicated to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).

2 . Criteria

Product Name: Brand Samsca or Generic tolvaptan	
Approval Length	30 Days [1]
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

Diagnosis of significant euvolemic hyponatremia [1-3, A-B]

Diagnosis of significant hypervolemic hyponatremia [1-3, A, C]

AND

2 - Treatment has been initiated or re-initiated in a hospital setting prior to discharge within the past 30 days [1, D]

AND

3 - Trial and failure or intolerance to generic tolvaptan (applies to Brand Samsca only)

Product Name: Jynarque	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD)

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient has received Jynarque for less than or equal to 18 months

AND

2.1.2 Alanine transaminase (ALT), aspartate transaminase (AST), and bilirubin will be measured prior to initiation, at 2 weeks and 4 weeks after initiation, then monthly for the first 18 months of therapy [E]

OR

2.2 Both of the following:

2.2.1 Patient has received Jynarque for longer than 18 months

AND

2.2.2 ALT, AST, and bilirubin will be measured at least every 3 months [E]

AND

3 - Patient does not have a history of significant liver impairment or injury, not including uncomplicated polycystic liver disease [E]

Product Name: Jynarque	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - One of the following:

2.1 Patient does not have signs or symptoms consistent with hepatic injury [E]

OR

2.2 Patient has uncomplicated polycystic liver disease

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 Patient has received Jynarque for less than or equal to 18 months

AND

3.1.2 Alanine transaminase (ALT), aspartate transaminase (AST), and bilirubin will be measured prior to initiation, at 2 weeks and 4 weeks after initiation, then monthly for the first 18 months of therapy [E]

OR

3.2 Both of the following:

3.2.1 Patient has received Jynarque for longer than 18 months

AND

3.2.2 ALT, AST, and bilirubin will be measured at least every 3 months [E]

Product Name: Jynarque	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

2.1 Both of the following:

2.1.1 Patient has received Jynarque for less than or equal to 18 months

AND

2.1.2 Alanine transaminase (ALT), aspartate transaminase (AST), and bilirubin will be measured prior to initiation, at 2 weeks and 4 weeks after initiation, then monthly for the first 18 months of therapy [E]

OR

2.2 Both of the following:

2.2.1 Patient has received Jynarque for longer than 18 months

AND

2.2.2 ALT, AST, and bilirubin will be measured at least every 3 months [E]

AND

3 - Patient does not have a history of significant liver impairment or injury, not including uncomplicated polycystic liver disease [E]

Product Name: Jynarque	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - One of the following:

2.1 Patient does not have signs or symptoms consistent with hepatic injury [E]

OR

2.2 Patient has uncomplicated polycystic liver disease

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

3.1 Both of the following:

3.1.1 Patient has received Jynarque for less than or equal to 18 months

AND

3.1.2 Alanine transaminase (ALT), aspartate transaminase (AST), and bilirubin will be

measured prior to initiation, at 2 weeks and 4 weeks after initiation, then monthly for the first 18 months of therapy [E]

OR

3.2 Both of the following:

3.2.1 Patient has received Jynarque for longer than 18 months

AND

3.2.2 ALT, AST, and bilirubin will be measured at least every 3 months [E]

3 . Endnotes

Normal extracellular fluid volume and osmolality are maintained when the serum sodium concentration is regulated within a narrow range (136 to 148 mEq/L). [2] Hypotonic hyponatremia, a disorder of impaired water excretion rather than salt depletion, results from the kidneys' inability to excrete enough free water to offset water intake. [2] Hypotonic hyponatremia is classified based on the patient's extracellular fluid (ECF) volume status as hypovolemic hyponatremia, euvolemic hyponatremia, or hypervolemic hyponatremia. [3] Samsca is indicated for the treatment of clinically significant euvolemic and hypervolemic hyponatremia, defined as a serum sodium of less than 125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction. [1]

Many different hypo-osmolar disorders can potentially present clinically with a normal ECF volume, or euvolemia, in part because it is difficult to detect modest changes in volume status using standard methods of clinical assessment. [3] Most patients with hyponatremia have clinical euvolemia (most commonly associated with the syndrome of inappropriate secretion of antidiuretic hormone [SIADH] or due to other causes [e.g., hypothyroidism, adrenal insufficiency, other disorders of excess water intake]) and are generally diagnosed clinically from the history, physical examination, and laboratory results. [2-3] Patients without clinical signs of volume depletion (e.g., orthostatic decreases in blood pressure and increases in pulse rate, dry mucus membranes, decreased skin turgor) or volume expansion (e.g., subcutaneous edema, ascites) should be considered to have euvolemia unless there is alternative evidence suggesting an abnormal ECF volume status. [3] Supportive laboratory results include a normal or low blood urea nitrogen (BUN) and a low serum uric acid level. [3] A spot urine sodium concentration should be greater than or equal to 30 mmol/L in most patients with euvolemic hyponatremia unless they have become secondarily sodium depleted. [3]

The presence of clinically detectable increased ECF volume generally reflects hypervolemia from some degree of body sodium excess. [3] Hyponatremia with ECF volume excess can arise in a variety of diseases (e.g., congestive heart failure, cirrhosis, renal failure). [3] Because intravascular volume cannot be easily measured directly, volume excess is generally diagnosed clinically from the history, physical examination, and laboratory results. [3] Patients with clinical signs of volume overload (e.g., subcutaneous edema, ascites, pulmonary edema) should be considered to have hypervolemia unless there are alternative explanations for these findings. [3] Elevation of plasma levels of brain natriuretic peptide (BNP) provides useful laboratory support for the presence of volume overload. [3] The urine sodium, or fractional sodium excretion, is usually low (spot urine sodium of less than 30 mmol/L) in patients with hypervolemic hyponatremia due to activation of the renin-angiotensin-aldosterone system (RAAS) with secondary renal sodium conservation despite the whole-body volume overload. [3]

Because of the risk of osmotic demyelination associated with overly-rapid correction of serum sodium, tolvaptan should be initiated in a hospital so that the serum sodium concentration can be monitored easily. If therapy is discontinued for any reason and the patient becomes hyponatremic, tolvaptan should be re-initiated in a hospital if further treatment with tolvaptan is indicated. "In a hospital" means anywhere in a hospital where the patient can be observed and serum sodium levels can be obtained (e.g., an emergency department, an observation unit, or an inpatient bed). [1]

Jynarque can cause serious and potentially fatal liver injury. Acute liver failure requiring liver transplantation has been reported in the post-marketing ADPKD experience. Discontinuation in response to laboratory abnormalities or signs or symptoms of liver injury (such as fatigue, anorexia, nausea, right upper abdominal discomfort, vomiting, fever, rash, pruritus, icterus, dark urine or jaundice) can reduce the risk of severe hepatotoxicity. ALT, AST and bilirubin should be monitored prior to initiation, at 2 weeks and 4 weeks after initiation, then monthly for 18 months and every 3 months thereafter. [4]

4 . References

Samsca Prescribing Information. Otsuka America Pharmaceuticals, Inc. Rockville, MD. April 2021.

Ghali JK. Mechanisms, risks, and new treatment options for hyponatremia. Cardiology. 2008;11:147-157.

Verbalis JG, Goldsmith SR, Greenberg A, et al. Diagnosis, evaluation, and treatment of hyponatremia: expert panel recommendations. The American Journal of Medicine. 2013;126(10 Suppl 1):S1-42.

Jynarque Prescribing Information. Otsuka America Pharmaceuticals, Inc. Rockville, MD. October 2020.

5 . Revision History

Date	Notes
3/14/2023	2023 UM Annual Review. No criteria changes. Separated out PA and NF criteria for Jynarque

Prior Authorization Guideline

Guideline Name	Topical Antifungals - PA, NF

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	2/15/2016
P&T Revision Date:	02/13/2020 ; 12/16/2020 ; 02/18/2021 ; 02/17/2022 ; 09/21/2022 ; 12/14/2022 ; 2/16/2023

1 . Indications

Drug Name: Ciclopirox Kit (ciclopirox)
Onychomycosis Indicated as topical treatment in immunocompetent patients with mild to moderate onychomycosis of fingernails and toenails without lunula involvement, due to Trichophyton rubrum. The comprehensive management program includes removal of the unattached, infected nails as frequently as monthly, by a health care professional who has special competence in the diagnosis and treatment of nail disorders, including minor nail procedures.
Drug Name: Jublia (efinaconazole) topical solution
Onychomycosis of the toenails Indicated for the topical treatment of onychomycosis of the toenail(s) due to Trichophyton rubrum and Trichophyton mentagrophytes.
Drug Name: Kerydin (tavaborole) topical solution
Onychomycosis of the toenails Indicated for the treatment of onychomycosis of the toenails due to Trichophyton rubrum or Trichophyton mentagrophytes.

2 . Criteria

Product Name: Ciclopirox Kit	
Diagnosis	Fingernail Onychomycosis
Approval Length	48 Weeks [3, 6, A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of onychomycosis of the fingernail(s)

AND

2 - The patient does not have dermatophytomas or lunula (matrix) involvement

AND

3 - Diagnosis of fingernail onychomycosis has been confirmed by one of the following:

Positive potassium hydroxide (KOH) preparation

Culture

Histology

AND

4 - Trial and failure (of a minimum 6-week supply), contraindication, or intolerance to oral terbinafine [B]

Product Name: Ciclopirox Kit, Generic tavaborole, Jublia	
Diagnosis	Toenail Onychomycosis
Approval Length	48 Weeks [3, 6, A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of onychomycosis of the toenail(s)

AND

2 - The patient does not have dermatophytomas or lunula (matrix) involvement

AND

3 - Diagnosis of toenail onychomycosis has been confirmed by one of the following:

Positive potassium hydroxide (KOH) preparation

Culture

Histology

AND

4 - Patient has mild to moderate disease involving at least one target toenail

AND

5 - Trial and failure, contraindication (of a minimum 12-week supply), or intolerance to oral terbinafine [B]

Product Name: Brand Kerydin	
Diagnosis	Toenail Onychomycosis
Approval Length	48 Weeks [3, 6, A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of onychomycosis of the toenail(s)

AND

2 - The patient does not have dermatophytomas or lunula (matrix) involvement

AND

3 - Diagnosis of toenail onychomycosis has been confirmed by one of the following:

Positive potassium hydroxide (KOH) preparation

Culture

Histology

AND

4 - Patient has mild to moderate disease involving at least one target toenail

AND

5 - Both of the following:

5.1 Trial and failure, contraindication (of a minimum 12-week supply), or intolerance to oral terbinafine [B]

AND

5.2 Trial and failure (of a minimum 48-week supply), contraindication, or intolerance to generic tavaborole

Product Name: Jublia	
Diagnosis	Toenail Onychomycosis
Approval Length	48 Weeks [3, 6, A]

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of onychomycosis of the toenail(s)

AND

2 - The patient does not have dermatophytomas or lunula (matrix) involvement

AND

3 - Diagnosis of toenail onychomycosis has been confirmed by one of the following:

Positive potassium hydroxide (KOH) preparation

Culture

Histology

AND

4 - Patient has mild to moderate disease involving at least one target toenail

AND

5 - Treatment is requested due to a documented medical condition and not for cosmetic purposes (e.g. patients with history of cellulitis of the lower extremity, patients with diabetes who have additional risk factors for cellulitis of lower extremity, patients who experience pain/discomfort associated with the infected nail)

AND

6 - One of the following:

6.1 Paid claims or submission of medical records (e.g., chart notes) confirming history of failure, contraindication, or intolerance to 12 weeks of treatment with ciclopirox

OR

6.2 Patient is 6 to 12 years of age

AND

7 - Paid claims or submission of medical records (e.g., chart notes) confirming history of failure, contraindication, or intolerance to 12 weeks of treatment with ONE of the following oral antifungal agents:

itraconazole

terbinafine

griseofulvin

3 . Endnotes

Considering that toenails can take 12 to 18 months to grow out, many clinicians consider that 1 year is too short to assess clinical effectiveness. [4] Reports of long-term follow-up of treated patients have been presented, suggesting that positive mycology at 12 and 24 weeks after commencement of therapy are poor prognostic signs and may indicate a need for retreatment or for a change of drug. [5]

Oral terbinafine has been shown to have superior efficacy compared to topical treatments and is recommended as first-line therapy for onychomycosis. [4, 6, 7] Compared to itraconazole, terbinafine has been found to have lower long-term mycological recurrence rates and better tolerability. [4, 6]

4 . References

Jublia prescribing information. Bausch Health Companies Inc. Bridgewater, NJ. March 2022.

Kerydin prescribing information. PharmaDerm, a division of Fougera Pharmaceuticals, Inc. Melville, NY. August 2018.

Sigurgeirsson B, Olafsson JH, Steinsson JP, et al. Long-term effectiveness of treatment with terbinafine vs. itraconazole in onychomycosis: a 5-year blinded prospective follow-up study. Arch Dermatol. 2002;138:353-7.

Roberts DT, Taylor WD, Boyle J. Guidelines for treatment of onychomycosis. Br J Dermatol. 2003;148:402-410.

Ameen M, Lear JT, Madan V, Mohd Mustapa MF, Richardson M. British Association of Dermatologists' guideline for the management of onychomycosis 2014. Br J Dermatol. 2014;171(5):937-58.

Gupta, AK, Daigle D, Paquet M. Therapies for onychomycosis a systematic review and network meta-analysis of mycological cure. J Am Podiatr Med Assoc. 2015;105(4):357-66.

Gupta AK, Daigle D, Foley KA. Topical therapy for toenail onychomycosis: an evidence-based review. Am J Clin Dermatol. 2014;15:489.

Tavaborole prescribing information. Alembic Pharmaceuticals, Inc. Bridgewater, NJ. November 2021.

5 . Revision History

Date	Notes
1/25/2023	2023 UM Annual Review. No changes to criteria. Updated references

Prior Authorization Guideline

Guideline Name	Topical Immunomodulators

Guideline Note:

Effective Date:	8/1/2022
P&T Approval Date:	6/19/2019
P&T Revision Date:	06/17/2020 ; 03/17/2021 ; 06/16/2021 ; 6/15/2022

1 . Indications

Drug Name: Elidel (pimecrolimus)
Mild to Moderate Atopic Dermatitis Indicated as second-line therapy for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adults and children 2 years of age and older, who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable.
Drug Name: Protopic (tacrolimus)
Moderate to Severe Atopic Dermatitis Indicated as second-line therapy for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis in non-immunocompromised adults and children who have failed to respond adequately to other topical prescription treatments for atopic dermatitis, or when those treatments are not advisable.

2 . Criteria

Product Name: Brand Elidel cream, generic pimecrolimus cream, Brand Protopic ointment	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply), contraindication or intolerance of generic tacrolimus ointment

3 . References

Elidel Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. September 2020.

Protopic Prescribing Information. LEO Pharma Inc. Madison, NJ. April 2019.

4 . Revision History

Date	Notes
6/16/2022	Annual Review. Added FDA approved diagnosis requirement to criter ia.

Prior Authorization Guideline

Guideline Name	Topical Retinoid Agents

Guideline Note:

Effective Date:	3/1/2023
P&T Approval Date:	12/16/2005
P&T Revision Date:	11/14/2019 ; 11/14/2019 ; 04/15/2020 ; 09/16/2020 ; 11/12/2020 ; 02/18/2021 ; 05/20/2021 ; 12/15/2021 ; 10/19/2022 ; 02/16/2023

1 . Indications

Drug Name: Atralin (tretinoin), Avita (tretinoin) cream and gel, Retin-A (tretinoin) cream and gel, Retin-A Micro (tretinoin) gel
Acne vulgaris Indicated for the topical treatment of acne vulgaris. **Off Label Uses: Wound healing (mild) [9]** Tretinoin 0.05% cream has been shown to decrease would healing time in patients receiving electroepilation. Enhanced healing of epidermal wounds in patients undergoing dermabrasion when pretreated with tretinoin 0.05% cream has been reported. DRUGDEX Recommendation: Adult, Class IIb, Evidence favors efficacy. **Actinic keratosis [9]** **Hyperkeratosis [9]** **Keloid scar [9]**
Drug Name: Aklief (trifarotene) cream, Arazlo (tazarotene) lotion

Acne vulgaris Indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

Drug Name: Altreno (tretinoin) lotion

Acne vulgaris Indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

Off Label Uses: Wound healing (mild) [9] Tretinoin 0.05% cream has been shown to decrease would healing time in patients receiving electroepilation. Enhanced healing of epidermal wounds in patients undergoing dermabrasion when pretreated with tretinoin 0.05% cream has been reported. DRUGDEX Recommendation: Adult, Class IIb, Evidence favors efficacy.

Actinic keratosis [9]

Hyperkeratosis [9]

Keloid scar [9]

Drug Name: Differin (adapalene) cream/lotion/gel/solution/pads

Acne vulgaris Indicated for the topical treatment of acne vulgaris.

Drug Name: Tazorac (tazarotene) cream 0.1%

Acne Vulgaris Indicated for the topical treatment of patients with acne vulgaris.

Plaque Psoriasis Indicated for the topical treatment of patients with plaque psoriasis.

Drug Name: Tazorac (tazarotene) cream 0.05%

Plaque Psoriasis Indicated for the topical treatment of patients with plaque psoriasis.

Drug Name: Tazorac (tazarotene) gel 0.1%

Acne Vulgaris Indicated for the topical treatment of patients with facial acne vulgaris of mild to moderate severity.

Plaque Psoriasis Indicated for the topical treatment of patients with plaque psoriasis of up to 20% body surface area involvement.

Drug Name: Tazorac (tazarotene) gel 0.05%

Plaque Psoriasis Indicated for the topical treatment of patients with plaque psoriasis of up to 20% body surface area involvement.

Drug Name: Fabior (tazarotene) foam

Acne Vulgaris Indicated for the topical treatment of acne vulgaris in patients 12 years of age or older.

2 . Criteria

Product Name: Generic adapalene (cream, gel), Avita, Brand Retin A Micro (0.06%, 0.08%)	
Diagnosis	Acne Vulgaris
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - One of the following: **1.1** Patient is 25 years of age or younger **OR** **1.2** Both of the following: Patient is older than 25 years of age Diagnosis of acne vulgaris (i.e., acne)	
Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name: Aklief, Altreno, Atralin, Brand Retin-A, Brand Retin-A Micro (0.1% 0.04%), Brand Adapalene 0.1% Soln, Brand Adapalene 0.1% Pads	
Diagnosis	Acne Vulgaris
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Patient is 25 years of age or younger

AND

1.1.2 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to BOTH of the following generics:

Adapalene (cream, gel)

Topical tretinoin or tretinoin microsphere

OR

1.2 All of the following:

1.2.1 Patient is older than 25 years of age

AND

1.2.2 Diagnosis of acne vulgaris (i.e., acne)

AND

1.2.3 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to BOTH of the following generics:

Adapalene (cream, gel)

Topical tretinoin or tretinoin microsphere

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name: Avita, Brand Retin A Micro (0.06%, 0.08%)	
Diagnosis	Other Medical Uses (Off-Label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses: [A, 9]

Actinic keratosis

Hyperkeratosis

Keloid scar

Wound healing (mild)

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name: Altreno, Atralin, Brand Retin-A, Brand Retin-A Micro (0.04%, 0.1%)	
Diagnosis	Other Medical Uses (Off-Label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses: [A, 9]

Actinic keratosis

Hyperkeratosis

Keloid Scar

Wound healing (mild)

AND

2 - Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to any generic topical tretinoin product

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name: Brand Differin	
Diagnosis	Acne Vulgaris
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Patient is 25 years of age or younger

AND

1.1.2 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to BOTH of the following generics:

adapalene (cream, gel)

Topical tretinoin or tretinoin microsphere

OR

1.2 All of the following:

1.2.1 Patient is older than 25 years of age

AND

1.2.2 Diagnosis of acne vulgaris (i.e., acne)

AND

1.2.3 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to BOTH of the following generics:

adapalene (cream, gel)

Topical tretinoin or tretinoin microsphere

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name: Arazlo, Fabior, Brand Tazarotene 0.1% foam, Brand Tazorac 0.1% cream and gel	
Diagnosis	Acne Vulgaris
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Patient is 25 years of age or younger

AND

1.1.2 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication or intolerance to BOTH of the following:

1.1.2.1 generic tazarotene

AND

1.1.2.2 One of the following:

generic adapalene

generic topical tretinoin or tretinoin microsphere

OR

1.2 All of the following:

1.2.1 Patient is older than 25 years of age

AND

1.2.2 Diagnosis of acne vulgaris (i.e., acne)

AND

1.2.3 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication or intolerance to BOTH of the following:

1.2.3.1 generic tazarotene

AND

1.2.3.2 One of the following:

generic adapalene

generic topical tretinoin or tretinoin microsphere	
Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name: Brand Tazorac	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of plaque psoriasis

AND

2 - Both of the following:

2.1 Trial and failure (of a minimum 30-day supply) within the past 180 days, or intolerance to generic tazarotene

AND

2.2 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to one medium to high potency topical corticosteroid (e.g., triamcinolone, fluocinonide)

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name: Generic tazarotene 0.1% cream, generic tazarotene 0.1% gel, generic tazarotene 0.05% gel	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of plaque psoriasis

AND

2 - Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to one medium to high potency topical corticosteroid (e.g., triamcinolone, fluocinonide)

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name: Generic tazarotene 0.1% cream, generic tazarotene 0.1% gel	
Diagnosis	Acne Vulgaris
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient is 25 years of age or younger

OR

1.2 Both of the following:

Patient is older than 25 years of age

Diagnosis of acne vulgaris (i.e., acne)

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar el astosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

3 . Background

Clinical Practice Guidelines

Table 1. The use of topical retinoids for the following conditions was clarified as either medical or cosmetic (plan exclusions) [10]

Uses	Medical vs. Cosmetic
Actinic keratosis	Medical
Alopecia areata	Medical
Chloasma	Cosmetic
Fine wrinkles on face	Cosmetic
Hyperkeratosis	Medical
Hyperpigmentation of skin, Facial mottling	Cosmetic
Keloid scar	Medical
Roughness of skin, Facial tactile roughness	Cosmetic
Systematized epidermal nevus	Medical
Ultraviolet-induced change in normal skin	Cosmetic
Wound healing (mild)	Medical

Table 2. Relative potencies of topical corticosteroids [14-15]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25

	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

4 . Endnotes

The use of topical retinoids for the following conditions was clarified as either medical or cosmetic (plan exclusions). [10] Please refer to Background section for table with details.

5 . References

Adapalene Topical Solution 0.1% Prescribing Information. Allegis Holdings LLC. Canton, MS. December 2020.

Aklief Prescribing Information. Galderma Laboratories, L.P. Fort Worth, Texas. January 2022.

Altreno Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. March 2020.

Atralin Prescribing Information. Valeant Pharmaceuticals. Bridgewater, NJ. July 2016.

Avita Prescribing Information. Mylan Pharmaceuticals Inc. Morgantown, WV. June 2018.

Differin Prescribing Information. Galderma Laboratories, L.P. Fort Worth, TX. June 2021.

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Retin-A Micro Prescribing Information. Valeant Pharmaceuticals. Bridgewater, NJ. October 2017.

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Prior Authorization Guideline

Guideline Name	Trastuzumab - PA, NF

Guideline Note:

Effective Date:	8/1/2022
P&T Approval Date:	9/8/2000
P&T Revision Date:	08/15/2019 ; 12/18/2019 ; 03/18/2020 ; 05/14/2020 ; 06/17/2020 ; 04/21/2021 ; 06/16/2021 ; 12/15/2021 ; 6/15/2022

1 . Indications

Drug Name: Herceptin (trastuzumab), Herzuma (trastuzumab-pkrb), Kanjinti (trastuzumab-anns), Ogivri (trastuzumab-dkst), Ontruzant (trastuzumab-dkst), Trazimera (trastuzumab-qyyp)
Adjuvant Breast Cancer Indicated for adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer: 1) as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel, 2) with docetaxel and carboplatin, 3) as a single agent following multi-modality anthracycline based therapy. **Metastatic Breast Cancer** Indicated: 1) In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer, 2) As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease. **Metastatic Gastric Cancer** Indicated in combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of patients with HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma, who have not received prior treatment for metastatic disease.
Drug Name: Herceptin Hylecta (trastuzumab and hyaluronidase-oysk)

Adjuvant Breast Cancer Indicated for adjuvant treatment of adults with HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer: 1) as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel, 2) as part of a treatment regimen with docetaxel and carboplatin, 3) as a single agent following multi-modality anthracycline based therapy.

Metastatic Breast Cancer Indicated in adults: 1) In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer, 2) As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease.

2 . Criteria

Product Name: Kanjinti, Trazimera	
Diagnosis	Adjuvant or Neoadjuvant Breast Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HER2-overexpressing of breast cancer [A]

AND

2 - One of the following treatment regimens: [4, C]

Adjuvant treatment

Used in combination with Perjeta (pertuzumab)

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Kanjinti, Trazimera

Diagnosis	Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HER2-overexpressing of breast cancer [A]

AND

2 - Disease is metastatic

AND

3 - One of the following treatment regimens: [3-5, 7, C]

Used in combination with a taxane

Used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease

Used in combination with Perjeta (pertuzumab)

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Kanjinti, Trazimera	
Diagnosis	Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Kanjinti, Trazimera	
Diagnosis	Metastatic Gastric Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HER2-overexpressing gastric or gastroesophageal junction adenocarcinoma (locally advanced, recurrent, or metastatic) [3-5, 7, A-C]

AND

2 - Used in combination with one of the following treatment regimens: [3-5, 7, C]

Platinol (cisplatin) and Adrucil (5-fluorouracil)

Platinol (cisplatin) and Xeloda (capecitabine)

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Kanjinti, Trazimera	
Diagnosis	Metastatic Gastric Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Herceptin Hylecta	
Diagnosis	Adjuvant Breast Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HER2-overexpressing breast cancer [A]

AND

2 - One of the following:

2.1 Administered as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel

OR

2.2 Administered as part of a treatment regimen with docetaxel and carboplatin

OR

2.3 Administered as a single agent following multi-modality anthracycline based therapy

AND

3 - One of the following:

3.1 Trial and failure, contraindication, or intolerance to both of the following:

Kanjinti

Trazimera

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Herceptin Hylecta	
Diagnosis	Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HER2-overexpressing breast cancer [A]

AND

2 - Disease is metastatic

AND

3 - One of the following:

3.1 Administered in combination with paclitaxel for first-line treatment

OR

3.2 Administered as a single agent for treatment in patients who have received one or more chemotherapy regimens for metastatic disease

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to both of the following:

Kanjinti

Trazimera

OR

4.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Herceptin Hylecta	
Diagnosis	Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to both of the following:

Kanjinti

Trazimera

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Herceptin, Herzuma, Ogivri, Ontruzant	
Diagnosis	Adjuvant or Neoadjuvant Breast Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HER2-overexpressing of breast cancer [A]

AND

2 - One of the following treatment regimens: [4, C]

Adjuvant treatment

Used in combination with Perjeta (pertuzumab)

AND

3 - One of the following:

3.1 Trial and failure, contraindication, or intolerance to both of the following:

Kanjinti

Trazimera

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Herzuma, Ogivri, Ontruzant	
Diagnosis	Adjuvant or Neoadjuvant Breast Cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of HER2-overexpressing of breast cancer [A]

AND

2 - One of the following treatment regimens: [4, C]

Adjuvant treatment

Used in combination with Perjeta (pertuzumab)

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to both of the following:

Kanjinti

Trazimera

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen, defined as no more than a 45-day gap in therapy

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Herceptin, Herzuma, Ogivri, Ontruzant	
Diagnosis	Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HER2-overexpressing of breast cancer [A]

AND

2 - Disease is metastatic

AND

3 - One of the following treatment regimens: [1, 4-6, 8-9, C]

Used in combination with a taxane

Used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease

Used in combination with Perjeta (pertuzumab)

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to both of the following:

Kanjinti

Trazimera

OR

4.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Herceptin, Herzuma, Ogivri, Ontruzant	
Diagnosis	Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to both of the following:

Kanjinti

Trazimera

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Herzuma, Ogivri, Ontruzant	
Diagnosis	Metastatic Breast Cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of HER2-overexpressing of breast cancer [A]

AND

2 - Disease is metastatic

AND

3 - One of the following treatment regimens: [1, 4-6, 8-9, C]

Used in combination with a taxane

Used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease

Used in combination with Perjeta (pertuzumab)

AND

4 - One of the following:

4.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to both of the following:

Kanjinti

Trazimera

OR

4.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen, defined as no more than a 45-day gap in therapy

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Herceptin, Herzuma, Ogivri, Ontruzant	
Diagnosis	Metastatic Gastric Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HER2-overexpressing gastric or gastroesophageal junction adenocarcinoma (locally advanced, recurrent, or metastatic) [1, 4-6, 8-9, A-C]

AND

2 - Used in combination with one of the following treatment regimens: [1, 4-6, 8-9, C]

Platinol (cisplatin) and Adrucil (5-fluorouracil)

Platinol (cisplatin) and Xeloda (capecitabine)

AND

3 - One of the following:

3.1 Trial and failure, contraindication, or intolerance to both of the following:

Kanjinti

Trazimera

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Herceptin, Herzuma, Ogivri, Ontruzant	
Diagnosis	Metastatic Gastric Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to both of the following:

Kanjinti

Trazimera

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Herzuma, Ogivri, Ontruzant	
Diagnosis	Metastatic Gastric Cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of HER2-overexpressing gastric or gastroesophageal junction adenocarcinoma (locally advanced, recurrent, or metastatic) [1, 4-6, 8-9, A-C]

AND

2 - Used in combination with one of the following treatment regimens: [1, 4-6, 8-9, C]

Platinol (cisplatin) and Adrucil (5-fluorouracil)

Platinol (cisplatin) and Xeloda (capecitabine)

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to both of the following:

Kanjinti

Trazimera

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen, defined as no more than a 45-day gap in therapy

AND

4 - Prescribed by or in consultation with an oncologist

3 . Endnotes

Detection of HER2 protein overexpression is necessary for selection of patients appropriate for trastuzumab therapy because these are the only patients studied and for whom benefit has been shown. Due to differences in tumor histopathology, use FDA-approved tests for the specific tumor type (e.g. breast or gastric/gastroesophageal adenocarcinoma) to assess HER2 protein overexpression and HER2 gene amplification. Assessment of HER2 protein overexpression and HER2 gene amplification should be performed using FDA-approved tests specific for breast cancer by laboratories with demonstrated proficiency. Improper assay performance, including use of suboptimally fixed tissue, failure to utilize specified reagents, deviation from specific assay instructions, and failure to include appropriate controls for assay validation, can lead to unreliable results. Assessment of HER2 protein overexpression and HER2 gene amplification in metastatic gastric cancer should be performed using FDA-approved tests specifically for gastric cancers due to differences in gastric vs. breast histopathology, including incomplete membrane staining and more frequent heterogeneous expression of HER2 seen in gastric cancers. Study 7 demonstrated that gene amplification and protein overexpression were not as well correlated as with breast cancer. Treatment

outcomes for metastatic gastric cancer (Study 7) are based on HER2 gene amplification (FISH) and HER 2 protein overexpression (IHC) test results. [1-3, 6-9]

Herceptin, Kanjinti, Ogivri, Trazimera, Herzuma and Ontruzant are indicated for the treatment of HER-2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. A pivotal study included patients previously untreated for metastatic gastric or gastroesophageal junction adenocarcinoma. [1, 3, 6-9]

The FDA defines biosimilar as a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. [5]

4 . References

Herceptin Prescribing Information. Genentech, Inc. South San Francisco, CA. February 2021.

Herceptin Hylecta Prescribing Information. Genentech, Inc. South San Francisco, CA. February 2019.

Kanjinti Prescribing Information. Amgen Inc. Thousand Oaks, CA. October 2019.

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Ogivri Prescribing Information. Mylan Institutional LLC. Rockford, IL. February 2021.

Trazimera Prescribing Information. Pfizer Laboratories Div Pfizer Inc. New York, NY. November 2020.

Herzuma Prescribing Information. Celltrion, Inc. Incheon, Republic of Korea. May 2019.

Ontruzant Prescribing Information. Merck Sharp & Dohme Corp. Whitehouse Station, NJ. March 2020.

5 . Revision History

Date	Notes

6/16/2022	Annual review - updated references.

Prior Authorization Guideline

Guideline Name	Tremfya (guselkumab)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	9/27/2017
P&T Revision Date:	03/18/2020 ; 09/16/2020 ; 03/17/2021 ; 03/16/2022 ; 10/19/2022 ; 3/15/2023

1 . Indications

Drug Name: Tremfya (guselkumab)
Plaque Psoriasis (PsO) Indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. **Psoriatic Arthritis (PsA)** Indicated for the treatment of adult patients with active psoriatic arthritis.

2 . Criteria

Product Name: Tremfya	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate-to-severe plaque psoriasis

AND

2 - One of the following [2]:

Greater than or equal to 3% body surface area involvement

Severe scalp psoriasis

Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

corticosteroids (e.g., betamethasone, clobetasol)

vitamin D analogs (e.g., calcitriol, calcipotriene)

tazarotene

calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

anthralin

coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name: Tremfya

Diagnosis	Plaque Psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1-3]:

Reduction the body surface area (BSA) involvement from baseline

Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name: Tremfya	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis (PsA)

AND

2 - One of the following [4]:

Actively inflamed joints

Dactylitis

Enthesitis

Axial disease

Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

Dermatologist

Rheumatologist

Product Name: Tremfya	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline

Reduction in the body surface area (BSA) involvement from baseline

3 . References

Tremfya prescribing information. Janssen Biotech, Inc. Horsham, PA. July 2020.

Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.

Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.

Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.

4 . Revision History

Date	Notes
2/26/2023	Annual review - no criteria changes; background updates

Prior Authorization Guideline

Guideline Name	Trogarzo (ibalizumab-uiyk) - PA, NF

Guideline Note:

Effective Date:	7/1/2022
P&T Approval Date:	5/17/2018
P&T Revision Date:	06/19/2019 ; 06/17/2020 ; 06/16/2021 ; 11/18/2021 ; 5/19/2022

1 . Indications

Drug Name: Trogarzo (ibalizumab-uiyk)
Multidrug Resistant HIV-1 Infection Indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen.

2 . Criteria

Product Name: Trogarzo	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of HIV-1 infection

AND

1.1.2 HIV-1 infection is multidrug resistant as confirmed by a resistance assay

AND

1.1.3 Patient is currently taking, or will be prescribed, an optimized background antiretroviral therapy regimen

AND

1.1.4 Prescribed by or in consultation with a clinician with HIV expertise

OR

1.2 For continuation of prior therapy

Product Name: Trogarzo	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of HIV-1 infection

AND

1.1.2 HIV-1 infection is multidrug resistant as confirmed by a resistance assay

AND

1.1.3 Patient is currently taking, or will be prescribed, an optimized background antiretroviral therapy regimen

AND

1.1.4 Prescribed by or in consultation with a clinician with HIV expertise

OR

1.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than 45-day gap in therapy

3 . References

Trogarzo Prescribing Information. Theratechnologies Inc. Montreal, Quebec Canada. September 2021.

4 . Revision History

Date	Notes
5/4/2022	Annual review - no changes.

Prior Authorization Guideline

Guideline Name	Tukysa (tucatinib)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	6/17/2020
P&T Revision Date:	06/16/2021 ; 06/15/2022 ; 3/15/2023

1 . Indications

Drug Name: Tukysa (tucatinib)
Breast Cancer Indicated in combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting. **Colorectal cancer** Indicated in combination with trastuzumab for the treatment of adult patients with RAS wild-type, HER2-positive unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

2 . Criteria

Product Name: Tukysa

Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Disease is one of the following:

Advanced unresectable

Metastatic

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

4 - Used in combination with trastuzumab and capecitabine

AND

5 - Patient has received one or more prior anti-HER2 based regimens (e.g., trastuzumab, pertuzumab, ado-trastuzumab emtansine)

AND

6 - Prescribed by or in consultation with an oncologist

Product Name: Tukysa	
Diagnosis	Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of colorectal cancer

AND

2 - Disease is one of the following:

Unresectable

Metastatic

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

4 - Patient has RAS wild-type tumors

AND

5 - Used in combination with trastuzumab

AND

6 - Patient has progressed following treatment with ONE of the following:

Fluoropyrimidine-based chemotherapy

Oxaliplatin-based chemotherapy

Irinotecan-based chemotherapy

AND

7 - Prescribed by or in consultation with an oncologist

Product Name: Tukysa	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Tukysa Prescribing Information. Seattle Genetics, Inc. Bothell, WA. January 2023.

4 . Revision History

Date	Notes
3/1/2023	Addition of new indication for colorectal cancer

Prior Authorization Guideline

Guideline Name	Turalio (pexidartinib)

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	9/18/2019
P&T Revision Date:	09/16/2020 ; 09/15/2021 ; 09/21/2022 ; 3/15/2023

1 . Indications

Drug Name: Turalio (pexidartinib)
Tenosynovial Giant Cell Tumor (TGCT) Indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery.

2 . Criteria

Product Name: Turalio	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of tenosynovial giant cell tumor (TGCT)

AND

2 - Patient is symptomatic

AND

3 - Patient is not a candidate for surgery due to worsening functional limitation or severe morbidity with surgical removal

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Turalio	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Turalio prescribing information. Daiichi Sankyo, Inc. Basking Ridge, NJ. October 2022.

4 . Revision History

Date	Notes
2/7/2023	Added new Turalio 125mg capsule to existing criteria

Prior Authorization Guideline

Guideline Name	Tykerb (lapatinib)

Guideline Note:

Effective Date:	11/1/2022
P&T Approval Date:	
P&T Revision Date:	09/18/2019 ; 09/16/2020 ; 11/12/2020 ; 09/15/2021 ; 09/21/2022

1 . Indications

Drug Name: Tykerb (lapatinib)
Metastatic breast cancer (1) In combination with Xeloda (capecitabine), indicated for the treatment of patients with advanced or metastatic breast cancer whose tumors over-express HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab. Limitations of use: Patients should have disease progression on trastuzumab prior to initiation of treatment with Tykerb in combination with capecitabine.; (2) In combination with Femara (letrozole), indicated for the treatment of postmenopausal women with hormone receptor positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated. Tykerb in combination with an aromatase inhibitor has not been compared to a trastuzumab-containing chemotherapy regimen for the treatment of metastatic breast cancer. **Off Label Uses: HER2-positive Breast Cancer [4-6]** Used for the first-line treatment of HER2-positive locally-advanced or metastatic breast cancer.

2 . Criteria

Product Name: Brand Tykerb, generic lapatinib	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HER2-positive metastatic or recurrent breast cancer [2-6]

AND

2 - Used in combination with one of the following: [3]

Trastuzumab

Xeloda (capecitabine)

Aromatase inhibitors [e.g., Aromasin (exemestane), Femara (letrozole), Arimidex (anastrozole)]

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Brand Tykerb, generic lapatinib	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease

3 . References

Tykerb Prescribing Information. Novartis Pharmaceuticals. East Hanover, NJ. March 2022.

Geyer CE, Forster J, Lindquist D, et al. Lapatinib plus capecitabine for HER2-positive advanced breast cancer. N Engl J Med. 2006;355(26):2733-2743.

National Comprehensive Cancer (NCCN) Drugs & Biologics Compendium. National Comprehensive Cancer Network, Inc. 2020. Accessed August 26, 2022.

DRUGDEX System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Accessed August 12, 2020.

Moy B, Goss PE. Lapatinib: current status and future directions in breast cancer. Oncologist. 2006;11:1047-57.

Gomez H, Doval D, Chavez M, et al. Efficacy and safety of lapatinib as first-line therapy for ErbB2-amplified locally advanced or metastatic breast cancer. J Clin Oncol. 2008 May 5 [Epub ahead of print].

Lapatinib Prescribing Information. Lupin Pharmaceuticals, Inc. Baltimore, MD. September 2020.

4 . Revision History

Date	Notes
10/18/2022	Minor grammatical updates

Prior Authorization Guideline

Guideline Name	Tysabri (natalizumab)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	11/20/2000
P&T Revision Date:	05/14/2020 ; 01/20/2021 ; 05/20/2021 ; 05/19/2022 ; 10/19/2022 ; 5/18/2023

1 . Indications

Drug Name: Tysabri (natalizumab)
Multiple Sclerosis (MS) Indicated as monotherapy for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Tysabri increases the risk of progressive multifocal leukoencephalopathy (PML). When initiating and continuing treatment with Tysabri, physicians should consider whether the expected benefit of Tysabri is sufficient to offset this risk. **Crohn's Disease (CD)** Indicated for inducing and maintaining clinical response and remission in adult patients with moderately to severely active CD with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of TNF-alpha. In CD, Tysabri should not be used in combination with immunosuppressants (e.g., 6-mercaptopurine, azathioprine, cyclosporine, or methotrexate) or inhibitors of TNF-alpha.

2 . Criteria

Product Name: Tysabri	
Diagnosis	Multiple Sclerosis (MS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [B]

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to one of the following disease-modifying therapies for MS:

Aubagio (teriflunomide)

Lemtrada (alemtuzumab)

Mavenclad (cladribine)

Plegridy (peginterferon beta-1a)

Any one of the interferon beta-1a injections (e.g., Avonex)

Any one of the interferon beta-1b injections (e.g., Betaseron)

Any one of the glatiramer acetate injections (e.g., Copaxone, Glatopa, generic glatiramer acetate)

Any one of the oral fumarates (e.g., generic dimethyl fumarate)

Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (e.g., Gilenya, Mayzent, Zeposia)

Any one of the B-cell targeted therapies (e.g., Kesimpta)

OR

2.2 Patient is not a candidate for any of the drugs listed as prerequisites due to the severity of their multiple sclerosis [2]

OR

2.3 For continuation of prior therapy [2]

AND

3 - Not used in combination with another disease-modifying therapy for MS

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Tysabri	
Diagnosis	Multiple Sclerosis (MS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS

AND

3 - Prescribed by or in consultation with a neurologist

Product Name: Tysabri	
Diagnosis	Crohn’s Disease (CD)
Approval Length	3 Months [1]**
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - Crohn's disease has evidence of inflammation (e.g., elevated C-reactive protein [CRP], elevated erythrocyte sedimentation rate, presence of fecal leukocytes)

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies [3, 7]:

corticosteroids (e.g., prednisone)

6-mercaptopurine

azathioprine

methotrexate

AND

4 - Trial and failure, contraindication, or intolerance to a tumor necrosis factor (TNF)-inhibitor (e.g., Cimzia [certolizumab pegol], Humira [adalimumab], infliximab)

AND

5 - Not used in combination with an immunosuppressant (e.g., 6-MP, azathioprine, cyclosporine, or methotrexate) [A, C]

AND

6 - Not used in combination with a TNF-inhibitor (e.g., Enbrel [etanercept], Humira [adalimumab], or infliximab) [A, C]

AND

7 - Prescribed by or in consultation with a gastroenterologist

Notes	**In CD, discontinue Tysabri in patients that have not experienced the rapeutic benefit by 12 weeks of induction therapy, and in patients that cannot discontinue chronic concomitant steroids within six months of s tarting therapy. [1]

Product Name: Tysabri	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 3, 7]:

Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline

Reversal of high fecal output state

AND

2 - Not used in combination with an immunosuppressant (e.g., 6-MP, azathioprine, cyclosporine, or methotrexate) [A, C]

AND

3 - Not used in combination with a TNF-inhibitor (e.g., Enbrel [etanercept], Humira [adalimumab], or infliximab) [A, C]

3 . Endnotes

To minimize the risk of progressive multifocal leukoencephalopathy, natalizumab must be administered as a monotherapy without concomitant immunosuppressive therapy. Aminosalicylates may be continued during treatment with Tysabri. [1, 3]

Of the four disease courses of MS, relapse-remitting MS (RRMS) is characterized primarily by relapse, while secondary-progressive MS (SPMS) has both relapsing and progressive characteristics. Most patients with RRMS eventually develop SPMS. As a person transitions from RRMS to SPMS, the disease begins to worsen more steadily, with or without occasional relapses, slight remissions, or plateaus. As long as the patient continues to have relapses, the SPMS course is considered to be both progressive and relapsing. [4]

In the postmarketing setting, additional cases of PML have been reported in multiple sclerosis and Crohn's disease patients who were receiving no concomitant immunomodulatory therapy. Three factors that are known to increase the risk of PML in TYSABRI-treated patients have been identified: 1) Longer treatment duration, especially beyond 2 years. There is limited experience in patients who have received more than 4 years of TYSABRI treatment. 2) Prior treatment with an immunosuppressant (e.g., mitoxantrone, azathioprine, methotrexate, cyclophosphamide, mycophenolate mofetil). 3) The presence of anti-JCV antibodies. Patients who are anti-JCV antibody positive have a higher risk for developing PML. [1]

4 . References

Tysabri Prescribing Information. Biogen Inc. Cambridge, MA. April 2023.

Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline: Disease-modifying therapies for adults with multiple sclerosis. Neurology 2018;90:777-788.

Lichtenstein GR, Loftus EV, Isaacs KL, et al. Management of Crohn's disease in adults. Am J Gastroenterol. 2018;113:481-517.

National Multiple Sclerosis Society. Types of MS. Available at: https://www.nationalmssociety.org/What-is-MS/Types-of-MS. Accessed April 11, 2022.

FDA Drug Safety Communication: New risk factor for progressive multifocal leukoencephalopathy (PML) associated with Tysabri (natalizumab). January 20, 2012. Available at: http://www.fda.gov/Drugs/DrugSafety/ucm288186.htm. Accessed April 11, 2022.

Nelson SML, Nguyen TM, McDonald J, MacDonald JK. Natalizumab for induction of remission in Crohn's disease. Cochrane Database of Systematic Reviews 2018, Issue 8. Art. No.: CD006097. DOI: 10.1002/14651858.CD006097.pub3.

Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508.

5 . Revision History

Date	Notes
4/26/2023	2023 UM Annual Review. No criteria changes. Updated references

Prior Authorization Guideline

Guideline Name	Ultomiris (ravulizumab-cwvz)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	2/14/2019
P&T Revision Date:	12/18/2019 ; 03/18/2020 ; 12/16/2020 ; 03/17/2021 ; 08/19/2021 ; 03/16/2022 ; 09/21/2022 ; 3/15/2023

1 . Indications

Drug Name: Ultomiris (ravulizumab-cwvz)
Paroxysmal Nocturnal Hemoglobinuria (PNH) Indicated for the treatment of patients one month of age and older with paroxysmal nocturnal hemoglobinuria (PNH). **Atypical Hemolytic Uremic Syndrome (aHUS)** Indicated for the treatment of adults and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA). **Generalized Myasthenia Gravis (gMG)** Indicated for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive.

2 . Criteria

Product Name: Ultomiris

Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)

AND

2 - Patient is one month of age and older

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Ultomiris	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to therapy

Product Name: Ultomiris	
Diagnosis	Atypical Hemolytic Uremic Syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of atypical hemolytic uremic syndrome (aHUS) [1]

AND

2 - Patient is one month of age and older

AND

3 - Prescribed by or in consultation with one of the following:

Hematologist

Nephrologist

Product Name: Ultomiris	
Diagnosis	Atypical Hemolytic Uremic Syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to therapy

Product Name: Ultomiris	
Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis (gMG)

AND

2 - Patient is anti-acetylcholine receptor (AChR) antibody positive

AND

3 - One of the following: [2]

3.1 Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

OR

3.2 Both of the following:

3.2.1 Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

AND

3.2.2 Trial and failure, contraindication, or intolerance to one of the following:

Chronic plasmapheresis or plasma exchange (PE)

Intravenous immunoglobulin (IVIG)

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Ultomiris	
Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	

3 . References

Ultomiris Prescribing Information. Alexion Pharmaceuticals, Inc. Boston, MA. April 2022.

Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis. Neurology. 2016;87(4):419-25.

4 . Revision History

Date	Notes
2/22/2023	2023 UM Annual Review. No changes

Prior Authorization Guideline

Guideline Name	Unituxin (dinutuximab)

Guideline Note:

Effective Date:	8/1/2021
P&T Approval Date:	5/20/2015
P&T Revision Date:	06/17/2020 ; 02/18/2021 ; 06/16/2021

1 . Indications

Drug Name: Unituxin (dinutuximab)
Neuroblastoma Indicated, in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and 13-cis-retinoic acid (RA), for the treatment of pediatric patients with high-risk neuroblastoma who achieve at least a partial response to prior first-line multiagent, multimodality therapy.

2 . Criteria

Product Name: Unituxin	
Diagnosis	Neuroblastoma
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of high-risk neuroblastoma

AND

2 - Used in combination with all of the following:

Granulocyte-macrophage colony-stimulating factor (GM-CSF) [e.g., Leukine (sargramostim)]

Interleukin-2 (IL-2) [e.g., Proleukin (aldesleukin)]

13-cis-retinoic acid (RA) [e.g., isotretinoin]

AND

3 - Patient responded to prior first-line multiagent, multimodality therapy (e.g., chemotherapy, surgery, stem cell transplant, radiation therapy)

AND

4 - Prescribed by a pediatric oncologist

3 . References

Unituxin Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. October 2020.

4 . Revision History

Date	Notes
9/27/2021	2021 Annual Review, no changes to criteria.

Prior Authorization Guideline

Guideline Name	Venclexta (venetoclax)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	6/22/2016
P&T Revision Date:	07/17/2019 ; 02/13/2020 ; 02/18/2021 ; 02/17/2022 ; 09/21/2022 ; 3/15/2023

1 . Indications

Drug Name: Venclexta (venetoclax)
Chronic lymphocytic leukemia or Small lymphocytic lymphoma Indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). **Acute Myeloid Leukemia** Indicated in combination with azacitidine or decitabine or low-dose cytarabine for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

2 . Criteria

Product Name: Venclexta	
Diagnosis	Chronic lymphocytic leukemia (CLL)/ Small Lymphocytic Lymphoma (SLL)

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)

AND

2 - Prescribed by or in consultation with one of the following:

Hematologist

Oncologist

Product Name: Venclexta	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of AML

AND

2 - Disease is one of the following:

Newly diagnosed

Relapsed

Refractory

AND

3 - Prescribed by or in consultation with one of the following:

Hematologist

Oncologist

Product Name: Venclexta	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Venclexta Prescribing Information. AbbVie, Inc. North Chicago, IL. June 2022.

National comprehensive cancer network (NCCN) clinical practice guidelines in oncology. Chronic lymphocytic leukemia/small lymphocytic lymphoma. v.5.2019. Available from: https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed June 4, 2019.

The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed on September 7, 2022.

4 . Revision History

Date	Notes

3/1/2023	Program update to remove NCCN supported off-label regimens withi n the indication-specific criteria.

Prior Authorization Guideline

Guideline Name	Viibryd (vilazodone)

Guideline Note:

Effective Date:	4/18/2023
P&T Approval Date:	7/20/2022
P&T Revision Date:	

1 . Indications

Drug Name: Viibryd (vilazodone)
Major Depressive Disorder Indicated for the treatment of major depressive disorder (MDD) in adults.

2 . Criteria

Product Name: Brand Viibryd	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Major Depressive Disorder (MDD)	

AND **2** - Trial and failure, or intolerance to generic vilazodone

3 . References

Viibryd prescribing information. Allergan USA, Inc. Madison, NJ. September 2021.

4 . Revision History

Date	Notes
4/17/2023	New program.

Prior Authorization Guideline

Guideline Name	Vimizim (elosulfase alfa)

Guideline Note:

Effective Date:	10/1/2022
P&T Approval Date:	6/24/2015
P&T Revision Date:	07/15/2020 ; 07/21/2021 ; 8/18/2022

1 . Indications

Drug Name: Vimizim (elosulfase alfa)
Mucopolysaccharidosis type IVA Indicated for patients with Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome).

2 . Criteria

Product Name: Vimizim	
Approval Length	60 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome) confirmed by both of the following: [1-3]

1.1 Documented clinical signs and symptoms of the disease (e.g., kyphoscoliosis, genu valgum, pectus carinatum, gait disturbance, growth deficiency, etc.)

AND

1.2 Documented reduced fibroblast or leukocyte GALNS enzyme activity or molecular genetic testing of GALNS

3 . References

Vimizim prescribing information. BioMarin Pharmaceutical Inc. Novato, CA. December 2019.

UptoDate. Mucopolysaccharidoses: Clinical features and diagnosis. Available at https://www.uptodate.com/contents/mucopolysaccharidoses-clinical-features-and-diagnosis?search=Mucopolysaccharidoses:%20clinical%20features%20and%20diagnosis.%20&source=search_result&selectedTitle=1~66&usage_type=default&display_rank=1. Accessed July 6, 2022.

Mucopolysaccharidosis IV. Available at https://rarediseases.org/rare-diseases/morquio-syndrome/#:~:text=Excessive%20amounts%20of%20keratan%20sulfate,to%20identify%20GALNS%20gene%20mutations. Accessed July 6, 2022.

4 . Revision History

Date	Notes
8/18/2022	2022 Annual Review.

Prior Authorization Guideline

Guideline Name	Votrient (pazopanib)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	2/16/2010
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 03/16/2022 ; 08/18/2022 ; 3/15/2023

1 . Indications

Drug Name: Votrient (pazopanib)
Renal Cell Carcinoma (RCC) Indicated for the treatment of patients with advanced renal cell carcinoma (RCC). **Soft tissue sarcoma (STS)** Indicated for the treatment of patients with advanced soft tissue sarcoma (STS) who have received prior chemotherapy. Limitation of Use: The efficacy of Votrient for the treatment of patients with adipocytic STS or gastrointestinal stromal tumors has not been demonstrated.

2 . Criteria

Product Name: Votrient	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of renal cell carcinoma

AND

2 - One of the following: [2]

Disease has relapsed

Diagnosis of stage IV disease

AND

3 - One of the following: [2]

3.1 One of the following:

3.1.1 Both of the following:

Used in the treatment of non-clear cell renal cell carcinoma

Trial and failure, contraindication or intolerance to generic sunitinib

OR

3.1.2 For continuation of prior therapy

OR

3.2 Patient has clear cell renal cell carcinoma

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Votrient	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Votrient	
Diagnosis	Soft tissue sarcoma (STS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced soft tissue sarcoma (STS) [4, A]

AND

2 - Patient received at least one prior chemotherapy

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Votrient

Diagnosis	Soft tissue sarcoma (STS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

Votrient is an active drug in anthracycline pretreated STS patients with an increase in median PFS of 13 weeks. [3]

4 . References

Votrient Prescribing Information. Novartis Pharmaceuticals. East Hanover, NJ. December 2021.

National comprehensive cancer network (NCCN). Clinical practice guidelines in oncology. Kidney cancer v.4.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed February 28, 2023.

PALETTE: a randomized, double-blind, phase III trial of pazopanib versus placebo in patients (pts) with soft-tissue sarcoma (STS) whose disease has progressed during or following prior chemotherapy-An EORTC STBSG Global Network Study (EORTC 62072). Available at: www.asco.org/ascov2/Meetings/Abstracts?&vmview=abst_detail_view&confID=102&abstractID=83283. Accessed April 30, 2012.

National comprehensive cancer network (NCCN). Clinical practice guidelines in oncology. Soft tissue sarcoma v.2.2022. Available at: http://www.nccn.org/professionals/physician_gls/PDF/sarcoma.pdf. Accessed February 28, 2023.

5 . Revision History

Date	Notes
3/21/2023	Annual Review: Updated Soft Tissue Sarcoma criteria to remove liste d chemotherapy examples.

Prior Authorization Guideline

Guideline Name	Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis)

Guideline Note:

Effective Date:	8/1/2022
P&T Approval Date:	
P&T Revision Date:	06/17/2020 ; 06/16/2021 ; 6/15/2022

1 . Indications

Drug Name: Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis)
Transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM) Indicated for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization

2 . Criteria

Product Name: Vyndaqel, Vyndamax	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM)

AND

2 - One of the following: [3, 4]

2.1 Patient has a transthyretin (TTR) mutation (e.g., V122I)

OR

2.2 Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of TTR amyloid deposits

OR

2.3 All of the following:

Echocardiogram or cardiac magnetic resonance imaging suggestive of amyloidosis

Scintigraphy scan suggestive of cardiac TTR amyloidosis

Absence of light-chain amyloidosis

AND

3 - One of the following: [2]

History of heart failure, with at least one prior hospitalization for heart failure

Presence of clinical signs and symptoms of heart failure (e.g., dyspnea, edema)

AND

4 - Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure [2]

AND

5 - Prescribed by or in consultation with a cardiologist

Product Name: Vyndaqel, Vyndamax	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure

AND

3 - Prescribed by or in consultation with a cardiologist

3 . References

Vyndaqel and Vyndamax prescribing information. Pfizer, Inc. New York, NY. May 2021.

Mauer MS, Schwartz JH, Gundapeneni B, et al. Tafamadis treatment for patients with transthyretin amyloid cardiomyopathy. N Engl J Med. 2018; 379:1007-16.

Gillmore JD, Maurer MS, Falk RH, et al. Nonbiopsy diagnosis of cardiac transthyretin amyloidosis. Circulation. 2016; 133:2404-12.

Nativi-Nicolau J and Maurer MS. Amyloidosis cardiomyopathy: update in the diagnosis and treatment of the most common types. Curr Opin Cardiol. 2018; 33(5):571-579.

4 . Revision History

Date	Notes
5/22/2022	2022 Annual Review

Prior Authorization Guideline

Guideline Name	Vyxeos (daunorubicin and cytarabine)

Guideline Note:

Effective Date:	8/1/2022
P&T Approval Date:	9/27/2017
P&T Revision Date:	06/17/2020 ; 06/16/2021 ; 6/15/2022

1 . Indications

Drug Name: Vyxeos (daunorubicin and cytarabine)
Newly-diagnosed therapy-related AML (t-AML) or AML with myelodysplasia-related changes (AML-MRC) Indicated for the treatment of newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) in adults and pediatric patients 1 year and older.

2 . Criteria

Product Name: Vyxeos	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses: [1-3]

Newly-diagnosed therapy-related acute myeloid leukemia (t-AML)

Newly-diagnosed acute myeloid leukemia with myelodysplasia-related changes (AML-MRC)

AND

2 - Prescribed by or in consultation with one of the following:

Oncologist

Hematologist

Product Name: Vyxeos	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Vyxeos Prescribing Information. Jazz Pharmaceuticals. Palo Alto, CA. April 2021.

National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium. Available by subscription at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed May 28,2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Acute Myeloid Leukemia v.3.2021. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed May 28, 2021.

4 . Revision History

Date	Notes
6/1/2022	2022 Annual Review - No changes to criteria

Prior Authorization Guideline

Guideline Name	Xalkori (crizotinib)

Guideline Note:

Effective Date:	11/1/2022
P&T Approval Date:	11/15/2011
P&T Revision Date:	05/14/2020 ; 02/18/2021 ; 05/20/2021 ; 05/19/2022 ; 9/21/2022

1 . Indications

Drug Name: Xalkori (crizotinib)
Non-small cell lung cancer (NSCLC) Indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)- or ROS1-positive as detected by an FDA-approved test. **Anaplastic Large Cell Lymphoma (ALCL)** Indicated for the treatment of pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK-positive. Limitations of use: The safety and efficacy of Xalkori have not been established in older adults with relapsed or refractory, systemic ALK-positive ALCL. **Inflammatory Myofibroblastic Tumor** Indicated for the treatment of adult and pediatric patients 1 year of age and older with unresectable, recurrent, or refractory inflammatory myofibroblastic tumor (IMT) that is ALK-positive.

2 . Criteria

Product Name: Xalkori	
Diagnosis	Non-small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer (NSCLC)

AND

2 - Prescribed by or in consultation with an oncologist

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3.1.2 One of the following:

3.1.2.1 Patient has had disease progression on, contraindication or intolerance to, or is not a candidate for one of the following:

Alecensa (alectinib)

Alunbrig (brugatinib)

OR

3.1.2.2 For continuation of prior therapy

OR

3.2 Patient has MET amplification- or ROS1 rearrangements-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

Product Name: Xalkori	
Diagnosis	Anaplastic Large Cell Lymphoma (ALCL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of systemic anaplastic large cell lymphoma (ALCL)

AND

2 - Disease is one of the following:

Relapsed

Refractory

AND

3 - Patient is 1 year of age or older

AND

4 - Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S.

Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

5 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Xalkori	
Diagnosis	Inflammatory Myofibroblastic Tumor (IMT)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of inflammatory myofibroblastic tumor (IMT)

AND

2 - Disease is one of the following:

Unresectable

Recurrent

Refractory

AND

3 - Patient is 1 year of age or older

AND

4 - Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S.

Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) **AND** **5** - Prescribed by or in consultation with an oncologist

Product Name: Xalkori	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on therapy	

3 . References

Xalkori Prescribing Information. Pfizer Labs. New York, NY. July 2022.

The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at www.nccn.org. Accessed August 12, 2022.

4 . Revision History

Date	Notes
9/6/2022	Added new indication IMT. Added age criterion to ALCL indication per prescribing information. Updated background and references.

Prior Authorization Guideline

Guideline Name	Xeljanz, Xeljanz XR (tofacitinib)

Guideline Note:

Effective Date:	2/1/2023
P&T Approval Date:	2/19/2013
P&T Revision Date:	09/18/2019 ; 11/14/2019 ; 02/13/2020 ; 05/14/2020 ; 09/16/2020 ; 12/16/2020 ; 03/17/2021 ; 09/15/2021 ; 03/16/2022 ; 04/20/2022 ; 06/15/2022 ; 09/21/2022 ; 10/19/2022 ; 12/14/2022

1 . Indications

Drug Name: Xeljanz (tofacitinib) tablets, Xeljanz XR (tofacitinib) extended-release tablets
Rheumatoid Arthritis (RA) Indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Xeljanz/Xeljanz XR in combination with biologic disease-modifying antirheumatic drugs (DMARDs) or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended. **Psoriatic Arthritis (PsA)** Indicated for the treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Xeljanz/Xeljanz XR in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended. **Ankylosing Spondylitis (AS)** Indicated for the treatment of adult patients with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Xeljanz/Xeljanz XR in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Ulcerative Colitis (UC) Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis, who have an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Xeljanz/Xeljanz XR in combination with biological therapies for UC or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.
Drug Name: Xeljanz (tofacitinib) tablets and oral solution
Polyarticular Course Juvenile Idiopathic Arthritis Indicated for the treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Xeljanz in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

2 . Criteria

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Rheumatoid Arthritis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

methotrexate

leflunomide

sulfasalazine

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia, Enbrel, Humira, Amjevita, Simponi)

AND

5 - Not used in combination with biologic DMARDs or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topi cal or inhaled corticosteroids, and/or low stable dosages of oral cortic osteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Rheumatoid Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - Not used in combination with biologic DMARDs or potent immunosuppressants (e.g., azathioprine or cyclosporine)*	
Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets and oral solution	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active polyarticular course juvenile idiopathic arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4]:

leflunomide

methotrexate

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Enbrel, Humira, Amjevita)

AND

5 - Not used in combination with biologic DMARDs or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Xeljanz may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets and oral solution	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - Not used in combination with biologic DMARDs or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Xeljanz may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Psoriatic Arthritis
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis (PsA)

AND

2 - One of the following [5]:

Actively inflamed joints

Dactylitis

Enthesitis

Axial disease

Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

Dermatologist

Rheumatologist

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia, Enbrel, Humira, Amjevita, Simponi)

AND

5 - Not used in combination with biologic DMARDs or potent immunosuppressants (e.g., azathioprine or cyclosporine)*	
Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 5]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline

Reduction in the body surface area (BSA) involvement from baseline

AND

2 - Not used in combination with biologic DMARDs or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [6]

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia, Enbrel, Humira, Amjevita, Simponi)

AND

5 - Not used in combination with biologic DMARDs or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following [1, 6]:

Disease activity (e.g., pain, fatigue, inflammation, stiffness)

Lab values (erythrocyte sedimentation rate, C-reactive protein level)

Function

Axial status (e.g., lumbar spine motion, chest expansion)

Total active (swollen and tender) joint count

AND

2 - Not used in combination with biologic DMARDs or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Ulcerative Colitis
Approval Length	4 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [7, 8]:

Greater than 6 stools per day

Frequent blood in the stools

Frequent urgency

Presence of ulcers

Abnormal lab values (e.g., hemoglobin, ESR, CRP)

Dependent on, or refractory to, corticosteroids

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [7, 8]:

6-mercaptopurine

Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)

Azathioprine

Corticosteroids (e.g., prednisone)

AND

4 - Prescribed by or in consultation with a gastroenterologist

AND

5 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Humira, Amjevita, Simponi)

AND

6 - Not used in combination with biological therapies for UC or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 7, 8]:

Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline

Reversal of high fecal output state

AND

2 - Not used in combination with biological therapies for UC or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

3 . Endnotes

Initial approval length of 4 months based on dosing recommendation provided in the labeling of Xeljanz 10 mg twice daily or Xeljanz XR 22 mg once daily for at least 8 weeks, followed by Xeljanz 5 mg once or twice daily, 10 mg twice daily, or Xeljanz XR 11 mg once daily depending on therapeutic response. Xeljanz should be discontinued after 16 weeks (4 months) of treatment with Xeljanz 10 mg twice daily or Xeljanz XR 22 mg once daily if adequate therapeutic response is not achieved.

4 . References

Xeljanz, Xeljanz XR Prescribing Information. Pfizer, Inc. New York, NY. January 2022.

Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.

Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.

Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Rheumatol. 2019;71(6):846-863.

Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.

Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613.

Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol 2019;114:384–413.

Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterol. 2020;158:1450-1461.

5 . Revision History

Date	Notes
2/1/2023	Addition of Amjevita as another TNF inhibitor example

Prior Authorization Guideline

Guideline Name	Xeloda (capecitabine)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	6/24/2015
P&T Revision Date:	10/21/2020 ; 10/20/2021 ; 04/20/2022 ; 09/21/2022 ; 10/19/2022 ; 3/15/2023

1 . Indications

Drug Name: Xeloda (capecitabine)
Colorectal Cancer Indicated for (1) for the adjuvant treatment of patients with Stage III colon cancer as a single agent or as a component of a combination chemotherapy regimen; 2) the perioperative treatment of adults with locally advanced rectal cancer as a component of chemoradiotherapy; 3) Indicated for the treatment of patients with unresectable or metastatic colorectal cancer as a single agent or as a component of a combination chemotherapy regimen. **Breast Cancer** Indicated for 1) the treatment of patients with advanced or metastatic breast cancer as a single agent if an anthracycline- or taxane-containing chemotherapy is not indicated; 2) the treatment of patients with advanced or metastatic breast cancer in combination with docetaxel after disease progression on prior anthracycline-containing chemotherapy. **Gastric, Esophageal, or Gastroesophageal Junction Cancer** Indicated for the 1) treatment of adults with unresectable or metastatic gastric, esophageal, or gastroesophageal junction cancer as a component of a combination chemotherapy regimen; 2) treatment of adults with HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease as a component of a combination regimen.

Pancreatic Cancer Indicated for the adjuvant treatment of adults with pancreatic adenocarcinoma as a component of a combination chemotherapy regimen.

2 . Criteria

Product Name: Brand Xeloda, generic capecitabine	
Diagnosis	Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of colorectal cancer

AND

2 - Disease is one of the following:

Stage III or Locally Advanced

Unresectable

Metastatic

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Brand Xeloda, generic capecitabine	
Diagnosis	Breast Cancer
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Disease is one of the following:

Advanced

Metastatic

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Brand Xeloda, generic capecitabine	
Diagnosis	Gastric, Esophageal, or Gastroesophageal Junction Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

Gastric Cancer

Esophageal Cancer

Gastroesophageal Junction Cancer

AND

2 - Disease is one of the following:

Unresectable

Metastatic

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Brand Xeloda, generic capecitabine	
Diagnosis	Pancreatic Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Pancreatic Cancer

AND

2 - Prescribed by or in consultation with an oncologist

Product Name: Brand Xeloda, generic capecitabine	
Diagnosis	All Indications Listed Above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Xeloda prescribing information. Genentech, Inc. South San Francisco, CA. December 2022.

4 . Revision History

Date	Notes
3/1/2023	Criteria update to reflect new FDA-approved indications.

Prior Authorization Guideline

Guideline Name	Xenazine (tetrabenazine)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	4/6/2010
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 05/19/2022 ; 5/18/2023

1 . Indications

Drug Name: Xenazine (tetrabenazine)
Chorea associated with Huntington's disease Indicated for the treatment of chorea associated with Huntington's disease. **Off Label Uses: Hyperkinetic movement disorders in tardive dyskinesia and Tourette's syndrome [2-5]** Has shown effectiveness in the treatment of hyperkinetic movement disorders (hyperkinesias) characterized by abnormal involuntary movements seen in tardive dyskinesia (TD), or issues such as tics (eye blink, shouting obscenities or profanities, etc.) observed in Tourette's syndrome (TS).

2 . Criteria

Product Name: Brand Xenazine	
Diagnosis	Chorea associated with Huntington's disease
Approval Length	3 months [B]

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chorea in patients with Huntington's disease

AND

2 - Prescribed by or in consultation with a neurologist [C]

AND

3 - Trial and failure or intolerance to a minimum 30 day supply of generic tetrabenazine

Product Name: Generic tetrabenazine	
Diagnosis	Chorea associated with Huntington's disease
Approval Length	3 months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chorea in patients with Huntington's disease

AND

2 - Prescribed by or in consultation with a neurologist [C]

Product Name: Brand Xenazine, Generic tetrabenazine	
Diagnosis	Chorea associated with Huntington's disease
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Brand Xenazine	
Diagnosis	Tourette's syndrome (Off-label)
Approval Length	3 Months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has tics associated with Tourette's syndrome [2, 4]

AND

2 - Trial and failure, contraindication, or intolerance to a minimum 30 day supply of Haldol (haloperidol)

AND

3 - Prescribed by or in consultation with one of the following:

Neurologist

Psychiatrist

AND

4 - Trial and failure or intolerance to a minimum 30 day supply of generic tetrabenazine

Product Name: Generic tetrabenazine	
Diagnosis	Tourette's syndrome (Off-label)
Approval Length	3 Months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has tics associated with Tourette's syndrome [2, 4]

AND

2 - Trial and failure, contraindication, or intolerance to a minimum 30 day supply of Haldol (haloperidol)

AND

3 - Prescribed by or in consultation with one of the following:

Neurologist

Psychiatrist

Product Name: Brand Xenazine, Generic tetrabenazine	
Diagnosis	Tourette's syndrome (Off-label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Brand Xenazine	
Diagnosis	Tardive dyskinesia (Off-label)
Approval Length	3 months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of tardive dyskinesia [3, 4]

AND

2 - One of the following [A, 5]:

2.1 Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication

OR

2.2 Patient is not a candidate for a trial of dose reduction, tapering or discontinuation of the offending medication

AND

3 - Prescribed by or in consultation with one of the following:

Neurologist

Psychiatrist

AND

4 - Trial and failure or intolerance to a minimum 30 day supply of generic tetrabenazine

Product Name: Generic tetrabenazine

Diagnosis	Tardive dyskinesia (Off-label)
Approval Length	3 months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of tardive dyskinesia [3, 4]

AND

2 - One of the following [A, 5]:

2.1 Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication

OR

2.2 Patient is not a candidate for a trial of dose reduction, tapering or discontinuation of the offending medication

AND

3 - Prescribed by or in consultation with one of the following:

Neurologist

Psychiatrist

Product Name: Brand Xenazine, Generic tetrabenazine	
Diagnosis	Tardive dyskinesia (Off-label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

3 . Endnotes

Verified with consultant for a previous medication (Ingrezza [valbenazine]) that dose reduction, tapering, or discontinuation of the offending medication is considered first-line treatment for tardive dyskinesia. [5]

Authorization period is based on the pivotal study duration of 12 weeks. [1]

Ensures the requirement for proper diagnosing and quantifying an adequate chorea score (total maximal chorea score of greater than or equal to 10 (moderate to severe chorea) from the subscale of the Unified Huntington's Disease Rating Scale (UHDRS). Note that the pivotal trial that established efficacy of tetrabenazine included patients with a total maximal chorea of greater than or equal to 10. [1]

4 . References

Xenazine Prescribing Information. Lundbeck. Deerfield, IL. November 2019.

Sweet RD, Brauun R, Shapiro E, Shapiro AK. Presynaptic catecholamine antagonists as treatment for Tourette syndrome. Effects of alpha methyl para tyrosine and tetrabenazine. Arch Gen Psych. 1974;31:857-861.

Kazamatsuri H, Chien C-P, Cole J. Treatment of Tardive Dyskinesia: clinical efficacy of a dopamine-depleting agent, tetrabenazine. Arch Gen Psychiat. 1972;27:95-99.

Micromedex® (electronic version). IBM Watson Health, Greenwood Village, Colorado. Available at: https://www.micromedexsolutions.com. Accessed April 1, 2021.

Per clinical consult with psychiatrist regarding Ingrezza (valbenazine), June 9, 2017.

5 . Revision History

Date	Notes

4/21/2023	2023 Annual Review.

Prior Authorization Guideline

Guideline Name	Xgeva (denosumab)

Guideline Note:

Effective Date:	9/1/2022
P&T Approval Date:	4/5/2011
P&T Revision Date:	06/17/2020 ; 07/15/2020 ; 07/21/2021 ; 05/19/2022 ; 7/20/2022

1 . Indications

Drug Name: Xgeva (denosumab)
Multiple myeloma and Bone metastasis from solid tumors Indicated for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors. **Giant cell tumor of bone** Indicated for the treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. **Hypercalcemia of malignancy** Indicated for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

2 . Criteria

Product Name: Xgeva

Diagnosis	Skeletal prevention in multiple myeloma and bone metastasis from solid tumors (BMST)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of multiple myeloma

AND

1.1.2 Trial and failure, contraindication (e.g., renal insufficiency), or intolerance, to one intravenous bisphosphonate (e.g., zoledronic acid) [9]

OR

1.2 Both of the following:

1.2.1 Diagnosis of solid tumors (e.g., breast cancer, kidney cancer, lung cancer, prostate cancer, thyroid cancer) [1-5]

AND

1.2.2 Documented evidence of one or more metastatic bone lesions

Product Name: Xgeva	
Diagnosis	Giant cell tumor of bone
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of giant cell tumor of bone

AND

2 - One of the following:

2.1 Tumor is unresectable

OR

2.2 Surgical resection is likely to result in severe morbidity

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Xgeva	
Diagnosis	Giant cell tumor of bone
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Xgeva therapy [A]

Product Name: Xgeva	
Diagnosis	Hypercalcemia of malignancy
Approval Length	2 Month [B]

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hypercalcemia of malignancy

AND

2 - Trial and failure, contraindication, or intolerance to one intravenous bisphosphonate (e.g., pamidronate, zoledronic acid) [6, 7]

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Xgeva	
Diagnosis	Hypercalcemia of malignancy
Approval Length	2 Month [B]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xgeva therapy

3 . Endnotes

Xgeva should be continued until disease progression in responding patients. [8]

Median time on the study for the treatment of hypercalcemia of malignancy was 56 days. [6]

4 . References

Xgeva prescribing information. Amgen Inc. Thousand Oaks, CA. June 2020.

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5 . Revision History

Date	Notes
7/6/2022	2022 Annual Review - No changes to criteria

Prior Authorization Guideline

Guideline Name	Xiaflex (collagenase clostridium histolyticum)

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	2/25/2016
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Xiaflex (collagenase clostridium histolyticum)
Dupuytren's Contracture Indicated for the treatment of adult patients with Dupuytren's contracture with a palpable cord. **Peyronie's Disease** Indicated for the treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy.

2 . Criteria

Product Name: Xiaflex	
Diagnosis	Dupuytren’s contracture
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Dupuytren's contracture with a palpable cord

AND

2 - Patient has a positive "table top test" (defined as the inability to simultaneously place the affected finger and palm flat against a table top) [A]

AND

3 - Patient has a documented contracture of at least 20 degrees flexion for a metacarpophalangeal joint or a proximal interphalangeal joint [B]

AND

4 - Patient has a flexion deformity that results in functional limitations

Product Name: Xiaflex	
Diagnosis	Peyronie's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Peyronie's disease

AND

2 - Patient has a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy [C]

AND

3 - The plaques do not involve the penile urethra

AND

4 - Patient has a curvature deformity that results in pain (e.g., pain upon erection or intercourse) [C]

Product Name: Xiaflex	
Diagnosis	Peyronie’s disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Peyronie’s disease

AND

2 - Patient has a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy

AND

3 - The plaques do not involve the penile urethra

AND

4 - Patient has a curvature deformity that results in pain (e.g., pain upon erection or intercourse)

AND **5** - Patient has a new plaque that results in a curvature deformity

3 . Endnotes

Dupuytren's disease diagnosis can include a table top test to assess the severity of the disease. When a patient is unable to place his or her palm and the affected finger flat on the table, the test can help diagnosis Dupuytren's disease. [1]

Dupuytren's disease is associated with joint contracture. Xiaflex was studied in a patient population with joint contracture of at least 20 degrees. Evidence does not support any benefit in patients with joint contracture less than 20 degrees. Our program requires that the patient has a flexion deformity that results in functional limitations to protect against cosmetic use. [1]

Peyronie's disease is characterized by a curvature deformity. Xiaflex was studied in a patient population with a curvature deformity of at least 30 degrees. Evidence does not support any benefit in patients with a curvature deformity less than 30 degrees. To prevent cosmetic use, patients must also have a curvature deformity that results in pain. [1]

4 . References

Xiaflex Prescribing Information. Endo Pharmaceuticals, Inc. Malvern, PA. July 2022.

5 . Revision History

Date	Notes
3/28/2023	2023 Annual Review. No criteria changes. Updated references

Prior Authorization Guideline

Guideline Name	Xifaxan (rifaximin)

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	12/6/2004
P&T Revision Date:	10/19/2022

1 . Indications

Drug Name: Xifaxan (rifaximin)
Travelers' Diarrhea 200mg is indicated for the treatment of travelers' diarrhea (TD) caused by noninvasive strains of Escherichia coli in adults and pediatric patients 12 years of age and older. Limitations of use: Do not use in patients with diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than Escherichia coli. [A] **Prophylaxis of Hepatic Encephalopathy Recurrence** 550 mg is indicated for reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults. In the trials of Xifaxan for HE, 91% of patients were using lactulose concomitantly. Differences in the treatment effect of those patients not using lactulose concomitantly could not be assessed. Xifaxan has not been studied in patients with MELD (Model for End-Stage Liver Disease) score greater than 25, and only 8.6% of patients in the controlled trial had MELD scores over 19. There is increased systemic exposure in patients with more severe hepatic dysfunction. **Irritable Bowel Syndrome with Diarrhea** 550 mg is indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults. **Off Label Uses: Treatment of Hepatic Encephalopathy** Used for the treatment of hepatic encephalopathy. [4, 5, 22]

Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO) Has been used for the treatment of small intestinal bacterial overgrowth. [7, 8, 10, 13]

2 . Criteria

Product Name: Xifaxan 200 mg tablets	
Diagnosis	Travelers' Diarrhea (TD)
Approval Length	1 Time only
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of travelers' diarrhea (TD)

AND

2 - Disease is moderate to severe [D, 9]

AND

3 - One of the following:

3.1 Trial and failure of one of the following: [2, 3, D, E]

Zithromax (azithromycin)

Cipro (ciprofloxacin)

Levaquin (levofloxacin)

Ofloxacin

OR

3.2 Resistance, contraindication, or intolerance to all of the following antibiotics:

Zithromax (azithromycin)

Cipro (ciprofloxacin)

Levaquin (levofloxacin)

Ofloxacin

Product Name: Xifaxan	
Diagnosis	Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO) (off-label)
Approval Length	3 Months [C]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO)

AND

2 - One of the following:

2.1 Trial and failure of two of the following antibiotics: [5, 16-21]

Neomycin

Augmentin (amoxicillin/clavulanic acid)

Cipro (ciprofloxacin)

Bactrim (trimethoprim-sulfamethoxazole)

Vibramycin (doxycycline) or Minocin (minocycline) or tetracycline

Flagyl (metronidazole)

Keflex (cephalexin)

OR

2.2 Resistance, contraindication, or intolerance to all of the following antibiotics:

Neomycin

Augmentin (amoxicillin/clavulanic acid)

Cipro (ciprofloxacin)

Bactrim (trimethoprim-sulfamethoxazole)

Vibramycin (doxycycline) or Minocin (minocycline) or tetracycline

Flagyl (metronidazole)

Keflex (cephalexin)

Product Name: Xifaxan	
Diagnosis	Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO) (off-label)
Approval Length	3 Months [C]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., resolution of symptoms or relapse with Xifaxan discontinuation) [B]

Product Name: Xifaxan 550 mg tablets	
Diagnosis	Irritable Bowel Syndrome with Diarrhea (IBS-D)
Approval Length	2 Weeks [1, I]

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of irritable bowel syndrome with diarrhea (IBS-D) [F]

AND

2 - Patient is 18 years of age or older [L]

AND

3 - Trial and failure, contraindication, or intolerance to a Tricyclic Antidepressant (e.g., amitriptyline)

Product Name: Xifaxan 550 mg tablets	
Diagnosis	Irritable Bowel Syndrome with Diarrhea (IBS-D)
Approval Length	2 Weeks [1, I]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Symptoms of Irritable Bowel Syndrome continue to persist [G, H]

AND

2 - Documentation of positive clinical response to therapy as evidenced by both of the following: [1]

Improvement in abdominal pain

Reduction in the Bristol Stool Scale

AND

3 - Trial and failure, contraindication, or intolerance to a Tricyclic Antidepressant (e.g., amitriptyline)

Product Name: Xifaxan 550 mg tablets	
Diagnosis	Prophylaxis of Hepatic Encephalopathy (HE) Recurrence
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Used for prophylaxis of hepatic encephalopathy (HE) recurrence

AND

2 - Patient is 18 years of age or older [L]

AND

3 - One of the following: [J, 22]

3.1 Both of the following:

3.1.1 Used as add-on therapy to lactulose

AND

3.1.2 Patient is unable to achieve an optimal clinical response with lactulose monotherapy

OR

3.2 History of contraindication or intolerance to lactulose

Product Name: Xifaxan 550 mg tablets	
Diagnosis	Prophylaxis of Hepatic Encephalopathy (HE) Recurrence
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy [M, 27, 28]

Product Name: Xifaxan	
Diagnosis	Treatment of Hepatic Encephalopathy (Off-Label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Used for the treatment of hepatic encephalopathy (HE) [5, K]

AND

2 - Patient is 18 years of age or older [L]

AND

3 - One of the following: [22, K]

3.1 Both of the following:

3.1.1 Used as add-on therapy to lactulose

AND

3.1.2 Patient is unable to achieve an optimal clinical response with lactulose monotherapy

OR

3.2 History of contraindication or intolerance to lactulose

3 . Endnotes

Antibiotic treatment should be avoided in diarrhea caused by enterohemorrhagic E. coli. [6]

The main goals in the treatment of SBBO are 1) treatment of underlying small intestinal abnormality, when possible; 2) concentration on long-term antibiotic therapy when surgical management is not feasible; 3) adjunctive treatment of dysmotility, such as a prokinetic agent; and 4) nutritional support, particularly in patients with weight loss or vitamin deficiency. [7]

In most patients, a single course of treatment (10 days) markedly improves symptoms, and patients may remain free of symptoms for months. In others, symptoms recur quickly, and acceptable results can only be obtained with cyclic treatment (1 of every 4 weeks). In still others, continuous treatment may be needed for 1 to 2 months. If the antimicrobial agent is effective, a resolution or marked diminution of symptoms will be notable within several days of initiating therapy. Diarrhea and steatorrhea will decrease, and cobalamin malabsorption will be corrected. [7]

According to the Centers for Disease Control and Prevention's Yellow Book, antibiotics may be used to treat cases of moderate to severe travelers’ diarrhea. Fluoroquinolones including, but not limited to, ciprofloxacin and levofloxacin, are considered first line agents in the treatment of Traveler's Diarrhea (TD). Azithromycin is also considered a first line agent for treatment of TD and is especially efficacious in the pediatric population. The overall usefulness of Rifaximin for empiric self-treatment remains to be determined as Rifaximin has only been shown to be efficacious in patients with noninvasive strains of E. coli. [9]

Levofloxacin, ofloxacin and ciprofloxacin have all been shown to be highly effective in the treatment and prevention of Travelers' Diarrhea and should be considered first-line therapy options for this indication. [11]

In the TARGET I, II and III pivotal trials, Irritable Bowel Syndrome was diagnosed using the ROME II diagnostic criteria. According to the ROME-II criteria, an IBS-D diagnosis requires at least 12 consecutive weeks in the previous 12 months of abdominal discomfort or pain that has two out of the three following features: relieved with defecation; and/or onset associated with a change in frequency of stool; and/or onset associated with a change in appearance of stool [12, 14]

In the TARGET III pivotal trial, a total of 636 responders (59%) required retreatment. The median time to recurrence for patients who experienced initial response was 10 weeks (range from 6 to 24 weeks) [14]

According to the ROME-IV criteria, recurrent signs and symptoms of IBS-D include the following: a return of abdominal pain or mushy/watery stool consistency for at least 3 weeks during a 4-week follow-up period. [15]

The recommended dose of Xifaxan for IBS-D is one 550 mg tablet taken orally three times a day for 14 days. [1]

The American Association for the Study of Liver Diseases (AASLD) and the European Association for the Study of the Liver (EASL) recommend rifaximin as an effective add-on therapy to lactulose for prevention of over hepatic encephalopathy with strength of recommendation 1A. No solid data support the use of rifaximin alone. [22]

Rifaximin has been used for the treatment of HE in a number of trials comparing it with placebo, other antibiotics, nonabsorable disaccharides, and in dose-ranging studies. These trials showed effect of rifaximin that was equivalent or superior to the compared agents with good tolerability. No solid data support the use of rifaximin alone. [22]

A minimum age requirement that aligns with the prescribing information was added for prophylaxis and treatment of hepatic encephalopathy and IBS-D to prevent misuse of Xifaxan in pediatrics. The same age requirement was not added for traveler’s diarrhea or SBBO/SIBO due to the patient population (e.g., pediatrics) that Xifaxan was studied in. [1, 8, 10, 13, 26]

The risk of a breakthrough episode of hepatic encephalopathy (HE) in patients who recently had history of recurrent overt HE was reduced while taking Xifaxan. Additionally, patients on Xifaxan achieved full resolution of HE, so there is benefit with long-term use of Xifaxan for the prophylaxis of HE. [27, 28]

4 . References

Xifaxan prescribing information. Salix Pharmaceuticals, Inc. Bridgewater, NJ. October 2020.

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5 . Revision History

Date	Notes
9/19/2022	Program Update.

Prior Authorization Guideline

Guideline Name	Xiidra (lifitegrast)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	8/18/2016
P&T Revision Date:	04/15/2020 ; 06/17/2020 ; 06/16/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Xiidra (lifitegrast)
Dry eye disease Indicated for the treatment of the signs and symptoms of dry eye disease (DED).

2 . Criteria

Product Name: Xiidra	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of dry eye disease

Product Name: Xiidra	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., increased tear production or improvement in dry eye symptoms)

3 . Endnotes

As disease severity increases, aqueous enhancement of the eye using topical agents is appropriate (i.e., emulsions, gels, and ointments can be used). Topical cyclosporine, topical corticosteroids, topical lifitegrast, systemic omega-3 fatty acid supplements, punctual plugs and spectacle side shields/moisture chambers may also be considered in addition to aqueous enhancement therapies in patients who need additional symptom management. [2]

4 . References

Xiidra Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. July 2020.

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5 . Revision History

Date	Notes

2/2/2023	2023 Annual Review.

Prior Authorization Guideline

Guideline Name	Xolair (omalizumab)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	7/14/2003
P&T Revision Date:	11/14/2019 ; 02/13/2020 ; 02/18/2021 ; 03/17/2021 ; 11/18/2021 ; 03/16/2022 ; 05/19/2022 ; 5/18/2023

1 . Indications

Drug Name: Xolair (omalizumab)
Allergic Asthma Indicated for adults and pediatric patients 6 years of age and older with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. Limitations of Use: Xolair is not indicated for treatment of other allergic conditions. Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus. **Chronic Spontaneous Urticaria (CSU)** Indicated for the treatment of adults and adolescents 12 years of age and older with chronic spontaneous urticaria who remain symptomatic despite H1 antihistamine treatment. Limitations of Use: Xolair is not indicated for treatment of other forms of urticaria. **Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)** Indicated for add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.

2 . Criteria

Product Name: Xolair	
Diagnosis	Allergic Asthma
Approval Length	6 months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe persistent allergic asthma [1, 2]

AND

2 - Positive skin test or in vitro reactivity to a perennial aeroallergen [1, D]

AND

3 - One of the following [1, F]:

3.1 Both of the following:

Patient is 12 years of age or older

Pre-treatment serum immunoglobulin (Ig)E level between 30 to 700 IU/mL

OR

3.2 Both of the following:

Patient is 6 years to less than 12 years of age

Pre-treatment serum immunoglobulin (Ig)E level between 30 to 1300 IU/mL

AND

4 - Patient is currently being treated with ONE of the following, unless there is a contraindication or intolerance to these medications: [3, A]

4.1 Both of the following:

High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day)

Additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium)

OR

4.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Symbicort [budesonide/formoterol], Breo Ellipta [fluticasone/vilanterol])

AND

5 - Prescribed by or in consultation with one of the following: [G]

Pulmonologist

Allergist/Immunologist

Product Name: Xolair	
Diagnosis	Allergic Asthma
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications)

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications [3]

AND

3 - Prescribed by or in consultation with one of the following: [G]

Pulmonologist

Allergist/immunologist

Product Name: Xolair	
Diagnosis	Chronic Spontaneous Urticaria (CSU)
Approval Length	3 months [E]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic spontaneous urticaria [1]

AND

2 - Persistent symptoms (itching and hives) for at least 4 consecutive weeks despite titrating to an optimal dose with a second generation H1 antihistamine (e.g., cetirizine, fexofenadine), unless there is a contraindication or intolerance to H1 antihistamines

AND

3 - Used concurrently with an H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamines

AND

4 - Patient has tried and had an inadequate response or intolerance at least TWO of the following additional therapies: [6, 7]

Doxepin

H1 antihistamine

H2 antagonist (e.g., famotidine, cimetidine)

Hydroxyzine

Leukotriene receptor antagonist (e.g., montelukast)

AND

5 - Prescribed by or in consultation with one of the following:

Allergist/immunologist

Dermatologist

Product Name: Xolair	
Diagnosis	Chronic Spontaneous Urticaria (CSU)
Approval Length	6 months [B]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient's disease status has been re-evaluated since the last authorization to confirm the patient's condition warrants continued treatment

AND

2 - Patient has experienced at least one of the following:

Reduction in itching severity from baseline

Reduction in the number of hives from baseline

Product Name: Xolair	
Diagnosis	Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP)

AND

2 - Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone) [8, 9]

AND

3 - Used in combination with another agent for chronic rhinosinusitis with nasal polyps (CRSwNP) [H]

AND

4 - Prescribed by or in consultation with one of the following:

Allergist/Immunologist

Otolaryngologist

Pulmonologist

Product Name: Xolair	
Diagnosis	Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS; 0-8 scale], improvement in nasal congestion/obstruction score [NCS; 0-3 scale])

AND

2 - Used in combination with another agent for chronic rhinosinusitis with nasal polyps (CRSwNP) [H]

AND

3 - Prescribed by or in consultation with one of the following:

Allergist/Immunologist

Otolaryngologist

Pulmonologist

3 . Background

Clinical Practice Guidelines

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 1. Low, medium and high daily doses of inhaled corticosteroids in adolescents and adults 12 years and older [3]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	> 500-1000	> 1000
Beclometasone dipropionate (DPI or pMDI, extrafine particle*, HFA)	100-200	> 200-400	> 400
Budesonide (DPI, or pMDI, standard particle, HFA)	200-400	> 400-800	> 800
Ciclesonide (pMDI, extrafine particle*, HFA)	80-160	> 160-320	> 320
Fluticasone furoate (DPI)	100		200
Fluticasone propionate (DPI)	100-250	> 250-500	> 500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	> 250-500	> 500
Mometasone furoate (DPI)	Depends on DPI device – see product information		
Mometasone furoate (pMDI, standard particle, HFA)	200-400		> 400

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.

***This is not a table of equivalence**,* but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply potency equivalence. Doses may be country -specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

4 . Endnotes

National treatment guidelines recommend the combination of an inhaled glucocorticosteroid and a long-acting beta2-agonist for the treatment of moderate persistent or severe persistent asthma. [2-5]

The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention update recommends that patients with asthma should be reviewed regularly to monitor their symptom control, risk factors and occurrence of exacerbations, as well as to document the response to any treatment changes. Ideally, response to Type 2-targeted therapy should be re-evaluated every 3-6 months, including re-evaluation of the need for ongoing biologic therapy for patients with good response to Type 2 targeted therapy. Clinical studies for allergic asthma evaluated an initial 16-week steroid stable phase in which subjects received omalizumab with a constant dose of inhaled steroids. This 16-week period may not be sufficient amount of time to show reduction in exacerbations. For allergic asthma, initial authorization duration increased from 16 weeks to 6 months. [3, 4]

Asthma treatment can often be reduced, once good asthma control has been achieved and maintained for three months and lung function has hit a plateau. However the approach to stepping down will depend on patient specific factors (e.g., current medications, risk factors). At this time evidence for optimal timing, sequence and magnitude of treatment reductions is limited. It is feasible and safe for most patients to reduce the ICS dose by 25-50% at three month intervals, but complete cessation of ICS is associated with a significant risk of exacerbations [3].

Sensitization to a perennial allergen (e.g., mite, cat, dog) should be required. [4] Xolair is indicated for children and adults (6 years of age and above) with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. [1]

For chronic idiopathic urticaria, response observed at 12 weeks (one 24-week trial with data reported at 12 weeks, and one 12-week trial) [1]

Per prescribing information, pretreatment serum total IgE levels of 30 to 700 IU/mL applies to patients 12 years of age and older with asthma. [1]

Referral to an asthma specialist for consultation or comanagement is recommended if Xolair is being considered. [2]

Other agents used for nasal polyps include intranasal corticosteroids and nasal saline.

5 . References

Xolair Prescribing Information. Genentech, Inc. South San Francisco, CA. March 2023.

National Heart, Lung, and Blood Institute, National Asthma Education and Prevention Program. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. National Institutes of Health Publication No.08-5846. Bethesda, MD, 2007. Available at: https://www.nhlbi.nih.gov/health-topics/guidelines-for-diagnosis-management-of-asthma. Accessed January 9, 2020.

Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention (2022 update). 2022 www.ginasthma.org. Accessed April 2023.

Per clinical consult with asthma specialist, January 6, 2011.

National Institute for Health and Care Excellence (NICE). Omalizumab for treating severe persistent allergic asthma (review of technology appraisal guidance 133 and 201). London (UK): National Institute for Health and Care Excellence (NICE); 2013 Apr. 64 p. (Technology appraisal guidance; no. 278). Available at https://www.nice.org.uk/guidance/ta278/resources/omalizumab-for-treating-severe-persistent-allergic-asthma-pdf-82600619176645. Accessed January 9, 2020.

Bernstein JA, Lang DM, Khan DA, et al. The diagnosis and management of acute and chronic urticaria: 2014 update. J Allergy Clin Immunol. 2014;133(5):1270-7.

DRUGDEX System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Accessed March 11, 2021.

Peters AT, Spector S, Hsu J, et al. Diagnosis and management of rhinosinusitis: a practice parameter update. Ann Allergy Asthma Immunol. 2014;113(4):347-85.

Orlandi RR, Kingdom TT, Hwang PH, et al. International consensus statement on allergy and rhinology: rhinosinusitis. Int Forum Allergy Rhinol. 2016 Feb; Suppl 1:S22-209.

6 . Revision History

Date	Notes
4/24/2023	2023 UM Annual Review. Updated indications to align with PI. Update chronic idiopathic urticaria to be chronic spontaneous urticaria and update nasal polyps to be Chronic rhinosinusitis with nasal polyps (CRSwNP) in criteria to align with updated indications. No changes to clinical intent. Background updates

Prior Authorization Guideline

Guideline Name	Xtandi (enzalutamide)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	11/13/2012
P&T Revision Date:	02/13/2020 ; 05/14/2020 ; 04/21/2021 ; 04/20/2022 ; 5/18/2023

1 . Indications

Drug Name: Xtandi (enzalutamide)
Castration-resistant prostate cancer (CRPC) Indicated for the treatment of patients with castration-resistant prostate cancer (CRPC). **Metastatic castration-sensitive prostate cancer (mCSPC)** Indicated for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC).

2 . Criteria

Product Name: Xtandi	
Diagnosis	Castration-resistant prostate cancer (CRPC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of castration-resistant (chemical or surgical) prostate cancer

AND

2 - Prescribed by or in consultation with one of the following:

Oncologist

Urologist

Product Name: Xtandi	
Diagnosis	Castration-sensitive prostate cancer (mCSPC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of castration-sensitive prostate cancer

AND

2 - Prescribed by or in consultation with one of the following:

Oncologist

Urologist

Product Name: Xtandi

Diagnosis	Castration-resistant prostate cancer (CRPC), Castration-sensitive prostate cancer (mCSPC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Xtandi prescribing information. Astellas Pharma Inc. Northbrook, IL. September 2022.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Prostate Cancer v.1.2020. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed April 2020.

4 . Revision History

Date	Notes
5/4/2023	Annual review: Updated criteria, updated references and background .

Prior Authorization Guideline

Guideline Name	Xultophy (insulin degludec/ liraglutide)

Guideline Note:

Effective Date:	8/1/2022
P&T Approval Date:	5/17/2017
P&T Revision Date:	04/15/2020 ; 06/17/2020 ; 06/16/2021 ; 6/15/2022

1 . Indications

Drug Name: Xultophy (insulin degludec/ liraglutide)
Type 2 diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: XULTOPHY 100/3.6 is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of the rodent C-cell tumor findings to humans. XULTOPHY 100/3.6 is not recommended for use in combination with any other product containing liraglutide or another GLP-1 receptor agonist. XULTOPHY 100/3.6 is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. XULTOPHY 100/3.6 has not been studied in combination with prandial insulin.

2 . Criteria

Product Name: Xultophy	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Trial and failure, contraindication, or intolerance to one of the following generics:

metformin

metformin ER

glipizide-metformin

glyburide-metformin

pioglitazone-metformin

3 . References

Xultophy Prescribing Information. Novo Nordisk Inc. Bagsvaerd, Denmark. November 2019.

4 . Revision History

Date	Notes
6/1/2022	Annual review: No criteria changes.

Prior Authorization Guideline

Guideline Name	Yonsa (abiraterone acetate) - PA, NF

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	7/18/2018
P&T Revision Date:	02/13/2020 ; 05/14/2020 ; 05/20/2021 ; 12/15/2021 ; 05/19/2022 ; 5/18/2023

1 . Indications

Drug Name: Yonsa (abiraterone acetate)
Metastatic Castration-Resistant Prostate Cancer (mCRPC) Indicated in combination with methylprednisolone for the treatment of patients with metastatic castration-resistant prostate cancer.

2 . Criteria

Product Name: Yonsa	
Diagnosis	Castration-Resistant Prostate Cancer (mCRPC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of castration resistant (chemical or surgical) prostate cancer

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to Xtandi (enzalutamide)

OR

2.2 For continuation of prior therapy

AND

3 - Prescribed by or in consultation with one of the following:

Oncologist

Urologist

Product Name: Yonsa	
Diagnosis	Castration-Resistant Prostate Cancer (mCRPC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Yonsa	
Diagnosis	Castration-Resistant Prostate Cancer (mCRPC)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of castration resistant (chemical or surgical) prostate cancer

AND

2 - One of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Xtandi (enzalutamide)

OR

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

3 - Prescribed by or in consultation with one of the following:

Oncologist

Urologist

3 . References

Yonsa prescribing information. Sun Pharmaceutical Industries, Inc. Cranbury, NJ. March 2022.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Prostate Cancer v.3.2022. Available by subscription at:

https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed May 3, 2022.

4 . Revision History

Date	Notes
5/4/2023	Annual review: Updated criteria, updated references and background .

Prior Authorization Guideline

Guideline Name	Zaltrap (ziv-aflibercept)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	11/13/2012
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 05/19/2022 ; 5/18/2023

1 . Indications

Drug Name: Zaltrap (ziv-aflibercept)
Metastatic Colorectal Cancer (mCRC) Indicated in combination with 5-fluorouracil, leucovorin, irinotecan-(FOLFIRI) for the treatment of patients with metastatic colorectal cancer (mCRC) that is resistant to or has progressed following an oxaliplatin-containing regimen.

2 . Criteria

Product Name: Zaltrap	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic colon and/or rectal cancer

AND

2 - Used in combination with 5-fluorouracil, leucovorin, and irinotecan (FOLFIRI) regimen

AND

3 - Patient has disease that is resistant to or has progressed following an oxaliplatin-containing regimen [e.g., 5-fluorouracil, leucovorin, and oxaliplatin (FOLFOX)] [1, 2]

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Zaltrap	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Zaltrap prescribing information. Sanofi-Aventis. Bridgewater, NJ. December 2020.

National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium [internet database]. National Comprehensive Cancer Network, Inc.; 2020. Updated periodically. Available by subscription at: www.nccn.org. Accessed April 6, 2023.

4 . Revision History

Date	Notes
5/3/2023	Annual review - updated reauth criteria to add "while on therapy" for clarification. Updated background and references.

Prior Authorization Guideline

Guideline Name	Zelboraf (vemurafenib)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	2/21/2012
P&T Revision Date:	03/18/2020 ; 03/17/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Zelboraf (vemurafenib)
Melanoma Indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test. It is not recommended for use in patients with wild-type BRAF melanoma. **Erdheim-Chester Disease** Indicated for the treatment of patients with Erdheim-Chester Disease with BRAF V600 mutation.

2 . Criteria

Product Name: Zelboraf	
Diagnosis	Melanoma
Approval Length	12 Month [A]
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses: [2]

Unresectable melanoma

Metastatic melanoma

AND

2 - Cancer is BRAF V600 mutant type as detected by an FDA-approved test (e.g., cobas 4600 BRAF V600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Zelboraf	
Diagnosis	Erdheim-Chester Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Erdheim-Chester disease (ECD)

AND

2 - Disease is BRAF V600 mutant type (MT)

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Zelboraf	
Diagnosis	All Indications
Approval Length	12 Month [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

In the pivotal trial (Trial 1) evaluating treatment naive patients who received Zelboraf (vemurafenib), the median follow-up was 6.2 months and the median progression free survival (PFS) was 5.3 months (95% CI, 4.9 - 6.6). In the pivotal trial (Trial 2) evaluating Zelboraf (vemurafenib) in patients who received prior systemic therapy, the best overall response rate was 52% (95% CI, 43 - 61%), the median time to response was 1.4 months, and the median duration of response was 6.5 months (95% CI, 5.6 - not reached). [1] According to the NCCN melanoma guidelines, Zelboraf (vemurafenib) is associated with a 40-50% response rate in patients with a V600 mutated BRAF gene; however, the median duration of response is only 5 - 6 months. [2]

4 . References

Zelboraf Prescribing Information. Genentech USA, Inc., May 2020.

National Comprehensive Cancer (NCCN) Drugs & Biologics Compendium [internet database]. Updated periodically. Available at: http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed February 14, 2023.

5 . Revision History

Date	Notes
3/15/2023	Annual review - updated references.

Prior Authorization Guideline

Guideline Name	Zepatier (elbasvir/grazoprevir)

Guideline Note:

Effective Date:	7/1/2022

1 . Indications

Drug Name: Zepatier (elbasvir/grazoprevir)
Chronic Hepatitis C Indicated with or without ribavirin for the treatment of chronic hepatitis C virus (HCV) genotypes 1 or 4 infection in adult and pediatric patients 12 years of age and older or weighing at least 30 kg.

2 . Criteria

Product Name: Zepatier	
Diagnosis	Chronic Hepatitis C - Genotype 1a: treatment-naïve or PegIFN/RBV-experienced or PegIFN/RBV/protease inhibitor-experienced WITHOUT baseline NS5A polymorphisms*
Approval Length	12 Week(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of chronic hepatitis C genotype 1a

AND

2 - One of the following:

Patient is 12 years of age or older

Patient weight is at least 30 kg

AND

3 - One of the following:

3.1 Patient is treatment-naive

OR

3.2 Patient has prior failure to peginterferon alfa plus ribavirin treatment

OR

3.3 Both of the following:

Patient has prior failure to treatment with peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, or telaprevir)

Used in combination with ribavirin

AND

4 - Both of the following: [1, A]

4.1 Patient has been tested for the presence of NS5A resistance-associated polymorphisms

AND

4.2 Patient is without baseline NS5A resistance-associated polymorphisms (i.e., polymorphisms at amino acid positions 28, 30, 31, or 93)

AND

5 - Prescribed by or in consultation with one of the following:

Hepatologist

Gastroenterologist

Infectious disease specialist

HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

7 - Patient does not have moderate to severe hepatic impairment (e.g., Child-Pugh Class B or C) [B]

AND

8 - One of the following:

8.1 Both of the following:

8.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

Epclusa (sofosbuvir/velpatasvir)

Harvoni (ledipasvir/sofosbuvir)

AND

8.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

8.2 For continuation of prior Zepatier (elbasvir/grazoprevir) therapy

Notes	*NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93.

Product Name: Zepatier	
Diagnosis	Chronic Hepatitis C - Genotype 1a: treatment-naïve or PegIFN/RBV-experienced or PegIFN/RBV/protease inhibitor-experienced WITH baseline NS5A polymorphisms*
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1a

AND

2 - One of the following:

Patient is 12 years of age or older

Patient weight is at least 30 kg

AND

3 - One of the following:

Patient is treatment-naive

Patient has prior failure to peginterferon alfa plus ribavirin treatment

Patient has prior failure to treatment with peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, or telaprevir)

AND

4 - Both of the following: [1, A]

4.1 Patient has been tested for the presence of NS5A resistance-associated polymorphisms

AND

4.2 Patient has baseline NS5A resistance-associated polymorphisms (i.e., polymorphisms at amino acid positions 28, 30, 31, or 93)

AND

5 - Used in combination with ribavirin

AND

6 - Prescribed by or in consultation with one of the following:

Hepatologist

Gastroenterologist

Infectious disease specialist

HIV specialist certified through the American Academy of HIV Medicine

AND

7 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

8 - Patient does not have moderate to severe hepatic impairment (e.g., Child-Pugh Class B or C) [B]

AND

9 - One of the following:

9.1 Both of the following:

9.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

Epclusa (sofosbuvir/velpatasvir)

Harvoni (ledipasvir/sofosbuvir)

AND

9.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

9.2 For continuation of prior Zepatier (elbasvir/grazoprevir) therapy

Notes	*NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93.

Product Name: Zepatier	
Diagnosis	Chronic Hepatitis C - Genotype 1b: treatment-naïve or PegIFN/RBV-experienced or PegIFN/RBV/protease inhibitor-experienced
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1b

AND

2 - One of the following:

Patient is 12 years of age or older

Patient weight is at least 30 kg

AND

3 - One of the following:

3.1 Patient is treatment-naive

OR

3.2 Patient has prior failure to peginterferon alfa plus ribavirin treatment

OR

3.3 Both of the following:

Patient has prior failure to treatment with peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, or telaprevir)

Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

Hepatologist

Gastroenterologist

Infectious disease specialist

HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

6 - Patient does not have moderate to severe hepatic impairment (e.g., Child-Pugh Class B or C) [B]

AND

7 - One of the following:

7.1 Both of the following:

7.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

Epclusa (sofosbuvir/velpatasvir)

Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 For continuation of prior Zepatier (elbasvir/grazoprevir) therapy

Product Name: Zepatier	
Diagnosis	Chronic Hepatitis C - Genotype 4: Treatment-naive
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 4

AND

2 - One of the following:

Patient is 12 years of age or older

Patient weight is at least 30 kg

AND

3 - Patient is treatment-naive

AND

4 - Prescribed by or in consultation with one of the following:

Hepatologist

Gastroenterologist

Infectious disease specialist

HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

6 - Patient does not have moderate to severe hepatic impairment (e.g., Child-Pugh Class B or C) [B]

AND

7 - One of the following:

7.1 Both of the following:

7.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

Epclusa (sofosbuvir/velpatasvir)

Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 For continuation of prior Zepatier (elbasvir/grazoprevir) therapy

Product Name: Zepatier	
Diagnosis	Chronic Hepatitis C - Genotype 4: PegIFN/RBV-experienced
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 4

AND

2 - One of the following:

Patient is 12 years of age or older

Patient weight is at least 30 kg

AND

3 - Patient has prior failure to peginterferon alfa plus ribavirin treatment

AND

4 - Used in combination with ribavirin

AND

5 - Prescribed by or in consultation with one of the following:

Hepatologist

Gastroenterologist

Infectious disease specialist

HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

7 - Patient does not have moderate to severe hepatic impairment (e.g., Child-Pugh Class B or C) [B]

AND

8 - One of the following:

8.1 Both of the following:

8.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

Epclusa (sofosbuvir/velpatasvir)

Harvoni (ledipasvir/sofosbuvir)

AND

8.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

8.2 For continuation of prior Zepatier (elbasvir/grazoprevir) therapy

3 . Endnotes

Testing patients with HCV genotype 1a infection for the presence of virus with NS5A resistance-associated polymorphisms is recommended prior to initiation of treatment with Zepatier to determine dosage regimen and duration. In subjects receiving Zepatier for 12 weeks, sustained virologic response (SVR12) rates were lower in genotype 1a-infected patients with one or more baseline NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93. [1]

Zepatier is contraindicated in patients with moderate or severe hepatic impairment (Child-Pugh B or C) due to the expected significantly increased grazoprevir plasma concentration and the increased risk of alanine aminotransferase (ALT) elevations. [1]

4 . References

Zepatier Prescribing Information. Merck Sharp & Dohme Corp. Whitehouse Station, NJ. December 2021.

American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. September 2021. http://www.hcvguidelines.org/full-report-view. Accessed May 16, 2022.

5 . Revision History

Date	Notes
6/22/2022	Updated guideline effective date to 7/1/22 to align with UM optimizati on updates. No other updates made to guideline.

Prior Authorization Guideline

Guideline Name	Zepzelca (lurbinectedin)

Guideline Note:

Effective Date:	10/1/2022
P&T Approval Date:	8/13/2020
P&T Revision Date:	08/19/2021 ; 8/18/2022

1 . Indications

Drug Name: Zepzelca (lurbinectedin)
Small Cell Lung Cancer (SCLC) Indicated for the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy.

2 . Criteria

Product Name: Zepzelca	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic small cell lung cancer (SCLC)

AND

2 - Disease has progressed on or after platinum-based chemotherapy (e.g., carboplatin, cisplatin, oxaliplatin)

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Zepzelca	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Zepzelca Prescribing Information. Jazz Pharmaceuticals, Inc. Palo Alto, CA. April 2022.

4 . Revision History

Date	Notes
7/11/2022	2022 Annual Review

Prior Authorization Guideline

Guideline Name	Zokinvy (lonafarnib)

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	2/18/2021
P&T Revision Date:	02/18/2021 ; 02/17/2022 ; 2/16/2023

1 . Indications

Drug Name: Zokinvy (lonafarnib)
Hutchinson-Gilford Progeria Syndrome (HGPS) Indicated in patients 12 months of age and older with a body surface area (BSA) of 0.39 m^2 and above to reduce the risk of mortality in Hutchinson-Gilford Progeria Syndrome (HGPS). Limitations of Use: ZOKINVY is not indicated for other Progeroid Syndromes or processing-proficient Progeroid Laminopathies. Based upon its mechanism of action, ZOKINVY would not be expected to be effective in these populations. **Processing-Deficient Progeroid Laminopathies** Indicated in patients 12 months of age and older with a body surface area (BSA) of 0.39 m^2 and above for the treatment of processing-deficient Progeroid Laminopathies with either heterozygous LMNA mutation with progerin-like protein accumulation or homozygous or compound heterozygous ZMPSTE24 mutations. Limitations of Use: ZOKINVY is not indicated for other Progeroid Syndromes or processing-proficient Progeroid Laminopathies. Based upon its mechanism of action, ZOKINVY would not be expected to be effective in these populations.

2 . Criteria

Product Name: Zokinvy	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of Hutchinson-Gilford Progeria Syndrome

OR

1.2 For treatment of processing-deficient Progeroid Laminopathies with one of the following:

Heterozygous LMNA mutation with progerin-like protein accumulation

Homozygous or compound heterozygous ZMPSTE24 mutations

AND

2 - Patient is 12 months of age or older

AND

3 - Patient has a body surface area of 0.39 m^2 and above

3 . References

Zokinvy Prescribing Information. Eiger BioPharmaceuticals, Inc. Palo Alto, CA. November 2020.

4 . Revision History

Date	Notes

2/17/2023	Annual review - no criteria changes.

Prior Authorization Guideline

Guideline Name	Zolinza (vorinostat)

Guideline Note:

Effective Date:	11/1/2022
P&T Approval Date:	2/20/2007
P&T Revision Date:	10/16/2019 ; 10/21/2020 ; 10/20/2021 ; 9/21/2022

1 . Indications

Drug Name: Zolinza (vorinostat)
Cutaneous T-cell Lymphoma Indicated for treatment of cutaneous manifestations in patients with cutaneous T-cell lymphoma (CTCL) who have progressive, persistent or recurrent disease on or following two systemic therapies.

2 . Criteria

Product Name: Zolinza	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cutaneous T-cell lymphoma

AND

2 - One of the following: [2]

2.1 Patient has progressive, persistent or recurrent disease on or following 2 systemic therapies (e.g., extracorporeal photopheresis [ECP], systemic retinoids, interferons, etc.) [A]

OR

2.2 History of contraindication or intolerance to other systemic therapies (e.g., Adcetris [brentuximab vedotin, Cytoxan [cyclophosphamide], Poteligeo [mogamulizumab], etc) [A]

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Zolinza	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

Examples of systemic therapies include (but are not limited to): [2] • Adcetris (brentuximab vedotin) • Cytoxan (cyclophosphamide) • Doxil (pegylated doxorubicin) • Extracorporeal photochemotherapy • Folotyn (pralatrexate) • Gemzar (gemcitabine) • Interferon-alpha • Leukeran (chlorambucil) • Nipent (pentostatin) • Poteligeo (mogamulizumab) • Targretin

(bexarotene) • Temodar (temozolamide) • Toposar (etoposide) • Trexall (methotrexate) • Velcade (bortezomib)

4 . References

Zolinza Prescribing Information. Merck & Co, Inc. Whitehouse Station, NJ. January 2020.

National comprehensive cancer network (NCCN) clinical practice guidelines in oncology: Primary cutaneous lymphomas. v.1.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf. Accessed September 9, 2021.

5 . Revision History

Date	Notes
8/14/2022	2022 Annual Review

Prior Authorization Guideline

Guideline Name	Zydelig (idelalisib)

Guideline Note:

Effective Date:	12/1/2022
P&T Approval Date:	10/14/2014
P&T Revision Date:	10/16/2019 ; 10/21/2020 ; 10/20/2021 ; 03/16/2022 ; 10/19/2022

1 . Indications

Drug Name: Zydelig (idelalisib)
Relapsed Chronic Lymphocytic Leukemia Indicated, in combination with rituximab, for the treatment of patients with relapsed chronic lymphocytic leukemia (CLL) for whom rituximab alone would be considered appropriate therapy due to other co-morbidities. Limitation of Use: Zydelig is not indicated and is not recommended for first-line treatment of any patient, including patients with CLL, small lymphocytic lymphoma (SLL), follicular lymphoma (FL), and other indolent non-Hodgkin lymphomas. Zydelig is not indicated and is not recommended in combination with bendamustine and rituximab, or in combination with rituximab for the treatment of patients with FL, SLL, and other indolent non-Hodgkin lymphomas.

2 . Criteria

Product Name: Zydelig	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Chronic Lymphocytic Leukemia (CLL)

AND

2 - Patient has relapsed on at least one prior therapy (e.g., purine analogues [fludarabine, pentostatin, cladribine], alkylating agents [chlorambucil, cyclophosphamide], or monoclonal antibodies [rituximab])

AND

3 - Used in combination with Rituxan (rituximab)* [2]

AND

4 - Patient is a candidate for Rituxan (rituximab) monotherapy due to presence of other comorbidities (e.g., coronary artery disease, peripheral vascular disease, diabetes mellitus, pulmonary disease [COPD], etc.)

AND

5 - Prescribed by or in consultation with an oncologist/hematologist

Notes	*This drug may require prior authorization.

Product Name: Zydelig	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Zydelig Prescribing Information. Gilead Sciences, Inc. Foster City, CA. February 2022.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Chronic lymphocytic leukemia/small lymphocytic lymphoma. v.3.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed August 2, 2022.

4 . Revision History

Date	Notes
10/14/2022	2022 Annual Review - updated background

Prior Authorization Guideline

Guideline Name	Zykadia (ceritinib)

Guideline Note:

Effective Date:	7/1/2022
P&T Approval Date:	7/8/2014
P&T Revision Date:	06/17/2020 ; 02/18/2021 ; 06/16/2021 ; 5/19/2022

1 . Indications

Drug Name: Zykadia (ceritinib)
Non-small Cell Lung Cancer (NSCLC) Indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.

2 . Criteria

Product Name: Zykadia	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - One of the following: [2]

Disease is metastatic

Disease is recurrent

AND

3 - Tumor is anaplastic lymphoma kinase (ALK)-positive as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - One of the following:

4.1 Patient has had disease progression on, contraindication or intolerance to, or is not a candidate for one of the following:

Alecensa (alectinib)

Alunbrig (brugatinib)

OR

4.2 For continuation of prior therapy

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Zykadia	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Zykadia Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. August 2021.

The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed April 28, 2022.

4 . Revision History

Date	Notes
4/28/2022	Annual review - No criteria changes, updated background

Prior Authorization Guideline

Guideline Name	Zytiga (abiraterone acetate) - PA, NF

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	7/9/2013
P&T Revision Date:	02/13/2020 ; 02/18/2021 ; 03/17/2021 ; 11/18/2021 ; 01/19/2022 ; 03/16/2022 ; 5/18/2023

1 . Indications

Drug Name: Zytiga (abiraterone acetate)
Metastatic castration-resistant prostate cancer (mCRPC) Indicated for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) in combination with prednisone. **Metastatic castration-sensitive prostate cancer (mCSPC)** Indicated for the treatment of patients with metastatic high risk castration-sensitive prostate cancer (mCSPC) in combination with prednisone.

2 . Criteria

Product Name: Brand Zytiga	
Diagnosis	Castration-resistant prostate cancer
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of castration resistant (chemical or surgical) prostate cancer [2]

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to Xtandi (enzalutamide)

OR

2.2 For continuation of prior therapy

AND

3 - Prescribed by or in consultation with one of the following:

Oncologist

Urologist

Product Name: Brand Zytiga	
Diagnosis	Castration-resistant prostate cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of castration resistant (chemical or surgical) prostate cancer [2]

AND

2 - One of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Xtandi (enzalutamide)

OR

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

3 - Prescribed by or in consultation with one of the following:

Oncologist

Urologist

Product Name: Generic abiraterone acetate	
Diagnosis	Castration-resistant prostate cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of castration resistant (chemical or surgical) prostate cancer [2]

AND

2 - Prescribed by or in consultation with one of the following:

Oncologist

Urologist

Product Name: Brand Zytiga	
Diagnosis	Castration-sensitive prostate cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of castration-sensitive prostate cancer

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to one of the following:

Xtandi (enzalutamide)

Erleada (apalutamide)

OR

2.2 For continuation of prior therapy

AND

3 - Prescribed by or in consultation with one of the following:

Oncologist

Urologist

Product Name: Brand Zytiga	
Diagnosis	Castration-sensitive prostate cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of castration-sensitive prostate cancer

AND

2 - One of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one of the following:

Xtandi (enzalutamide)

Erleada (apalutamide)

OR

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

3 - Prescribed by or in consultation with one of the following:

Oncologist

Urologist

Product Name: Generic abiraterone acetate	
Diagnosis	Castration-sensitive prostate cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of castration-sensitive prostate cancer

AND

2 - Prescribed by or in consultation with one of the following:

Oncologist

Urologist

Product Name: Brand Zytiga, Generic abiraterone acetate	
Diagnosis	Castration-sensitive prostate cancer, castration-resistant prostate cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Zytiga Prescribing Information. Janssen Biotech Inc. Horsham, PA. August 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Prostate Cancer. v.4.2018. Available by subscription at: http://www.nccn.org/professionals/physician_gls/PDF/prostate.pdf. Accessed September 18, 2018.

4 . Revision History

Date	Notes
5/1/2023	Program update to remove requirement that drug must be used in co mbination with prednisone