InterCommunity Health Network CCO

Prior Authorization Criteria

InterCommunity Health Network

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

Updated on 09/01/2026. For more recent information or other questions, please contact Pharmacy Services at **541-768-7863 or toll free at 866-203-3435 (TTY 800-735-2900 or 711)** or visit **samhealthplans.org.** Pharmacy Services is available Monday through Friday, from 8 a.m. to 5 p.m.

Abatacept (Orencia)

Products Affected

- Orencia PFS
- Orencia IV (Specialty Fusion drug)
- Orencia Clickjet

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Juvenile Idiopathic Arthritis
	  ○ Psoriatic Arthritis
	  ○ Rheumatoid Arthritis
	  ○ Graft Versus Host Disease (Orencia IV only)

Required Medical Information and Criteria	**<u>All diagnoses</u>**
	• Initial testing for latent TB and treatment, if necessary, before starting treatment.
	• No current active infection at initiation of therapy.
	• Risks and benefits documented in cases of chronic or recurrent infection.
	• Will NOT be used in combination with another biologic or Otezla
	
	<u>Juvenile Idiopathic Arthritis (JIA)</u>
	• Documentation of juvenile idiopathic arthritis with active systemic features of JIA, with a physician global assessment of 5 or higher (or any systemic activity in the absence of active joint involvement) or JIA without active systemic features
	• The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of the following:
	  ○ NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated
	  ○ At least 6 months of 2 of Methotrexate, leflunomide, sulfasalazine, hydroxychloroquine, or systemic corticosteroids
	• Documented intolerance or contraindication to DMARDs OR DMARD will be continued
	• Trial and failure of both infliximab and adalimumab
	• Trial and failure of tocilizumab
	
	<u>Psoriatic Arthritis (PsA)</u>
	• Documentation of psoriatic arthritis based on at least 3 out of 5 of the following:

	○ Psoriasis (1 point for personal or family history, 2 points for current) ○ Psoriatic nail dystrophy ○ Negative test result for RF ○ Dactylitis (current of history) ○ Radiological evidence of juxta-articular new bone formation • The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of conventional therapy with both of the following ○ NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND ○ Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine • Trial and failure of infliximab, adalimumab, and ustekinumab **<u>Rheumatoid Arthritis (RA)</u>** • Documentation of a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI) • The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of nonbiologic DMARD therapy: methotrexate (dosed at least 20mg per week for at least 8 weeks), leflunomide or sulfasalazine • Trial and failure of infliximab, adalimumab, and tocilizumab **<u>Graft versus Host Disease (GVHD) *Orencia IV only</u>** • Used for prophylaxis of acute graft versus host disease (aGVHD) • Patient will receive hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor • 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 • Abatacept will be used in combination with both a calcineurin inhibitor (e.g. cyclosporine, tacrolimus) and methotrexate
Renewal Criteria	• **JIA:** Evidence of 20% or greater improvement in tender joint count and swollen joint count or has there been an improvement in functional ability. • **PsA:** Evidence of a 20% or greater improvement in tender joint count and swollen joint count.

	• **RA:** Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
Age Restriction	2 years of age or older
Prescriber Restriction	• **Psoriatic Arthritis:** Dermatologist or Rheumatologist • **Rheumatoid Arthritis, Juvenile Idiopathic Arthritis:** Rheumatologist • **Graft versus Host Disease:** Hematologist or oncologist
Coverage Duration	• **PsA, RA, JIA** o Initial: 6 months o Renewal: 12 months • **GVHD** o Initial: 2 months

Effective Date:	07/01/2026
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References

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- Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Care Res (Hoboken).* 2021;73(7):924-939.
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- Ringold S, Angeles-Han ST, Beukelman T, 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 Care Res (Hoboken).* 2022;74(4):521-537.

Acne Combo Products

Products Affected

- Clindamycin/Benzoyl Peroxide 1-5% Gel
- Erythromycin/Benzoyl Peroxide 3-5% Gel

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Acne vulgaris
Required Medical Information and Criteria	**<u>Acne Vulgaris</u>** • Documentation of trial and failure, intolerance, or contraindication to clindamycin/benzoyl peroxide 1.2-5% gel
Renewal Criteria	• Documentation of positive clinical response to therapy
Exclusion Criteria	
Age Restriction	
Prescriber Restriction	
Coverage Duration	• Initial: 12 months • Renewal: 12 months

Effective Date:	02/01/2023
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P&T Revision Date:	01/10/2023

Adalimumab

Products Affected

- Adalimumab-adaz 40mg/0.4mL, 80mg/0.8mL (auto-injector and prefilled syringe)
- Adalimuimab-fkjp 40mg/0.8mL, 20 mg/0.4mL, (auto-injector and prefilled syringe)
- Hadlima 40mg/0.4mL, 40mg/0.8mL (auto-injector and prefilled syringe)
- Yusimry 40mg/0.8mL
- Simlandi 40mg/0.4mL

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Ankylosing Spondylitis/Axial Spondyloarthritis
	  ○ Crohn's Disease
	  ○ Hidradenitis Suppurativa
	  ○ Juvenile Idiopathic Arthritis
	  ○ Plaque Psoriasis
	  ○ Psoriatic Arthritis
	  ○ Rheumatoid Arthritis
	  ○ Ulcerative Colitis
	  ○ Uveitis

Required Medical Information and Criteria	**<u>All diagnoses</u>**
	• Initial testing for latent TB and treatment, if necessary, before starting treatment.
	• No current active infection at initiation of therapy.
	• Risks and benefits documented in cases of chronic or recurrent infection.
	• Will NOT be used in combination with another biologic or Otezla.
	
	<u>Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA)</u>
	• Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by:
	  ○ Back pain and stiffness for more than 3 months AND
	  ○ Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive AND
	  ○ BASDAI score of >=4
	• One of the following:
	  ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR

	○ Documented failure of conventional therapy with both of the following: ▪ At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated AND ▪ Physical therapy/exercise program **<u>Crohn's Disease (CD)</u>** • Documentation of moderate-to-severe Crohn's Disease **<u>Hidradenitis Suppurativa (HS)</u>** • Documentation of a diagnosis of moderate to severe hidradenitis suppurativa (Hurley Stage II or Hurley Stage III) • One of the following: ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR ○ Documented failure of conventional therapy (e.g. oral antibiotics). **<u>Juvenile Idiopathic Arthritis (JIA)</u>** • Documentation of juvenile idiopathic arthritis with active systemic features of JIA, with a physician global assessment of 5 or higher (or any systemic activity in the absence of active joint involvement) or JIA without active systemic features • One of the following: ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR ○ Documented trial and failure of the following: ▪ NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND ▪ At least 6 months of 2 of Methotrexate, leflunomide, sulfasalazine, hydroxychloroquine, or systemic corticosteroids • Documented intolerance or contraindication to DMARDs OR DMARD will be continued with adalimumab. **<u>Plaque Psoriasis (PP):</u>** • Documentation of severe plaque psoriasis, defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) = 11 or Children's Dermatology Life Quality Index (CDLQI) = 13 (or severe score on other validated tool) AND one or more of the following: ○ At least 10% of body surface area involved

	○ Hand, foot, face, or mucous membrane involvement • One of the following: ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR ○ Documented trial and failure of all the following: ▪ High-potency topical corticosteroids (augmented betamethasone, clobetasol, etc.) ▪ At least one other topical agent (calcipotriene, tazarotene, anthralin, tar, etc.) ▪ PUVA or UVB Phototherapy ▪ Methotrexate ▪ At least 1 other second line systemic agent such as cyclosporine or acitretin. **<u>Psoriatic Arthritis (PsA):</u>** • Documentation of psoriatic arthritis based on at least 3 out of 5 of the following: ○ Psoriasis (1 point for personal or family history, 2 points for current) ○ Psoriatic nail dystrophy ○ Negative test result for RF ○ Dactylitis (current of history) ○ Radiological evidence of juxta-articular new bone formation • One of the following: ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR ○ Documented trial and failure of conventional therapy with both of the following: ▪ NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND ▪ Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine. **<u>Rheumatoid Arthritis (RA):</u>** • Documentation of a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI) • One of the following: ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR

	○ Documented trial and failure of nonbiologic DMARD therapy: methotrexate (dosed at least 20mg per week for at least 8 weeks), leflunomide or sulfasalazine **<u>Ulcerative Colitis (UC):</u>** • Documentation of moderate-to-severe ulcerative colitis • One of the following: ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR ○ Documented trial and failure of at least 1 of the following: mesalamine, sulfasalazine, mercaptopurine, azathioprine, or corticosteroids (prednisone, methylprednisolone). **<u>Uveitis:</u>** • Documentation of non-infectious, intermediate-, posterior- or pan-uveitis • Documented trial and failure of all the following: ○ Topical glucocorticoids for at least 1 month OR periocular steroid injection, and ○ Oral corticosteroids, and ○ At least one of the following: mycophenolate, tacrolimus, cyclosporine, azathioprine, or methotrexate
Renewal Criteria	• **Ankylosing Spondylitis/Axial Spondyloarthritis:** Evidence of significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI. • **Crohn's Disease:** Evidence of a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission. • **Hidradenitis Suppurativa:** Evidence of a reduction of 25% or more of the total abscess and inflammatory nodule count and no increase in abscesses and draining fistulas. • **Juvenile Idiopathic Arthritis:** Evidence of 20% or greater improvement in tender joint count and swollen joint count or has there been an improvement in functional ability. • **Plaque Psoriasis:** Evidence of positive clinical response to therapy as evidenced by ONE of the following: reduction of body surface area (BSA) involvement from baseline, improvement in symptoms (e.g. pruritus, inflammation) from baseline, or evidence of functional improvement.

	• **Psoriatic Arthritis:** Evidence of a 20% or greater improvement in tender joint count and swollen joint count. • **Rheumatoid Arthritis:** Evidence of a 20% or greater improvement in tender joint count and swollen joint count. • **Ulcerative Colitis:** Evidence of a significant response such as a decrease in bloody stools per day or elimination of signs of toxicity. • **Uveitis:** Evidence that that disease activity has been controlled, such as a lack of inflammation, no new inflammatory vascular lesions, no vitreous haze or decreases in visual acuity.
Prescriber Restriction	• **Crohn's Disease and Ulcerative Colitis:** Gastroenterologist. • **Hidradenitis Suppurativa and Plaque Psoriasis:** Dermatologist. • **Psoriatic Arthritis:** Dermatologist or Rheumatologist. • **Rheumatoid Arthritis, Juvenile Idiopathic Arthritis**: Rheumatologist. • **Ankylosing Spondylitis**, **Axial Spondyloarthritis:** Rheumatologist. • **Uveitis:** Ophthalmologist or Rheumatologist.
Coverage Duration	• **All diagnoses:** o Initial: 6 months o Renewal: 12 months

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Alpelisib (Vijoice)

Products Affected

- Vijoice tab

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ PIK3CA-related overgrowth spectrum (PROS)
Required Medical Information and Criteria	**PIK3CA-related overgrowth spectrum (PROS)** • Confirmed diagnosis of PROS • At least one severe clinical manifestation of PROS • A PIK3CA mutation that is confirmed by genetic testing.
Renewal Criteria	• Documentation of a reduction in volume from baseline in at least one lesion AND • Improvement in at least one symptom of PROS from baseline
Exclusion Criteria	
Age Restriction	• Two years of age and older
Prescriber Restriction	• Prescribed by or in consultation with a provider who specializes in treatment of genetic disorders.
Coverage Duration	• Initial: 24 weeks • Renewal: 6 months

Effective Date:	10/01/2022
P&T Approval Date:	09/13/2022
P&T Revision Date:	09/13/2022

Anakinra (Kineret)

Products Affected

- Kineret 100MG/0.67ML

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Rheumatoid Arthritis
	  ○ Neonatal-Onset Multisystem Inflammatory Disease.
	  ○ Deficiency of Interleukin-1 Receptor Antagonist
	• Compendia-supported uses
	  ○ Systemic Juvenile Idiopathic Arthritis (Formerly Still's disease)
	  ○ Adult-Onset Still's Disease

Required Medical Information and Criteria	**<u>All Diagnoses</u>** • Will NOT be used in combination with another biologic or Otezla **<u>Rheumatoid Arthritis (RA)</u>** • Documentation of a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI) • The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of nonbiologic DMARD therapy: methotrexate (dosed at least 20mg per week for at least 8 weeks), leflunomide or sulfasalazine • Trial and failure of infliximab, adalimumab, and tocilizumab **<u>Neonatal-Onset Multisystem Inflammatory Disease (NOMID)</u>** • Documentation confirming a diagnosis of NOMID **<u>Deficiency of Interleukin-1 Receptor Antagonist</u>** • Documentation of genetically confirmed DIRA **<u>Systemic Juvenile Idiopathic Arthritis (Formerly Still's disease)</u>** • Documentation confirming a diagnosis of JIA with active systemic features of JIA • Trial and failure of systemic corticosteroids • Trial and failure of methotrexate or leflunomide (or contraindication to both) • Trial and failure of tocilizumab **<u>Adult-Onset Still's Disease (AOSD)</u>**

	• Documentation confirming a diagnosis of Stills Disease with active systemic features (e.g. fever, arthralgia/arthritis, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, sore throat)
	• Documentation of any of the following:
	  ○ Inadequate response to a trial of non-steroidal anti-inflammatory drugs (NSAIDs)
	  ○ Inadequate response to a trial of corticosteroids
	  ○ Inadequate response to a trial of a conventional synthetic drug (e.g., methotrexate)

Renewal Criteria	• **Rheumatoid Arthritis:** Evidence of a 20% or greater improvement in tender joint count and swollen joint count. • **NOMID, DIRA:** Documentation of positive clinical response to therapy. • **AOSD, SJIA:** Improvement in functional ability, systemic features, number of joints with active arthritis or number of joints with limitation of movement
Prescriber Restriction	• **All Diagnoses:** Rheumatologist.

Coverage Duration	• **All Diagnoses**
	  ○ Initial: 6 months
	  ○ Renewal: 12 months

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- Onel KB, Horton DB, Lovell DJ, 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 (Hoboken).* 2019;71(6):717-734.
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- National Organization for Rare Disorders (NORD). Adult-onset Still's disease. Accessed April 2026. https://rarediseases.org/rare-diseases/adult-onset-stills-disease

Anticholinergic Overactive Bladder Step Therapy

Products Affected

- Trospium IR tablets
- Fesoterodine
- Tolterodine ER capsules
- Trospium ER capsules
- Tolterodine IR tablets

Step Therapy Criteria	• Trial and failure of ○ Oxybutynin IR or ER

Effective Date:	7/1/2025
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P&T Revision Date:	5/13/2025

Apremilast (Otezla)

Products Affected

- Otezla IR tablets
- Otezla ER tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Plaque Psoriasis
	  ○ Psoriatic Arthritis
	  ○ Behcet's Disease

Required Medical Information and Criteria	**<u>All Diagnoses</u>**
	• Will NOT be used in combination with another biologic
	
	<u>Plaque Psoriasis</u>
	• Documentation of severe plaque psoriasis, defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) = 11 or Children's Dermatology Life Quality Index (CDLQI) = 13 (or severe score on other validated tool) AND one or more of the following:
	  ○ At least 10% of body surface area involved
	  ○ Hand, foot, face or mucous membrane involvement
	• One of the following:
	  ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
	  ○ Documented trial and failure of all the following:
	  ▪ High-potency topical corticosteroids (augmented betamethasone, clobetasol, etc.)
	  ▪ At least one other topical agent (calcipotriene, tazarotene, anthralin, tar, etc.)
	  ▪ PUVA or UVB Phototherapy
	  ▪ Methotrexate
	  ▪ At least 1 other second line systemic agent such as cyclosporine or acitretin.
	• Trial and failure of infliximab, adalimumab, and ustekinumab.
	
	<u>Psoriatic Arthritis</u>
	• Documentation of psoriatic arthritis based on at least 3 out of 5 of the following:

	○ Psoriasis (1 point for personal or family history, 2 points for current) ○ Psoriatic nail dystrophy ○ Negative test result for RF ○ Dactylitis (current or history) • One of the following: ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR ○ Documented trial and failure of all the following: ▪ NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated ▪ Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine • Trial and failure of infliximab, adalimumab, and ustekinumab. **<u>Behcet's Disease</u>** • Documentation of active recurrent ulcers associated with Behcet's Disease • Failure of all of the following: ○ Topical corticosteroid (e.g., triamcinolone acetonide cream) ○ Oral corticosteroid (e.g., prednisone) ○ Colchicine
Renewal Criteria	• **Plaque Psoriasis:** Evidence of positive clinical response to therapy as evidenced by ONE of the following: reduction of body surface area (BSA) involvement from baseline, improvement in symptoms (e.g. pruritus, inflammation) from baseline, or evidence of functional improvement. • **Psoriatic Arthritis:** Evidence of a 20% or greater improvement in tender joint count and swollen joint count. • **Behcet's Disease:** Decrease in the number or pain level of oral ulcers.
Prescriber Restriction	• **Plaque Psoriasis:** Dermatologist. • **Psoriatic Arthritis, Behcet's Disease:** Dermatologist or Rheumatologist.
Coverage Duration	• **All diagnoses:** ○ Initial: 6 months ○ Renewal: 12 months

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Aprepitant (Emend)

Products Affected

- Aprepitant Capsule

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Prevention of nausea and vomiting associated with initial and repeat courses of highly emetogenic chemotherapy
	  ○ Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy

Required Medical Information and Criteria	**<u>Prevention of chemotherapy induced nausea and vomiting</u>**
	• Documentation of patient receiving treatment with a moderate to highly emetogenic chemotherapy agent.
	• Documentation patient is receiving concurrent treatment with all the following:
	  ○ IV or oral ondansetron, granisetron or palonosetron
	  ○ Dexamethasone

Renewal Criteria	• Positive clinical response to therapy
Exclusion Criteria	
Age Restriction	
Prescriber Restriction	
Coverage Duration	• Initial: 12 months • Renewal: 12 months

Effective Date:	10/01/2021
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Asthma Triple Combination Inhaler Step Therapy

Products Affected

- Trelegy
- Breztri

Step Therapy Criteria	• Trial and failure of at least 4 weeks of 2 of the following
	  ○ A Long-Acting Beta Agonist (LABA)
	  ○ An Inhaled Corticosteroid (ICS)
	  ○ A Long-Acting Muscarinic Antagonist (LAMA)

Effective Date:	7/1/2024
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Atovaquone-proguanil (MALARONE)

Products Affected

- Atovaquone-proguanil 62.5mg-25mg tablet
- Atovaquone-proguanil 250mg-100mg tablet

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Prevention of malaria infection
	  ○ Treatment of malaria infection

Required Medical Information and Criteria	**Prevention of malaria infection:** • Travel to a location where CDC recommends the use of atovaquone-proguanil • Clinical contraindication to doxycycline **OR** doxycycline is not recommended by CDC for the travel location. **Treatment of malaria infection:** • Recommended by the CDC
Renewal Criteria	N/A
Age Restriction	Refer to FDA label

Coverage Duration	• **Prevention of malaria infection:**
	  ○ Initial: 3
	  ○ Renewal: N/A
	
	• **Treatment of malaria infection:**
	  ○ Initial: 1
	  ○ Renewal: N/A

Effective Date:	11/1/2024
P&T Approval Date:	9/10/2024
P&T Revision Date:	9/10/2024

Baricitinib (OLUMIANT)

Products Affected

- Olumiant tablet

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Rheumatoid Arthritis (RA)

Required Medical Information and Criteria	**All diagnoses**:
	• Will NOT be used in combination with another biologic or Otezla
	
	Rheumatoid Arthritis (RA):
	• Documentation of a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI)
	• One of the following:
	  ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
	  ○ Documented trial and failure of nonbiologic DMARD therapy: methotrexate (dosed at least 20mg per week for at least 8 weeks), leflunomide or sulfasalazine
	• Trial and failure of infliximab, adalimumab, and tocilizumab or contraindication to all

Renewal Criteria	• Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
Prescriber Restriction	• **Rheumatoid Arthritis:** Rheumatologist

Coverage Duration	• **Rheumatoid Arthritis**
	  ○ Initial: 6 months
	  ○ Renewal: 12 months

Effective Date:	07/01/2023
P&T Approval Date:	07/11/2026
P&T Revision Date:	05/12/2026, 07/11/2023, 01/11/2022

References

- Olumiant [package insert]. Indianapolis, IN: Lilly USA, LLC. 2022.
- Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Care Res (Hoboken)*. 2021;73(7):924-939.

Bedaquiline (Sirturo)

Products Affected

- Sirturo Tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Pulmonary Tuberculosis
Required Medical Information and Criteria	**<u>Pulmonary Tuberculosis</u>** • Evidence of active pulmonary tuberculosis caused by mycobacterium tuberculosis that is resistant to at least rifampin and isoniazid • The member weighs at least 15kg • Sirturo is prescribed as part of a guideline recommended multi-drug treatment regimen.
Renewal Criteria	• Renewal not appropriate
Exclusions	• Medication is being received though a county clinic with a state funded TB program.
Age Restriction	• 5 years of age and older.
Prescriber Restriction	• **Pulmonary Tuberculosis:** Infectious Disease

Coverage Duration	• **Pulmonary Tuberculosis:**
	  ○ Initial: 24 weeks
	  ○ Renewal: N/A

Effective Date:	5/1/2025
P&T Approval Date:	3/11/2025
P&T Revision Date:	3/11/2025

References
• Sirturo [package insert]. Horsham, PA: Janssen Products, LP; 2024.

Belumosudil (Rezurock)

Products Affected

- Rezurock tablet

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Chronic graft-versus-host disease
Required Medical Information and Criteria	Chronic graft-versus-host disease • Trial and failure of at least two prior lines of systemic therapy for cGVHD • Not currently taking Imbruvica (ibrutinib)
Renewal Criteria	• Documented positive clinical response to therapy
Exclusion Criteria	
Age Restriction	• 12 years of age or older
Prescriber Restriction	• **cGVHD:** oncologist or transplant specialist

Coverage Duration	• **cGVHD:**
	  ○ Initial: 3 months
	  ○ Renewal: 6 months

Effective Date:	4/1/2022
P&T Approval Date:	3/8/2022
P&T Revision Date:	3/8/2022

Bempedoic acid (Nexletol/Nexlizet)

Products Affected

- Nexletol tablet
- Nexlizet tablet

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Clinical ASCVD
	  ○ Primary or familial hyperlipidemia

Required Medical Information and Criteria	**Clinical ASCVD**
	• Documentation of very high risk ASCVD as evidenced by either:
	  ○ History of multiple major ASCVD events
	  ○ One major ASCVD event AND multiple high-risk conditions
	• Documentation of a current LDL greater than or equal to 55 mg/dl
	• Documentation of all the following
	  ○ Patient is receiving maximally tolerated statin therapy (atorvastatin 40-80mg, rosuvastatin 20-40mg) or has a documented clinical intolerance to statins
	  ○ Is receiving ezetimibe or has a documented intolerance to ezetimibe.
	• Documentation of failure of PCSK9 inhibitor (Repatha or Prluent)
	
	Primary or familial hyperlipidemia
	• Documentation of an untreated (i.e., prior to lipid lowering therapy) LDL greater than 190 mg/dL
	• Documentation of current LDL greater than 100 mg/dL
	• Documentation of all the following
	  ○ Patient is receiving maximally tolerated statin therapy (atorvastatin 40-80mg, rosuvastatin 20-40mg) or has a documented clinical intolerance to statins
	  ○ Is receiving ezetimibe or has a documented intolerance to ezetimibe.
	• Documentation of failure of PCSK9 inhibitor (Repatha or Prluent)

Renewal Criteria	• Documented positive clinical response to therapy (significant decrease in lipid levels).
Exclusion Criteria	
Age Restriction	
Prescriber Restriction	• **ASCVD & Primary or familial hyperlipidemia:** Cardiologist, Endocrinologist, or lipid specialist

Coverage Duration	**ASCVD & Primary or familial hyperlipidemia:** o Initial: 6 months o Renewal: 12 months

Effective Date:	11/1/2024
P&T Approval Date:	9/10/2024
P&T Revision Date:	9/10/2024

Betaxolol Ophth Step Therapy

Products Affected

- Betaxolol Ophthalmic Solution 0.5%

Step Therapy Criteria	• Trial and failure of
	  ○ Carteolol 1% solution
	  ○ Levobunolol 0.5% solution
	  ○ Timolol Maleate 0.25% or 0.5% solution

Effective Date:	03/01/2026
P&T Approval Date:	01/13/2026
P&T Revision Date:	01/13/2026

Bimatoprost Ophth (Lumigan) Step Therapy

Products Affected

- Lumigan 0.01% Ophthalmic Solution

Step Therapy Criteria	• Trial and failure of ○ Latanoprost 0.005% ophthalmic solution ○ Travoprost 0.004% ophthalmic solution (BAK free) ○ Tafluprost 0.0015% solution (BAK free)

Effective Date:	03/01/2026
P&T Approval Date:	01/13/2026
P&T Revision Date:	01/13/2026

Bimekizumab (Bimzelx)

Products Affected

- Bimzelx 160mg/mL PFS
- Bimzelx 320mg/2mL PFS
- Bimzelx 160mg/mL auto-injector
- Bimzelx 320mg/2mL auto-injector

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Ankylosing Spondylitis/Axial Spondyloarthritis
	  ○ Hidradenitis Suppurativa
	  ○ Plaque Psoriasis
	  ○ Psoriatic Arthritis

Required Medical Information and Criteria	**<u>Ankylosing Spondylitis/Axial Spondyloarthritis</u>**
	• Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by:
	  ○ Back pain and stiffness for more than 3 months AND
	  ○ Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive AND
	  ○ BASDAI score of >=4
	• The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR Documented failure of conventional therapy with both of the following:
	  ○ At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND
	  ○ Physical therapy/exercise program
	• Trial and failure of infliximab and adalimumab or contraindication to both.
	• Trial and failure of Cimzia, Cosentyx, Simponi, Taltz, and Xeljanz/Xeljanz XR, or contraindication to all.
	
	<u>Hidradenitis Suppurativa</u>
	• Documentation of one of the following:
	  ○ Moderate to severe hidradenitis suppurative (Hurley Stage II or Hurley Stage III)
	  ○ Patient is on a current biologic product and experiencing intolerable side effects.
	• The patient is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented

	failure of the following: ○ 90-day trial of conventional therapy (e.g. oral antibiotics) • Trial and failure of infliximab, adalimumab, and ustekinumab or contraindication to all. • Trial and failure of, or contraindication to, secukinumab (Cosentyx). **<u>Plaque Psoriasis</u>** • Defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) = 11 or Children's Dermatology Life Quality Index (CDLQI) = 13 (or severe score on other validated tool) • One or more of the following: ○ At least 10% of body surface area involved ○ Hand, foot, face, or mucous membrane involvement ○ The patient on a current biologic product and experiencing intolerable side effects • The patient tried and failed or have contraindications to ALL of the following ○ High-potency topical corticosteroids (augmented betamethasone, clobetasol, etc.) ○ At least one other topical agent: calcipotriene, tazarotene, anthralin, tar, etc. ○ PUVA or UVB Phototherapy ○ Methotrexate ○ At least 1 other second line systemic agent such as cyclosporine or acitretin • Trial and failure of infliximab, adalimumab, and ustekinumab or contraindication to all. • Trial and failure of secukinumab (Cosentyx), apremilast (Otezla), Ilumya, Siliq, Sotyktu or contraindication to all. • Trial and failure of, or contraindication to, Skyrizi. **<u>Psoriatic Arthritis</u>** • Documentation of psoriatic arthritis based on at least 3 out of 5 of the following: ○ Psoriasis (1 point for personal or family history, 2 points for current) ○ Psoriatic nail dystrophy ○ Negative test result for RF ○ Dactylitis (current of history) ○ Radiological evidence of juxta-articular new bone formation

	• The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of conventional therapy with both of the following:
	  ○ NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND
	  ○ Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine
	• Trial and failure of infliximab, adalimumab, and ustekinumab or contraindication to all
	• Trial and failure of Cimzia, Cosentyx, Otezla, Orencia, Simponi, Xeljanz/Xeljanz XR or contraindication to all.
	• Trial and failure of Rinvoq and Taltz, or contraindication to both.

Renewal Criteria	• **Plaque Psoriasis:** Evidence of positive clinical response to therapy as evidenced by ONE of the following: reduction of body surface area (BSA) involvement from baseline, improvement in symptoms (e.g. pruritus, inflammation) from baseline, or evidence of functional improvement. • **Psoriatic Arthritis:** Evidence of a 20% or greater improvement in tender joint count and swollen joint count. • **Ankylosing Spondylitis/Axial Spondyloarthritis:** Evidence of significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI. • **Hidradenitis Suppurativa:** Evidence of a reduction of 25% or more of the total abscess and inflammatory nodule count and no increase in abscesses and draining fistulas.
Exclusion Criteria	• Not to be used in combination with other biologics or Otezla
Age Restriction	• Refer to FDA label
Prescriber Restriction	• **Plaque Psoriasis, Hidradenitis Suppurativa:** Dermatologist. • **Psoriatic Arthritis:** Dermatologist or Rheumatologist. • **Ankylosing Spondylitis, Axial Spondyloarthritis:** Rheumatologist.
Coverage Duration	○ Initial: 6 months ○ Renewal: 12 months

Effective Date:	07/01/2026
P&T Approval Date:	5/13/2024
P&T Revision Date:	05/12/2026, 07/08/2025, 05/13/2024

References

- Bimzelx (bimekizumab-bkzx). Prescribing Information. UCB, Inc. Smyrna, GA 2024.
- Gordon KB, et al. Bimekizumab efficacy and safety in moderate to severe plaque psoriasis (BE READY): a multicentre, double-blind, placebo-controlled, randomised withdrawal phase 3 trial. Lancet. 2021; 37:475-86.
- Gordon KB, et al. Bimekizumab safety in patients with moderate to severe plaque psoriasis: Pooled results from Phase 2 and Phase 3 randomized clinical trials. JAMA Dermatol. 2022;158(7):735-744.
- Gordon KB, et al. Bimekizumab safety in patients with moderate-to-severe plaque psoriasis: poled data from up to 3 years of treatment in randomized phase III trials. Br J Dermatol 2024; 190: 477-485.
- Alikhan A, Sayed C, Alavi A, et al. Practical guidelines for managing patients with hidradenitis suppurativa: An update. *J Am Acad Dermatol.* 2022;86(4):861-891.
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- 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.
- Ramiro S, Nikiphorou E, Sepriano A, et al. EULAR recommendations for the management of axial spondyloarthritis: 2022 update. *Ann Rheum Dis.* 2023;82(1):19-34.

Brinzolamide Ophth Step Therapy

Products Affected

- Brinzolamide 1% ophthalmic suspension

Step Therapy Criteria	• Trial and failure of ○ Dorzolamide 2% ophthalmic solution

Effective Date:	03/01/2026
P&T Approval Date:	01/13/2026
P&T Revision Date:	01/13/2026

Buprenorphine Patch (Butrans)

Products Affected

- Buprenorphine Patch

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Cancer, severe burns, sickle cell disease, or Palliative Care
	  ○ Pain from conditions of the back and spine
	  ○ Other Chronic Pain for a funded condition that meets criteria for medical appropriateness and medical necessity

Required Medical Information and Criteria	**Pain Related to Cancer, severe burns, sickle cell disease, or Palliative Care** • Member is being treated for pain associated with cancer, severe burns, sickle cell disease, or palliative care • Documented trial and failure of scheduled short-acting opioid therapy • Documented trial and failure of, or contraindication to long-acting morphine sulfate therapy • Documented trial/failure of, or reason why fentanyl patch is not appropriate **Pain Related to conditions of the Back and Spine (Guideline Note 60)** • The request is for long-term therapy for the treatment of acute injury, acute flare or chronic pain, or surgery (≥90 days after event) • Documented pain is severe enough to require around the clock analgesic therapy • Documentation includes a comprehensive individual treatment plan for chronic pain, taking into account the biological, behavioral, psychological and social factors which may influence each individual's experience of chronic pain as well as any current and past treatments. • Member's function has been improved with opioid therapy. • Buprenorphine patches have been prescribed with a plan to keep active (home or prescribed exercise regimen) and additional therapies such as spinal manipulation, PT, yoga, or acupuncture when available. • Prescribed is enrolled in the Oregon Prescription Drug Monitoring Program (PDMP) and has verified that the prescribing is appropriate • All the following risks have been assessed, and the prescriber has determined that the benefits outweigh the risks ○ Risk of abuse

	○ Risk of respiratory adverse events ○ Mental health/Depression screening ○ PDMP report ○ Urine drug screen, after acute phase of treatment • Documented trial and failure of scheduled short-acting opioid therapy • Documented trial and failure of, or contraindication to long-acting morphine sulfate therapy • Documented trial/failure of, or reason why fentanyl is not appropriate • Maximum dose of 20mcg/hr **Other Chronic Pain** • Medication is intended for use for the treatment of pain for a funded condition or there is an applicable comorbid condition • Documented use of current and/or recent usage of opioid therapy for at least 15 days (considered treatment experienced) and the member's function has been improved while on opioid therapy • Documented pain that is severe enough to require around the clock analgesic therapy • The prescriber is enrolled in the Oregon Prescription Drug Monitoring Program (PDMP) and has verified that prescribing is appropriate • All of the following risks have been assessed, and the prescriber has determined that the benefits outweigh the risks: ○ Risk of abuse ○ Risk of respiratory adverse events ○ Mental health/depression screening ○ Urine drug screen • Appropriate non-pharmacologic and non-opioid therapies have been maximized for submitted condition (NSAID, muscle relaxants, anticonvulsant, DMARD, PT, etc.) • Documented trial and failure of scheduled short-acting opioid therapy • Documented trial and failure of, or contraindication to long-acting morphine sulfate therapy • Documented trial/failure of, or reason why fentanyl is not appropriate • Maximum dose is 20mcg/hr
Renewal Criteria	**Pain Related to Cancer, severe burns, sickle cell disease, or Palliative Care** • Documented continued need for requested buprenorphine therapy **Pain Related to conditions of the Back and Spine**

	• Buprenorphine patches have been prescribed with a plan to keep active (home or prescribed exercise regimen) and additional therapies such as spinal manipulation, PT, yoga, or acupuncture, when available
	• Member's function has been improved while on buprenorphine patch therapy
	• Member's risk has been assessed for ALL of the following
	  ○ Risk of abuse
	  ○ Risk of respiratory adverse events
	  ○ Mental Health/Depression screening
	  ○ Urine drug screen
	  ○ PDMP report
	• Maximum buprenorphine patch does is 20mcg/hr
	
	Other Pain
	• Patches have been prescribed with a plan to keep active (home or prescribed exercise regimen) and additional therapies such as spinal manipulation, PT, yoga, or acupuncture, when available?
	• Continued use of appropriate non-opioid therapies
	• Member's function has been improved while on buprenorphine patches with continued need of therapy
	• Member's risk has been assessed for ALL of the following
	  ○ Risk of abuse
	  ○ Risk of respiratory adverse events
	  ○ Mental Health/Depression screening
	  ○ Urine drug screen
	  ○ PDMP report
	• Total buprenorphine patch does not exceed 20mcg/hr

Coverage Duration	• **All Diagnoses:**
	  ○ Initial: 12 months
	  ○ Renewal: 12 months

Effective Date:	07/01/2026
P&T Approval Date:	09/14/2021
P&T Revision Date:	05/12/2026, 9/14/2021

References
• 2022 CDC Opioid Treatment Guidelines • Oregon Chronic Opioid Prescribing Guidelines

- Guideline Note 60 of the Prioritized List
- 2022 VA Opioid Treatment Guidelines

Calcitonin Gene Related Peptide (CGRP) Antagonists

Products Affected

- Aimovig (erenumab)
- Emgality (galcanezumab)
- Ajovy (fremanezumab)

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Migraine prophylaxis
	  ○ Cluster headache (Emgality only)

Required Medical Information and Criteria	**<u>Migraine Prophylaxis</u>**
	• Documentation showing member experiences at least 4 migraines per month.
	• For members with chronic migraine (≥ 15 headache days & 8 migraine episodes per month) Trial and failure of at least 8 weeks of:
	  ○ 3 or more prophylactic medications from at least 2 of the following classes:
	  ▪ beta blockers
	  ▪ antidepressants
	  ▪ anticonvulsants
	  ○ Botox.
	• For members without a diagnosis of chronic migraine:
	• Trial and failure of:
	  ○ at least 3 prophylactic medications from 2 or more of the following classes:
	  ▪ beta blockers
	  ▪ antidepressants
	  ▪ anticonvulsants
	• The requested treatment will not be used in combination with another CGRP inhibitor.
	
	<u>Cluster Headache</u>
	• The request is for Emgality 300mg dose
	• The member does not have any of the following exclusions:
	  ○ ECG abnormalities compatible with an acute CV event,
	  ○ history of unstable angina, percutaneous coronary intervention, coronary artery bypass grafting, deep vein thrombosis, or pulmonary embolism within the past 6 months,

	○ history of stroke, intracranial or carotid aneurysm, intracranial hemorrhage, vasospastic angina, or peripheral vascular disease • Trial and failure of at least a 3-month trial of both of the following: ○ Verapamil ○ Topiramate • The requested treatment will not be used in combination with another CGRP inhibitor.
Renewal Criteria	• **Migraine Prophylaxis:** ○ Reduction in monthly headache days by at least 2 days from pre-CGRP treatment baseline ○ Clinical documented improvement in migraine-related disability • Cluster Headache ○ Documented positive clinical response to therapy
Age Restriction	• 18 years of age and older
Prescriber Restriction	• **Migraine Prophylaxis and Cluster Headache:** Prescribed by or in consultation with a neurologist
Coverage Duration	• **Migraine Prophylaxis:** ○ Initial: 6 months ○ Renewal: 12 months • **Cluster Headache:** ○ Initial: 3 months ○ Renewal: 6 months

Effective Date:	9/1/2025
P&T Approval Date:	11/08/2022
P&T Revision Date:	7/8/2025, 12/1/2022, 1/11/2022

References

- Qaseem A, et al. Prevention of Episodic Migraine Headache Using Pharmacologic Treatment in Outpatient Settings: A Clinical Guideline From the American College of Physicians. Ann Intern Med. 2025;178:426-433.
- Ailani J., et al. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021;61:1021-1039.

- Timotheussen Lund NL, et al. Current treatment options for cluster headache: limitations and the unmet need for better and specific treatments—a consensus article. The Journal of Headache and Pain. 2023;24:121.

Carbamazepine ER Capsules

Products Affected

- Carbamazepine Cap ER 12HR

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design

Required Medical Information and Criteria	**<u>All Diagnoses</u>**
	• Confirmation that carbamazepine is FDA indicated, or guideline supported for the treatment of the condition for which it is being requested
	• One of the following: Trial and failure of carbamazepine ER tablets or patient is currently stable on capsules
	  ○ Trial and failure of carbamazepine ER tablets
	  ○ Patient is currently stable on ER capsules

Coverage Duration	• **All Diagnoses:** ○ Initial: Lifetime

Effective Date:	01/01/2026
P&T Approval Date:	11/11/2025
P&T Revision Date:	11/11/2025

References
• Epilepsy: Presented by Grinalds, McKenzie. ACSAP 2025

Cenegermin (Oxervate)

Products Affected

- Oxervate Ophthalmic

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Neurotrophic Keratitis
Required Medical Information and Criteria	**<u>Neurotrophic Keratitis</u>** • Confirmed diagnosis of stage 2 or 3 neurotrophic keratitis. • Trial and failure of at least one ocular lubricant used for at least 2 weeks.
Renewal Criteria	• Maximum treatment duration of 8 weeks. Renewal is not allowed.
Prescriber Restriction	• **Neurotrophic Keratitis:** Ophthalmologist

Coverage Duration	• **Neurotrophic Keratitis:**
	  ○ Initial: 8 weeks
	  ○ Renewal: N/A

Effective Date:	11/1/2025
P&T Approval Date:	9/9/2025
P&T Revision Date:	9/9/2025

References

- Oxervate [package insert]. San Mateo, CA: Dompe U.S. Inc.; 2024

Certolizumab (Cimzia)

Products Affected

- Cimzia PFS
- Cimzia Auto-injector

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA)
	  ○ Crohn's Disease (CD)
	  ○ Juvenile Idiopathic Arthritis (JIA)
	  ○ Plaque Psoriasis (PsO)
	  ○ Psoriatic Arthritis (PsA)
	  ○ Rheumatoid Arthritis (RA)

Required Medical Information and Criteria	**All diagnoses**
	• Initial testing for latent TB and treatment, if necessary, before starting treatment
	• No current active infection at initiation of therapy
	• Risks and benefits documented in cases of chronic or recurrent infection
	• Will NOT be used in combination with another biologic or Otezla
	
	Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA)
	• Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by
	  ○ Back pain and stiffness for more than 3 months
	  ○ Signs of active inflammation on MRI
	  ○ Radiological evidence of sacroiliitis OR HLA-B27 positive
	  ○ BASDAI score of >=4
	• The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR Documented failure of conventional therapy with both of the following
	  ○ At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated
	  ○ Physical therapy/exercise program
	• Trial and failure of, or contraindication to, both infliximab and adalimumab
	
	Crohn's Disease (CD)

	• Documentation of moderate-to-severe Crohn's Disease • Trial and failure of infliximab, adalimumab, and ustekinumab (dosed every 4 weeks) or contraindication to all **Juvenile Idiopathic Arthritis (JIA)** • Documentation of juvenile idiopathic arthritis with active systemic features of JIA, with a physician global assessment of 5 or higher (or any systemic activity in the absence of active joint involvement) or JIA without active systemic features • The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of the following: o NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND o At least 6 months of 2 of Methotrexate, leflunomide, sulfasalazine, hydroxychloroquine, or systemic corticosteroids • Documented intolerance or contraindication to DMARDs OR DMARD will be continued • Trial and failure of infliximab and adalimumab or contraindication to both • Trial and failure of Actemra and Simponi or contraindication to both **Plaque Psoriasis (PsO)** • Documentation of severe plaque psoriasis, defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) = 11 or Children's Dermatology Life Quality Index (CDLQI) = 13 (or severe score on other validated tool) • One or more of the following o At least 10% of body surface area involved o Hand, foot, face, or mucous membrane involvement • The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of all the following o High-potency topical corticosteroids (augmented betamethasone, clobetasol, etc.) o At least one other topical agent (calcipotriene, tazarotene, anthralin, tar, etc.) o PUVA or UVB Phototherapy o Methotrexate

	○ At least 1 other second line systemic agent such as cyclosporine or acitretin • Trial and failure of infliximab, adalimumab, and ustekinumab or contraindication to all • Trial and failure of secukinumab (Cosentyx), apremilast (Otezla), Ilumya, Siliq, Sotyktu or contraindication to all • Trial and failure of, or contraindication to, Skyrizi **Psoriatic Arthritis (PsA)** • Documentation of psoriatic arthritis based on at least 3 out of 5 of the following Psoriasis (1 point for personal or family history, 2 points for current) ○ Psoriatic nail dystrophy ○ Negative test result for RF ○ Dactylitis (current of history) ○ Radiological evidence of juxta-articular new bone formation • The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of conventional therapy with both of the following ○ NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated ○ Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine • Trial and failure of infliximab, adalimumab, and ustekinumab or contraindication to all **Rheumatoid Arthritis (RA)** • Documentation of a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI) • The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of nonbiologic DMARD therapy: methotrexate (dosed at least 20mg per week for at least 8 weeks), leflunomide or sulfasalazine • Trial and failure of infliximab, adalimumab, and tocilizumab or contraindication to all

Renewal Criteria	• **AS/SpA:** Evidence of significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI. • **CD:** Evidence of a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission. • **JIA:** Evidence of 20% or greater improvement in tender joint count and swollen joint count or has there been an improvement in functional ability. • **PsO:** Evidence of positive clinical response to therapy as evidenced by ONE of the following: reduction of body surface area (BSA) involvement from baseline, improvement in symptoms (e.g. pruritus, inflammation) from baseline, or evidence of functional improvement. • **PsA:** Evidence of a 20% or greater improvement in tender joint count and swollen joint count. • **RA:** Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
Prescriber Restriction	• **Ankylosing Spondylitis/Axial Spondyloarthritis**: Rheumatologist. • **Crohn's Disease:** Gastroenterologist • **Juvenile Idiopathic Arthritis:** Rheumatologist • **Plaque Psoriasis:** Dermatologist • **Psoriatic Arthritis:** Dermatologist or Rheumatologist • **Rheumatoid Arthritis**: Rheumatologist
Coverage Duration	• **All diagnoses:** o Initial: 6 months o Renewal: 12 months

Effective Date:	07/01/2026
P&T Approval Date:	7/11/2023
P&T Revision Date:	05/12/2026, 7/11/2023

References

- 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.
- Ramiro S, Nikiphorou E, Sepriano A, et al. EULAR recommendations for the management of axial spondyloarthritis: 2022 update. *Ann Rheum Dis.* 2023;82(1):19-34.

- Scott FI, Ananthakrishnan AN, Click B, et al. AGA living clinical practice guideline on the pharmacologic management of moderate-to-severe Crohn's disease. *Gastroenterology.* 2025;169(7):1397-1448.
- Lichtenstein GR, Loftus EV Jr, Afzali A, et al. ACG clinical guideline: Management of Crohn's disease in adults. *Am J Gastroenterol.* 2025;120(6):1225-1264.
- 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(4):1029-1072.
- Gossec L, Baraliakos X, Kerschbaumer A, et al.EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2023 update. *Ann Rheum Dis.* 2024;83(6):706-719.
- Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Care Res (Hoboken).* 2021;73(7):924-939.
- Onel KB, Horton DB, Lovell DJ, 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 (Hoboken).* 2019;71(6):717-734.
- Ringold S, Angeles-Han ST, Beukelman T, 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 Care Res (Hoboken).* 2022;74(4):521-537.

Chloroquine Phosphate

Products Affected

- Chloroquine tablet

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of malaria
	  ○ Extraintestinal amebiasis
	  ○ Prevention of malarial infection

Required Medical Information and Criteria	**Prevention of malaria infection:** • Travel to a location where CDC recommends the use of chloroquine **Treatment of malaria** • Confirmed diagnosis of Malaria **Extraintestinal amebiasis** • Confirmed diagnosis of amebiasis
Renewal Criteria	N/A

Coverage Duration	• **Treatment of malaria & extraintestinal amebiasis:**
	  ○ Initial: 3 months
	  ○ Renewal: N/A

Effective Date:	11/01/2024
P&T Approval Date:	7/15/2013
P&T Revision Date:	7/15/2013, 9/10/2024

Cinacalcet Hydrochloride

Products Affected

- Cinacalcet tablet

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of secondary hyperparathyroidism in patients with CKD on dialysis
	  ○ Treatment of hypercalcemia in patients with parathyroid carcinoma.
	  ○ Treatment of severe hypercalcemia in patients with primary hyperparathyroidism

Required Medical Information and Criteria	**Secondary hyperparathyroidism in patients with CKD** • Confirmed diagnosis of secondary hyperparathyroidism in patients with CKD on dialysis. **Hypercalcemia in patients with parathyroid carcinoma** • Confirmed diagnosis of hypercalcemia in patients with parathyroid carcinoma **Severe hypercalcemia in patients with primary hyperparathyroidism** • Confirmed diagnosis of severe hypercalcemia in patients with primary hyperparathyroidism who are unable to undergo parathyroidectomy
Renewal Criteria	• Documented positive clinical response to therapy
Age Restriction	• 18 years of age and older

Coverage Duration	• **All diagnoses:**
	  ○ Initial: 12 months
	  ○ Renewal: 12 months

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

Clobazam (Onfi)

Products Affected

- Clobazam tablets
- Clobazam suspension

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Lennox-Gastaut Syndrome
	  ○ Refractory Seizures

Required Medical Information and Criteria	**<u>Lennox-Gastaut Syndrome</u>** • Confirmation of diagnosis • **Suspension only:** Member under age 10 or unable to use tablets **<u>Refractory Seizures</u>** • Documentation showing appropriate trial of 2 or more tolerated anticonvulsant therapies • **Suspension only:** Member under age 10 or unable to use tablets
Renewal Criteria	• Documentation of positive clinical response to therapy
Age Restriction	• Age 2 or older • **Suspension only:** Member under age 10 or unable to use tablets
Prescriber Restriction	• **All Diagnoses:** Neurologist

Coverage Duration	• **All Diagnoses:**
	  ○ Initial: 12 months
	  ○ Renewal: Lifetime

Effective Date:	05/01/2025
P&T Approval Date:	07/11/2023
P&T Revision Date:	03/12/2024, 03/11/2025

References
• Onfi [package insert]. Deerfield, IL: Lundbeck.; 2024.

Clonazepam ODT Step Therapy

Products Affected

- Clonazepam oral disintegrating tablet

Step Therapy Criteria	• Claims for any antiepileptic medication Or • Submitted diagnosis of a seizure condition

Effective Date:	5/1/2026
P&T Approval Date:	3/10/2026
P&T Revision Date:	3/10/2026

Clotrimazole Troche Step Therapy

Products Affected

- Clotrimazole Troche

Step Therapy Criteria	• Trial and failure of ○ Formulary nystatin

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

Colony-Stimulating Factors (Filgrastim, Pegfilgrastim)

Products Affected

- Nivestym Syringe and Inj.
- Zarxio Syringe
- Udenyca Syringe, Pen and Onbody
- Neulasta Syringe, Onpro
- Ziextenzo Syringe

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Bone Marrow/Stem Cell Transplant
	  ○ Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy
	  ○ Febrile Neutropenia Prophylaxis
	  ○ Treatment of High-Risk Febrile Neutropenia
	  ○ Severe Chronic Neutropenia
	  ○ Acute Radiation Syndrome
	  ○ Human Immunodeficiency Virus (HIV) Related Neutropenia

Required Medical Information and Criteria	**<u>Bone Marrow/Stem Cell Transplant</u>**
	• One of the following
	  ○ Patient has non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT)
	  ○ Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
	  ○ Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy
	
	<u>Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy</u>
	• Diagnosis of acute myeloid leukemia (AML)
	• Patient has completed induction or consolidation chemotherapy
	
	<u>Febrile Neutropenia Prophylaxis</u>
	• Patient will be receiving prophylaxis for febrile neutropenia (FN) due to one of the following:
	  ○ Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer.
	  ○ Patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown.

	○ Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN. ○ Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN and has one or more risk factors associated with chemotherapy induced infection, FN, or neutropenia. ○ Patient is receiving myelosuppressive anticancer drugs associated with neutropenia and has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis). **Treatment of High-Risk Febrile Neutropenia** • Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia. • Diagnosis of febrile neutropenia (FN). • Patient is at high risk for infection-associated complications. **Severe Chronic Neutropenia (SCN)** • 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) **Acute Radiation Syndrome (ARS)** • Patient was/will be acutely exposed to myelosuppressive doses of radiation cells/mm^3) **Human Immunodeficiency Virus (HIV) Related Neutropenia** • Patient is infected with HIV virus. • ANC less than or equal to 1,000 (cells/mm3).
Renewal Criteria	• Renewal criteria
Prescriber Restriction	• **HIV Related Neutropenia:** Hematologist, Oncologist, or Infectious Disease Specialist • **All Other Diagnoses:** Hematologist or Oncologist
Coverage Duration	• **Severe Chronic Neutropenia:** ○ Initial: 12 months ○ Renewal: 12 months • **Acute Radiation Syndrome:** ○ Initial: 1 month ○ Renewal: N/A • **All other Diagnoses:**

	○ Initial: 3 months or duration of therapy ○ Renewal: 3 months or duration of therapy

Effective Date:	9/1/2024
P&T Approval Date:	7/9/2024
P&T Revision Date:	7/9/2024

References

- Neulasta Prescribing Information. Amgen Inc. Thousand Oaks, CA. February 2021.
- Neupogen Prescribing Information. Amgen Inc. Thousand Oaks, CA. February 2021.

Compounds (standard criteria for all compounded medications)

Products Affected

- All compounded medications

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical Information and Criteria	**All diagnoses** • The requested medication is being used to treat an above the line diagnosis on the OHA Prioritized list OR the member has an above the line comorbid condition that will be treated indirectly by the requested medication OR the member is under the age of 21. • Each active ingredient in the compounded drug is FDA-approved or national compendia supported for the condition being treated. • The requested amounts are supported by national compendia or at least two peer-reviewed studies for the condition being treated in the requested route of delivery. • If any prescription ingredients require prior authorization and/or step therapy, all drug-specific criteria must be also met. • The patient has tried and failed therapy, or had an intolerance to all FDA-approved commercially available prescription therapeutic alternatives, unless one of the following criteria are met: o Patient has a contraindication to all commercially available products. o No other therapeutic alternatives are commercially available. o Prepared strength(s) is/are not commercially available or currently in short supply and the strength is medically necessary. o 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). o Patient has an allergy or sensitivity to inactive ingredients (e.g. dyes, preservatives, sugars, etc.) that are found in commercially available products.
Renewal Criteria	• Documented positive clinical response to therapy
Coverage Duration	• **All diagnoses:** o Initial: 6 months

	○ Renewal: 12 months

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

Conjugated Estrogens (Premarin Tablets)

Products Affected

- Premarin TAB 0.3MG, 0.45MG, 0.625MG, 0.9MG, 1.25MG

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical Information and Criteria	**All FDA indicated or guideline supported diagnoses** • Trial and failure of generic estradiol tablets and patches
Coverage Duration	• **All FDA indications** ○ Initial: Lifetime

Effective Date:	3/1/2024
P&T Approval Date:	1/9/2024
P&T Revision Date:	

Conjugated estrogens and medroxyprogesterone acetate (Prempro/Premphase)

Products Affected

- Prempro
- Premphase

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design

Required Medical Information and Criteria	**All FDA indicated or guideline supported diagnoses**
	• One of the following:
	  ○ Trial and failure of generic combination products
	  ○ Estradiol tablets/patches used in combination with medroxyprogesterone capsules.

Coverage Duration	• **All FDA indications:** ○ Initial: Lifetime

Effective Date:	3/1/2024
P&T Approval Date:	1/9/2024
P&T Revision Date:	1/9/2024

Continuous Glucose Monitors (CGM)

Products Affected

- Dexcom G6/G7
- Freestyle Libre 2/3

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Type 1 Diabetes Mellitus
	  ○ Type 2 Diabetes
	  ○ Gestational Diabetes

Required Medical Information and Criteria	**Type 1 Diabetes Mellitus**
	• One of the following:
	  ○ Use of continuous insulin infusion via pump
	  ○ Child or adolescent under the age of 21
	  ○ Member is pregnant or plans to become pregnant within 6 months
	  ○ Using short or intermediate acting insulin
	• The criteria listed under "applies to all requests" has been met.
	
	Type 2 Diabetes Mellitus OR Gestational Diabetes
	• Using short or intermediate acting insulin
	• The criteria listed under "applies to all requests" has been met.
	
	Applies to all requests
	• Must meet at least one of the following:
	  ○ Baseline HbA1c levels greater than or equal to 8%
	  ○ Frequent or severe hypoglycemia
	  ○ Impaired awareness of hypoglycemia (including presence of these conditions prior to initiation of CGM)
	  ○ Diabetes related complications (e.g. peripheral neuropathy, end-organ damage, etc.)
	• Member has received or will receive diabetes education specific to the use of the CGM device.
	
	** If the request is for a **Dexcom** one of the following criteria must apply:
	• Use of an insulin pump compatible with the requested Dexcom and not Freestyle
	• Pediatric member under the age of 16 years old
	• Inability to use preferred Freestyle CGM device

Renewal Criteria	• Use of CGM device for at least 50% of the time for a 90-day period by the time of first follow-up visit (within 3-6 months) and provider visits

	within the last 6 months. **Note: two trials per year of CGM are allowed to meet adherence for continuation of coverage.
Coverage Duration	• **All diagnoses:** o Initial: 6 months o Renewal: 12 months

Effective Date:	6/1/2022
P&T Approval Date:	5/8/2022
P&T Revision Date:	5/8/2022

Cromolyn

Products Affected

- Cromolyn oral solution

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Systemic Mastocytosis
	  ○ Mass Cell Activation Syndrome (MCAS)

Required Medical Information and Criteria	**<u>Mast Cell Activation Syndrome (MCAS)</u>**
	• Confirmed diagnosis of MCAS defined by meeting ALL of the following:
	  ○ Episodic, objective signs and symptoms consistent with mast cell activation involving at least two of the following organ systems: skin, upper or lower respiratory systems, gastrointestinal, or cardiovascular
	  ○ Evidence of systemic mast cell mediator release, corresponding temporally to the presence of symptoms defined as ONE of the following:
	  ▪ Serum total tryptase level increase from the patient's baseline to a level of (1.2 x baseline) + 2 ng/mL
	  ▪ Increase of more than 30 percent above baseline of N-methyl-histamine, 2,3-dinor-11-beta-prostaglandin F2-alpha or Leukotriene E4 (LTE4)
	  ▪ Increase in serum tryptase of 1.685x baseline
	• Trial and failure of H1 antihistamines (e.g. loratadine, cetirizine, etc.), H2 antihistamines (e.g. famotidine, cimetidine), and leukotriene receptor antagonist (e.g. montelukast).
	
	<u>Systemic Mastocytosis</u>
	• Documentation of confirmed diagnosis of Systemic Mastocytosis defined by meeting the major criteria plus one minor criterion or meeting three of the minor criteria listed below:
	  ○ **Major criteria:** Multifocal dense infiltrates of mast cells (MCs) (> 15 MCs in aggregate) in tryptase stained biopsy sections of the bone marrow or other extracutaneous organs such as the gastrointestinal tract.
	  ○ **Minor criteria:**

	▪ More than 25% of MCs in bone marrow or other extracutaneous organ(s) show abnormal morphology (i.e., are atypical MC type 1 or are spindle–shaped MCs) in multifocal lesions in histologic examination ▪ KIT mutation at codon 816 in extracutaneous organ(s) (in most cases bone marrow) or peripheral blood ▪ KIT+ MCs in bone marrow show aberrant expression of CD25 (and/or less specifically CD2) ▪ Serum total tryptase > 20 ng/mL (except in patients with associated hematologic neoplasm (AHN)-type disease.) • Documentation stating at least one of the following symptoms: o Chronic diarrhea o Abdominal cramping/pain o Nausea/vomiting o Flushing o Pruritus o Neuro symptoms (brain fog, headaches) o Nasal stuffiness or conjunctival injection
Renewal Criteria	• Documentation of positive clinical response to therapy
Prescriber Restriction	• **Systemic Mastocytosis**: Hematologist, Oncologist, Gastroenterologist, Immunologist • **Mast Cell Activation Syndrome:** Allergist, Gastroenterologist, Immunologist
Coverage Duration	• **Mast Cell Activation Syndrome:** o Initial: 6 months o Renewal: 12 months • **Systemic Mastocytosis:** o Initial: 6 months o Renewal: 12 months

Effective Date:	09/01/2026
P&T Approval Date:	07/14/2026
P&T Revision Date:	07/14/2026

References

- American Academy of Allergy, Asthma & Immunology. Systemic mastocytosis. AAAAI. Published 2024.
- IBM Micromedex. Cromolyn. IBM Watson Health; 2026.
- National Comprehensive Cancer Network. NCCN Guidelines for Patients: Systemic Mastocytosis. Plymouth Meeting, PA: NCCN; 2024. Accessed May 14, 2026.

Cyclosporine Oral

Products Affected

- Cyclosporine capsules
- Cyclosporine solution
- Cyclosporine Modified capsules

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Solid Organ Transplant
	  ○ Rheumatoid Arthritis
	  ○ Psoriasis

Required Medical Information and Criteria	**<u>All diagnoses</u>** • Documentation of an FDA approved indication
Renewal Criteria	• Documented positive clinical response to therapy
Age Restriction	• **Liquid only:** Member is under age 10 or unable to use tablets/capsules.

Coverage Duration	• **All diagnoses:**
	  ○ Initial: 12 months
	  ○ Renewal: 12 months

Effective Date:	5/1/2024
P&T Approval Date:	3/12/2024
P&T Revision Date:	3/12/2024

References

- Gengraf [package insert]. North Chicago, IL: Abbvie.; 2024.
- Sandimmune/Neoral [package insert]. East Hanover, NJ: Novartis.; 2020.

Cyclosporine ophthalmic (Restasis)

Products Affected

- Cyclosporine 0.05% emulsion

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Dry eye syndrome or keratoconjunctivitis sicca for EPSDT members

Required Medical Information and Criteria	**<u>Dry Eye Syndrome or Keratoconjunctivitis Sicca for members under age 21</u>**
	• Clinically documented trial and failure of both:
	  ○ Ocular lubricants in solution form
	  ○ Ocular lubricants in ointment form.
	• Clinical documentation that topical and systemic contributors to dry eye disease have been discussed and either:
	  ○ Eliminated **or**
	  ○ Contributing agents are medically necessary.
	
	<u>Dry Eye Syndrome or Keratoconjunctivitis Sicca for members age 21 or older</u>
	• Documented clinical evidence of a funded (above the line) comorbid condition for which the following applies:
	  ○ Clinical evidence shows that the funded treatments are not working or are contraindicated
	  ○ Treating dry eye syndrome or keratoconjunctivitis sicca would significantly improve the outcome of treating the funded condition.
	• Clinically documented trial and failure of both:
	  ○ Ocular lubricants in solution form.
	  ○ Ocular lubricants in ointment form.
	• Clinical documentation that topical and systemic contributors to dry eye disease have been discussed and either:
	  ○ Eliminated **or**
	  ○ Contributing agents are medically necessary.

Renewal Criteria	• Clinical documentation of efficacy.
Age Restriction	• 16 years of age or older.

Coverage Duration	• **All diagnoses:**
	  ○ Initial: 6 months
	  ○ Renewal: 12 months

Effective Date:	7/1/2025
P&T Approval Date:	5/13/2025
P&T Revision Date:	5/13/2025

References

- Dermatologic and Eyes, Ears, Nose, and Throat, and Immunologic Disorders: Presented by Jamie L. McConaha.
- https://www.aao.org/education/preferred-practice-pattern/dry-eye-syndrome-ppp-2023
- Restasis [package insert]. North Chicago, IL: Abbvie.; 2024.

Deferasirox

Products Affected

- Deferasirox 125MG, 250MG, 500MG tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Chronic iron overload due to blood transfusion
	  ○ Non-transfusion-dependent thalassemia syndromes

Required Medical Information and Criteria	**Chronic iron overload due to blood transfusion**
	• One of the following:
	  ○ A creatinine clearance of greater than or equal to 40 mL/minute
	  ○ Serum creatinine less than or equal to 2 times the age-appropriate level
	• Patient has a serum ferritin levels consistently greater than 1,000 mcg/L (as demonstrated with at least two lab values within the previous two months)
	• Patient has had a failure or contraindication to deferoxamine injection
	
	Non-transfusion-dependent thalassemia syndromes
	• One of the following:
	  ○ A creatinine clearance of greater than or equal to 40 mL/minute
	  ○ Serum creatinine less than or equal to 2 times the age-appropriate level
	• Patient has a serum ferritin levels consistently greater than 1,000 mcg/L (as demonstrated with at least two lab values within the previous two months)
	• Patient has had a failure or contraindication to deferoxamine injection

Renewal Criteria	• Documented positive clinical response to therapy
Age Restriction	• Patient is 2 years of age or older

Coverage Duration	• **Both Diagnoses:**
	  ○ Initial: 12 months
	  ○ Renewal: 12 months

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

Depemokimab (Exdensur)

Products Affected

- Exdensur Pen
- Exdensur Prefilled Solution

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Severe Asthma

Required Medical Information and Criteria	**<u>Severe Asthma</u>**
	• Confirmed diagnosis of severe asthma
	• Asthma is an eosinophilic phenotype as defined by one of the following:
	  ○ Baseline (pre-treatment) peripheral blood eosinophil 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
	• One of the following:
	  ○ Patient has had at least two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months
	  ○ Prior asthma-related hospitalization within the past 12 months
	• One of the following:
	  ○ The Patient is being treated with both:
	  ▪ A high-dose inhaled corticosteroid AND
	  ▪ An additional asthma control medication (leukotriene receptor antagonist, long-acting beta-2 agonist, long-acting muscarinic antagonist
	  ○ One maximally dosed ICS/LABA combined inhaler

Renewal Criteria	• 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) • Patient continues to be treated with an inhaled corticosteroid (ICS)
Age Restriction	• Age 12 years and older
Prescriber Restriction	• **Severe Asthma:** Pulmonologist or Allergist/Immunologist

Coverage Duration	• **Severe Asthma:**
	  ○ Initial: 6 months
	  ○ Renewal: 12 months

Effective Date:	5/1/2026
P&T Approval Date:	3/10/2026
P&T Revision Date:	3/10/2026

References

- Depemokimab applications accepted for review by the US FDA for asthma with type 2 inflammation and for chronic rhinosinusitis with nasal polyps (CRSwNP). News release. GSK. March 3, 2025. Accessed February 22, 2026.
- Exdensur (depemokimab) [package insert]. GSK; Philadelphia, PA: January 2026.
- IPD Analytics. New Drug Review: Exdensur (depemokimuab-ulaa); Payer and Provider Insights. Published January 2026.

Desmopressin

Products Affected

- Desmopressin Acetate Nasal Spray & Injections

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design o Diabetes Insipidus o Maintenance of hemostasis and control of bleeding in hemophilia A with factor VIII coagulant activity levels greater than 5% o Mild-to-moderate classic von Willebrand's disease (type 1) with factor VIII coagulant activity greater than 5%.
Required Medical Information and Criteria	**All diagnoses** • Documentation of one of the conditions listed under "covered uses"
Renewal Criteria	• Documentation of positive clinical response to therapy.
Coverage Duration	• **All Diagnoses:** o Initial: 12 months o Renewal: 12 months

Effective Date:	9/1/2023
P&T Approval Date:	7/11/2023
P&T Revision Date:	7/11/2023

References
• Stimate [package insert]. King of Prussia, PA: CSL Behring LLC.; 2015.

Deucravacitinib (Sotyktu)

Products Affected

- Sotyktu tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Plaque Psoriasis
	  ○ Psoriatic Arthritis

Required Medical Information and Criteria	**<u>All Diagnoses</u>**
	• Will NOT be used in combination with another biologic
	
	<u>Plaque Psoriasis</u>
	• Documentation of severe plaque psoriasis, defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) = 11 or Children's Dermatology Life Quality Index (CDLQI) = 13 (or severe score on other validated tool) AND one or more of the following:
	  ○ At least 10% of body surface area involved
	  ○ Hand, foot, face or mucous membrane involvement
	• One of the following:
	  ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
	  ○ Documented trial and failure of all the following:
	  ▪ High-potency topical corticosteroids (augmented betamethasone, clobetasol, etc.)
	  ▪ At least one other topical agent (calcipotriene, tazarotene, anthralin, tar, etc.)
	  ▪ PUVA or UVB Phototherapy
	  ▪ Methotrexate
	  ▪ At least 1 other second line systemic agent such as cyclosporine or acitretin.
	• Trial and failure of infliximab, adalimumab, and ustekinumab.
	
	<u>Psoriatic Arthritis</u>
	• Documentation of psoriatic arthritis based on at least 3 out of 5 of the following:
	  ○ Psoriasis (1 point for personal or family history, 2 points for current)

	○ Psoriatic nail dystrophy ○ Negative test result for RF ○ Dactylitis (current or history) • One of the following: ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR ○ Documented trial and failure of all the following: ▪ NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated ▪ Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine • Trial and failure of infliximab, adalimumab, and ustekinumab.
Renewal Criteria	• **Plaque Psoriasis:** Evidence of positive clinical response to therapy as evidenced by ONE of the following: reduction of body surface area (BSA) involvement from baseline, improvement in symptoms (e.g. pruritus, inflammation) from baseline, or evidence of functional improvement. • **Psoriatic Arthritis:** Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
Prescriber Restriction	• **Plaque Psoriasis:** Dermatologist. • **Psoriatic Arthritis:** Dermatologist or Rheumatologist.
Coverage Duration	• **All diagnoses:** ○ Initial: 6 months ○ Renewal: 12 months

Effective Date:	07/01/2026
P&T Approval Date:	07/11/2023
P&T Revision Date:	05/12/2026, 01/13/2026, 07/11/2023, 01/11/2022

References

- Sotyktu [package insert]. Princeton, NJ: Bristol-Myers Squibb Company, 2026.
- 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(4):1029-1072.

- Gossec L, Baraliakos X, Kerschbaumer A, et al.EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2023 update. *Ann Rheum Dis.* 2024;83(6):706-719.

Deutetrabenazine (Austedo)

Products Affected

- Austedo tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Chorea associated with Huntington's Disease
	  ○ Tardive Dyskinesia

Required Medical Information and Criteria	**<u>Chorea associated with Huntington's Disease</u>**
	• Documentation of the degree of chorea present and the impact on functional ability and/or quality of life.
	• Documentation of mental status, specifically depression and suicidality.
	
	<u>Tardive Dyskinesia</u>
	• Clinical documentation of tardive dyskinesia including:
	  ○ At least one month of past or current exposure to a dopamine receptor blocker
	  ○ Dyskinetic or dystonic involuntary movements
	  ○ Exclusion of other causes of abnormal movements
	• Clear documentation that tardive dyskinesia causes functional impairment
	• Documentation of the degree of tardive dyskinesia with the AIMS scale as a baseline
	• One of the following:
	  ○ Discontinuation of the medication precipitating TD
	  ○ Documentation that the patient has tried and failed an 8-week trial of at least 2 other agents within the same therapeutic category at a clinically effective and maximally tolerated dose for the patient's primary neuropsychiatric diagnosis
	  ○ Evidence the medications precipitating tardive dyskinesia are medically necessary
	• Trial and failure of both of the following:
	  ○ Clonazepam
	  ○ Amantadine

Renewal Criteria	**Huntington's Chorea**

	• Clinical response such as improvement in chorea, ability to perform ADLs, reduction in falls, or increase in quality of life. AND • Documentation of continued monitoring of mental status specifically for depression and suicidality. **Tardive Dyskinesia** • Follow-up AIMS assessment showing improvement from Baseline AND • Documented improvement in functioning such as ability to perform ADLs, reduction in falls and increase in quality of life.
Age Restriction	• Age 18 and older
Prescriber Restriction	• **Huntington's Chorea:** Neurologist • **Tardive Dyskinesia:** Neurologist or Psychiatrist
Coverage Duration	• **All diagnoses:** o Initial: 3 months o Renewal: 12 months

Effective Date:	7/1/2023
P&T Approval Date:	5/9/2023
P&T Revision Date:	5/9/2023

References

- Austedo [package insert]. Parsippany, NJ: Teva Neuroscience, Inc.; 2025.

Dihydroergotamine Injection

Products Affected

- Dihydroergotamine Inj

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Acute treatment of migraine
	  ○ Acute treatment of cluster headaches

Required Medical Information and Criteria	**<u>Acute treatment of migraine</u>** • Diagnosis of migraine with or without aura • Trial and failure of, or contraindication to 5-HT1B/1D agonist (triptans) **<u>Acute treatment of cluster headaches</u>** • Diagnosis of cluster headache • Trial and failure of, or contraindication to 5-HT1B/1D agonist (triptans)
Renewal Criteria	• Documented positive clinical response to therapy

Coverage Duration	• **All Diagnoses:**
	  ○ Initial: 12 months
	  ○ Renewal: 12 months

Effective Date:	7/1/2023
P&T Approval Date:	
P&T Revision Date:	5/9/2023

References

- Migranal [package insert]. Bridgewater, NJ: Bausch Health US, LLC; 2022.

Dimethyl Fumarate

Products Affected

- Dimethyl Fumarate DR Capsules

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Multiple sclerosis

Required Medical Information and Criteria	**<u>Multiple Sclerosis</u>**
	• Documented diagnosis of one of the following:
	  ○ A relapsing form of multiple sclerosis.
	  ○ A secondary progressive form of multiple sclerosis.
	• Medication is intended for use as monotherapy.

Renewal Criteria	• Documented positive clinical response to therapy
Prescriber Restriction	• **Multiple sclerosis:** Neurologist
Coverage Duration	• **Multiple sclerosis:** ○ Initial: lifetime

Effective Date:	11/1/2025
P&T Approval Date:	1/10/2023
P&T Revision Date:	9/9/2025, 1/10/2023

References

- Tecfidera [package insert]. Cambridge, MA: Biogen INC.; 2024.
- Practice guideline: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Approved by the Guideline Development, Dissemination, and Implementation Subcommittee on October 9, 2017; by the Practice Committee on October 21, 2017; and by the AAN Institute Board of Directors on March 6, 2018.
- The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. A consensus Paper by the Multiple Sclerosis Coalition. Updated June 2019.

Disposable Insulin Pump (Omnipod)

Products Affected

- Omnipod 5
- Omnipod Dash

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Insulin dependent diabetes mellitus

Required Medical Information and Criteria	**<u>Insulin Dependent Diabetes Mellitus – Pediatric</u>**
	• Documentation of Type 1 Diabetes Mellitus or Diabetes with C-reactive protein levels indicating insulin dependence
	• On intensive insulin therapy (>3 daily insulin injections) requiring frequent self-adjustments for at least 6 months prior to initiation of the insulin pump
	• Documentation self-testing of blood glucose at least 4 times per day during the previous 2 months
	• Evidence of completion of a comprehensive diabetes education program in the last 12 months (member or caregiver/parent)
	
	<u>Insulin Dependent Diabetes Mellitus – Adult</u>
	• All of the above pediatric requirements AND
	• Documentation of one of the following:
	  ○ HbA1c >7%
	  ○ History of recurring hypoglycemia
	  ○ Wide fluctuations in blood glucose before mealtime
	  ○ Dawn phenomenon with fasting blood sugars frequently exceeding 200mg/dL
	  ○ History of severe glycemic excursions
	• Inability to use a traditional (non-disposable) insulin pump

Renewal Criteria	• Clinical documentation of positive clinical response to therapy, and an in-person visit with the prescribing provider within the last 6 months

Coverage Duration	• **All diagnoses:**
	  ○ Initial: 6 months
	  ○ Renewal: 12 months

Effective Date:	3/1/2024

P&T Approval Date:	1/9/2024
P&T Revision Date:	1/9/2024

References
•

Dipeptidyl Peptidase 4 (DPP-4) Inhibitor Step Therapy

Products Affected

- Sitagliptin
- Saxagliptin
- Sitagliptin/metformin

Step Therapy Criteria	• Clinical diagnosis of Type 2 Diabetes Mellitus (T2DM)
	• Trial and failure of the following:
	  ○ Metformin
	  ○ Sulfonylurea or pioglitazone (or contraindication to both)

Effective Date:	09/01/2026
P&T Approval Date:	05/09/2017
P&T Revision Date:	7/14/2026, 11/10/2020, 05/09/2017

Dronabinol

Products Affected

- Dronabinol capsules

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Nausea and vomiting associated with cancer chemotherapy (CINV)
	  ○ AIDS anorexia

Required Medical Information and Criteria	**<u>Nausea and Vomiting Associated with Cancer Chemotherapy</u>**
	• Confirmation of treatment with chemotherapy
	• Trial and failure or contraindication to all of the following:
	  ○ At least one 5HT-3 receptor antagonist (e.g. ondansetron, granisetron, etc.)
	  ○ At least one of:
	  ▪ Prochlorperazine
	  ▪ Dexamethasone
	  ▪ Haloperidol
	  ▪ Olanzapine
	
	<u>AIDS Anorexia</u>
	• Confirmed diagnosis of anorexia with weight loss in patients with AIDS
	• Patient is on antiretroviral therapy

Renewal Criteria	• Documented positive clinical response to therapy

Coverage Duration	• **All diagnoses:**
	  ○ Initial: 12 months
	  ○ Renewal: 12 months

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

References
• Marinol [package insert]. North Chicago, IL: Abbvie; 2017.

Dupilumab (Dupixent)

Products Affected

- Dupixent Prefilled Syringe
- Dupixent Auto-Injector

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Moderate to Severe Asthma
	  ○ Atopic Dermatitis
	  ○ Eosinophilic Esophagitis
	  ○ Chronic Rhinosinusitis with Nasal Polyps
	  ○ Prurigo Nodularis
	  ○ Chronic Obstructive Pulmonary Disease

Required Medical Information and Criteria	**<u>Moderate to Severe Asthma</u>**
	• Confirmed diagnosis of moderate to severe asthma
	• Inadequate control of asthma symptoms despite fully maximized treatment with one of the following:
	  ○ Inhaled corticosteroids combined with long-acting beta-2 agonist
	  ○ Inhaled corticosteroids combined with long-acting muscarinic antagonist
	
	<u>Atopic Dermatitis</u>
	• Diagnosed with severe atopic dermatitis defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's Dermatology Life Quality Index (CDLQI) ≥ 13 (or severe score on another validated tool)
	• One or more of the following:
	  ○ At least 10% of body surface area involvement
	  ○ Hand, foot, or mucous membrane involvement
	• Documented contraindication or failed trial to ALL of the following:
	  ○ Moderate-high potency corticosteroid (e.g., clobetasol, fluocinonide, fluticasone)
	  ○ Topical calcineurin inhibitor (e.g. tacrolimus)
	  ○ Oral immunomodulator therapy (e.g. cyclosporine, methotrexate, azathioprine, mycophenolate mofetil) **OR** the member is oral corticosteroid dependent.
	• Trial and failure of, or contraindication to nemolizumab (Nemluvio).
	
	<u>Eosinophilic Esophagitis</u>

	• Confirmed diagnosis of Eosinophilic Esophagitis
	• Weight ≥ 15 kg
	• Two or more episodes of dysphagia per week
	• Inadequate response to an 8-week trial, intolerance, or contraindication to high-dose PPI therapy
	• **I**nadequate response to and 8-to-12-week trial, intolerance, or contraindication to swallowed inhaled respiratory corticosteroid therapy.
	
	<u>Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)</u>
	• Diagnosis of CRSwNP, including objective evidence of the presence of bilateral nasal polyps
	• Will not be used in combination with other biologics for eosinophilic indications.
	• Trial and failure to adequately reduce symptoms with:
	  ○ At least 2 months of saline nasal irrigations and inhaled nasal corticosteroids used at doses appropriate for nasal polyp treatment.
	  ○ Systemic corticosteroid treatment for nasal polyps at least once within the last 2 years or prior nasal polyp removal surgery.
	• Inhaled nasal corticosteroids will be used concomitantly with dupilumab (unless not tolerated or contraindicated).
	
	<u>Prurigo Nodularis</u>
	• Funded condition (as defined by guideline note 21 of the prioritized list) or age under 21.
	• Diagnosis of PN verified by a dermatologist and the patient has had the diagnosis for at least 3 months.
	• Severe or very severe itch (WI-NRS score ≥7) reported within the past week.
	• At least 20 PN lesions in total on both legs and/or both arms and/or trunk
	• Trial and failure (inadequate efficacy after 4-week trial, intolerable side effects) or contraindication to recommended first line agents for the treatment of PN including:
	  ○ High potency topical steroids
	  ○ Phototherapy
	  ○ At least one systemic agent (immunosuppressant, gabapentinoid, or antidepressant).
	
	<u>Chronic Obstructive Pulmonary Disease (COPD)</u>

	• Diagnosis of COPD confirmed by post-bronchodilator FEV1/FVC < 0.7 on spirometry. • Blood eosinophil count (BEC) ≥300 cells/μL within the past 3 months. • Chronic bronchitis, defined as a chronic productive cough for ≥ 3 months in the past year, in the absence of other known causes of chronic cough. • ≥ 2 moderate COPD exacerbation (defined as requiring treatment with either systemic corticosteroids and/or antibiotics) or ≥ 1 severe COPD exacerbation (defined as requiring hospitalization or observation for over 24 hours in emergency department of urgent care) within the past year despite the adherent use of inhaled LABA + LAMA+ ICS triple therapy [or LABA + LAMA dual therapy if ICS are contraindicated].
Renewal Criteria	• Documentation of positive clinical response to therapy
Age Restriction	• **Moderate to Severe Asthma:** 6 years and older • **Atopic Dermatitis:** 6 months and older • **Eosinophilic Esophagitis:** 1 years and older • **CRSwNP:** 12 years and older • **Prurigo Nodularis:** 18 years and older • **COPD:** 18 years and older
Prescriber Restriction	• **Atopic dermatitis**: Dermatologist • **Eosinophilic Esophagitis**: Gastroenterologist or Immunologist • **CRSwNP**: ENT or Immunologist • **Prurigo Nodularis**: Dermatologist • **Asthma, COPD:** Pulmonologist

Coverage Duration	• **All Diagnoses:**
	  ○ Initial: 6 months
	  ○ Renewal: 12 months

Effective Date:	7/1/2026
P&T Approval Date:	11/8/2022
P&T Revision Date:	5/12/2026, 1/14/2025, 1/9/2024, 11/8/2022

References
• Dupixent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals Inc.; 2024.

Elagolix (Orilissa)

Products Affected

- Orilissa tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Moderate to Severe Pain Associated with Endometriosis

Required Medical Information and Criteria	**<u>Moderate to Severe Pain Associated with Endometriosis</u>**
	• Confirmed diagnosis of endometriosis with documentation of moderate to severe pain associated with the condition
	• Trial and failure of, or contraindication to, both of the following:
	  ○ A 3-month trial of prescription strength NSAIDs
	  ○ Two 3-month trials of hormonal therapies (e.g. combined oral contraceptives, progestins, or levonorgestrel IUD, etc.)
	• **Additional info required for 200mg twice daily dosing:**
	  ○ Documentation of coexisting dyspareunia

Renewal Criteria	• **Renewal only allowed for 150mg dose**
	• Criteria requires documentation of:
	  ○ A positive clinical response to therapy
	  ○ Total therapy duration is 24 months or less

Age Restriction	• At least 18 years of age or older but not yet through menopause
Prescriber Restriction	• **All Diagnoses:** Obstetrician or Gynecologist

Coverage Duration	• **150mg dose:**
	  ○ Initial: 6 months
	  ○ Renewal: 18 months (maximum treatment duration of 24 months)
	• **200mg dose:**
	  ○ Initial: 6 months
	  ○ Renewal: no renewals allowed

Effective Date:	2/1/2023
P&T Approval Date:	1/10/2023
P&T Revision Date:	1/10/2023

References
• Orilissa [package insert]. North Chicago, IL: Abbvie.; 2023.

Elefibranor (Iqirvo)

Products Affected

- Iqirvo tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Primary Biliary Cholangitis

Required Medical Information and Criteria	**<u>Primary Biliary Cholangitis</u>**
	• Diagnosis of primary biliary cholangitis (PBC) confirmed by two of the following:
	  ○ Biochemical evidence of cholestasis based on ALP elevation
	  ○ Presence of AMA or other PBC-specific autoantibodies
	  ○ Histology confirmation after biopsy
	• Trial and failure of 12 months of ursodiol.
	• No current decompensated cirrhosis.

Renewal Criteria	• Documented positive clinical response to therapy
Prescriber Restriction	• **Primary Biliary Cholangitis:** Gastroenterologist or Hepatologist

Coverage Duration	• **Primary Biliary Cholangitis:**
	  ○ Initial: 6 months
	  ○ Renewal: 12 months

Effective Date:	11/1/2024
P&T Approval Date:	9/10/2024
P&T Revision Date:	9/10/2024

References
• Iqirvo [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals Inc.; 2024.

Elexacaftor-tezacaftor-ivacaftor (Trikafta)

Products Affected

- Trikafta

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design. ○ Cystic Fibrosis
Required Medical Information and Criteria	**<u>Cystic Fibrosis</u>** • Documentation of cystic fibrosis diagnosis with at least one F508del mutation • Not used in combination with other CFTR modulator treatments
Renewal Criteria	• Documented clinical response to therapy
Age Restriction	• 2 years of age and older
Prescriber Restriction	• **Cystic Fibrosis:** Pulmonologist

Coverage Duration	• **Cystic Fibrosis:**
	  ○ Initial: 6 months
	  ○ Renewal: 12 months

Effective Date:	05/01/2025
P&T Approval Date:	05/01/2021
P&T Revision Date:	09/01/2021, 03/11/2025

References

- Trikafta [package insert]. Boston, MA: Vertex Pharmaceuticals Incorporated; 2024.

Eltrombopag (Promacta)

Products Affected

- Eltrombopag tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Aplastic Anemia, Severe
	  ○ Chronic hepatitis C-associated thrombocytopenia
	  ○ Immune thrombocytopenia (persistent or chronic)

Required Medical Information and Criteria	**<u>Immune Thrombocytopenia (ITP)</u>**
	• Diagnosis of immune thrombocytopenia
	• Member is not pregnant
	• One of the following:
	  ○ Member is less than 18 years of age
	  ○ Member is 18 years of age or older with persistent or chronic ITP (3+ months since diagnosis)
	• Documentation of one of the following:
	  ○ Platelet count less than 20,000/mcL (mm^3)
	  ○ Platelet count less than 30,000/mcL (mm^3) with symptoms of bleeding
	• The member is considered steroid dependent or unresponsive to steroids
	• One of the following:
	  ○ Member is less that 18 years of age
	  ○ Member has tried and failed rituximab
	  ▪ History of splenectomy is allowed in place of rituximab but is not required if rituximab can't be used
	
	<u>Aplastic Anemia</u>
	• Confirmed diagnosis of aplastic anemia
	• Documentation of platelet count less than 30,000/mcL (mm^3)
	• One of the following:
	  ○ Trial and failure of the following immunosuppressive therapies:
	  ▪ Antithymocyte globulin (ATG)
	  ▪ Cyclosporine
	  ○ Eltombopag will be used as part of triple therapy with ATG and cyclosporine (Triple IST)

Renewal Criteria	<u>Immune Thrombocytopenia</u> • Documentation shows maintenance platelet counts between 30,000/mcL and 100,000/mcL or a doubling of platelet counts from baseline with resolution of bleeding episodes <u>Aplastic Anemia</u> Documentation that hematologic response has occurred with treatment
Exclusion Criteria	• Use in combination with another medication in the TPO-RA class or Travalisse
Age Restriction	• 1 year of age and older
Prescriber Restriction	• **Immune Thrombocytopenia:** Hematologist • **Aplastic Anemia:** Hematologist
Coverage Duration	• **Immune Thrombocytopenia:** o Initial: 3 months o Renewal: 3 months • **Aplastic Anemia:** o Initial: 16 weeks o Renewal: 6 months

Effective Date:	1/1/2026
P&T Approval Date:	11/11/2025
P&T Revision Date:	11/11/2025

References

- Neunert C. et al. American Society of Hematology 2019 Guidelines for immune thrombocytopenia. Blood Advances 10 December 2019;Vol 3 (23): 3829-3866.
- Neunert CE, et al. The 2022 review of the 2019 American Society of Hematology guidelines on immune thrombocytopenia. Blood Advances. 9 July 2024;Vol 8(13):3578-3582.
- Neunert C., et al. Management of Immune Thrombocytopenia (ITP): A pocket guide for the clinician. Based on the American Society of Hematology 2019 Guideline for Immune Thrombocytopenia. November 2019.
- Kulasekarraraj A. et al. Guidelines for the diagnosis and management of adult aplastic anaemia: A British Society of Haematology Guideline. B J Haematol. 2024;204:784-804.

- Scheinberg P. and Kulasekararaj A. Consensus recommendations for severe aplastic anemia. Blood advances. 12 November 2024. Vol 8(21):5719-5720.
- ASH Draft Recommendations for Aplastic Anemia. 2025 American Society of Hematology.

Endothelin Receptor Antagonists

Products Affected

- Ambrisentan tablets
- Bosentan tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Pulmonary Arterial Hypertension
Required Medical Information and Criteria	**<u>Pulmonary Arterial Hypertension</u>** • Clinically documented diagnosis of Pulmonary Arterial Hypertension (WHO group 1 pulmonary hypertension)
Renewal Criteria	• Documented positive clinical response to therapy
Age Restriction	• Ambrisentan: 18 years of age and over • Bosentan: 3 years and up
Prescriber Restriction	• **Pulmonary Arterial Hypertension:** Cardiologist or Pulmonologist

Coverage Duration	• **Pulmonary Arterial Hypertension:**
	  ○ Initial: 6 months
	  ○ Renewal: 12 months

Effective Date:	9/1/2025
P&T Approval Date:	7/13/2021
P&T Revision Date:	7/8/2025, 7/13/2021

References

- Tracleer [package insert]. Titusville, NJ: Actelion Pharmaceuticals Inc; 2024.
- Letairis [package insert]. Foster City, CA: Gilead Sciences Inc; 2025.

Erythromycin Gel and Solution

Products Affected

- Erythromycin 2% gel
- Erythromycin 2% solution

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical Information and Criteria	**<u>All Diagnoses</u>** • Documentation of trial and failure, intolerance, or contraindication to clindamycin 1% gel or solution
Renewal Criteria	• Documented positive clinical response to therapy
Coverage Duration	• **All Diagnoses:** o Initial: 12 months o Renewal: 12 months

Effective Date:	3/1/2023
P&T Approval Date:	1/10/2023
P&T Revision Date:	1/10/2023

References
• Acne clinical guideline (aad.org)

Erythropoietic Agents

Products Affected

- Retacrit

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Anemia Due to Chronic Kidney Disease (CKD)
	  ○ Anemia Due to Chemotherapy
	  ○ Anemia Associated with HIV Infection
	  ○ Preoperative Use for Reduction of Allogeneic Blood Transfusion in Patients Undergoing Surgery
	  ○ Anemia in Myelodysplastic Syndrome (MDS)

Required Medical Information and Criteria	**<u>Anemia Due to Chronic Kidney Disease (CKD)</u>**
	• Confirmed diagnosis of anemia with hematocrit less than 30% or hemoglobin less than 10g/dL within 30 days of request
	• Verification of iron evaluation for adequate iron stores
	• One of the following:
	  ○ Patient is on dialysis
	  ○ Patient is not on dialysis, but the rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal.
	
	<u>Anemia Due to Chemotherapy</u>
	• Verification that other causes of anemia have been ruled out
	• Verification of anemia with hematocrit less than 30% or hemoglobin less than 10g/dL within the prior 2 weeks
	• Verification of iron evaluation for adequate iron stores
	• Verification that the cancer is a non-myeloid malignancy
	• Patient is receiving chemotherapy
	
	<u>Anemia Associated with HIV Infection</u>
	• Verification of anemia with hematocrit less than 36% or hemoglobin less than 12 g/dL within the prior 30 days
	• Verification of iron evaluation for adequate iron stores
	• Serum erythropoietin level less than or equal to 500 mU/mL
	• One of the following:
	  ○ Patient is receiving zidovudine

	○ Diagnosis of HIV infection **<u>Preoperative use for reduction of allogeneic blood transfusion in patients undergoing surgery</u>** • Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery • Hemoglobin (Hgb) is greater than 10 to less than or equal to 13 g/dL • Patient is at high risk for perioperative transfusions • Patient is unwilling or unable to donate autologous blood pre-operatively • Verification of iron evaluation for adequate iron stores **<u>Anemia in Myelodysplastic Syndrome (MDS)</u>** • Diagnosis of MDS • One of the following: ○ Serum erythropoietin level less than or equal to 500 mU/mL ○ Diagnosis of transfusion-dependent MDS • Verification of iron evaluation for adequate iron stores
Renewal Criteria	**Anemia Due to CKD** • There is a documented response to treatment • One of the following: ○ Patient is on dialysis and Hgb is 11g/dL or less ○ Patient is NOT on dialysis and Hgb is 10g/dL or less **Anemia Due to Chemotherapy** • There is a documented response to treatment as indicated by a decrease in the need to blood transfusion or Hgb increase from pre-treatment level • Documented Hct less than 30% or Hgb less than 10 g/dL • Patient is receiving chemotherapy **Anemia Associated with HIV Infection** • There is a documented response to treatment as indicated by a decrease in the need to blood transfusion or Hgb increase from pre-treatment level • Documented Hct less than 36% or Hgb less than 12 g/dL **Anemia in Myelodysplastic Syndrome** • There is a documented response to treatment as indicated by a decrease in the need to blood transfusion or Hgb increase from pre-treatment level

	• Documented Hct less than 36% or Hgb less than 12 g/dL

Coverage Duration	• **Anemia due to CKD:**
	  ○ Initial: 3 months
	  ○ Renewal: 12 months
	
	• **Anemia Due to Chemotherapy:**
	  ○ Initial: 3 months
	  ○ Renewal: 3 months
	
	• **Anemia Associated with HIV:**
	  ○ Initial: 3 months
	  ○ Renewal: 12 months
	
	• **Anemia in MDS:**
	  ○ Initial: 3 months
	  ○ Renewal: 12 months
	
	• **Preoperative:**
	  ○ Initial: 1 months
	  ○ Renewal: N/A

Effective Date:	9/1/2024
P&T Approval Date:	7/9/2024
P&T Revision Date:	7/9/2024

References

- Oregon Health Authority. (2024). *Guideline Note GN7: Erythropoiesis-Stimulating Agent (ESA) Guideline*. Health Evidence Review Commission.

Estradiol Ring (Estring)

Products Affected

- Estring 2mg vaginal ring

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical Information and Criteria	**All FDA approved diagnoses** • Trial and failure of estradiol vaginal cream and estradiol vaginal tablet
Renewal Criteria	• Documented positive clinical response to therapy
Coverage Duration	• **All Diagnoses:** o Initial: 6 months o Renewal: 12 months

Effective Date:	7/1/2023
P&T Approval Date:	5/9/2023
P&T Revision Date:	5/9/2023

References
• Estring [package insert]. New York, NY: Pfizer; 2023.

Etrasimod arginine (Velsipity)

Products Affected

- Velsipity tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Ulcerative Colitis

Required Medical Information and Criteria	**<u>Ulcerative Colitis</u>**
	• Documentation of moderate-to-severe ulcerative colitis
	• The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of at least 1 of the following:
	  ○ Mesalamine, sulfasalazine OR
	  ○ Mercaptopurine, azathioprine, OR
	  ○ Corticosteroids (prednisone, methylprednisolone)
	• Trial and failure of infliximab, adalimumab, and ustekinumab (dosed every 4 weeks) or contraindication to all

Renewal Criteria	• Evidence of a significant response such as a decrease in bloody stools per day or elimination of signs of toxicity.
Age Restriction	• 18 years of age or older
Prescriber Restriction	• **Ulcerative colitis:** Gastroenterologist

Coverage Duration	• **Ulcerative colitis:**
	  ○ Initial: 6 months
	  ○ Renewal: 12 months

Effective Date:	07/01/2026
P&T Approval Date:	01/09/2024
P&T Revision Date:	05/12/2026, 01/09/2024

References

- Velsipity [package insert]. New York, NY: Pfizer Inc.; 2024.
- Rubin DT, Ananthakrishnan AN, Siegel CA, Barnes EL, Long MD. ACG clinical guideline update: Ulcerative colitis in adults. *Am J Gastroenterol.* 2025;120(6):1187-1224.

- Singh S, Loftus EV Jr, Limketkai BN, et al. AGA living clinical practice guideline on pharmacological management of moderate-to-severe ulcerative colitis. *Gastroenterology.* 2024;167(7):1307-1343.

Ferrous Sulfate

Products Affected

- Ferrous Sulfate 300mg/5mL

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical Information and Criteria	**<u>All Diagnoses</u>** • Documentation of inability to use ferrous sulfate tabs or 200mg/5mL liquid
Coverage Duration	• **All Diagnoses:** o Initial: Lifetime

Effective Date:	1/11/2024
P&T Approval Date:	11/14/2023
P&T Revision Date:	11/14/2023

Fezolinetant (Veozah)

Products Affected

- Veozah tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Vasomotor Symptoms Associated with Menopause
Required Medical Information and Criteria	**<u>Vasomotor Symptoms Associated with Menopause</u>** • Diagnosis of moderate to severe vasomotor symptoms due to menopause. • Documented contraindication, intolerance, or inadequate response to at least 2 hormonal therapies. • Documented contraindication, intolerance, or inadequate response to two nonhormonal therapies (e.g., one SNRI and one SSRI).
Renewal Criteria	• Documentation of at least 50% reduction in VMS from baseline.
Prescriber Restriction	• **All Diagnoses:** Gynecologist

Coverage Duration	• **All Diagnoses:**
	  ○ Initial: 3 months
	  ○ Renewal: 12 months

Effective Date:	9/1/2023
P&T Approval Date:	7/11/2023
P&T Revision Date:	7/11/2023

References
• Veozah [package insert]. Northbrook, IL: Astellas Pharma US Inc.; 2023

Fingolimod

Products Affected

- Fingolimod 0.5mg capsules

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of Multiple Sclerosis

Required Medical Information and Criteria	**<u>Multiple Sclerosis</u>**
	• Documented diagnosis of one of the following:
	  ○ A relapsing form of multiple sclerosis.
	  ○ A secondary progressive form of multiple sclerosis.
	• Medication is intended for use as monotherapy.

Renewal Criteria	• Positive clinical response to therapy
Prescriber Restriction	• **Multiple Sclerosis:** Neurologist
Coverage Duration	• **Multiple Sclerosis:** ○ Initial: lifetime

Effective Date:	11/1/2025
P&T Approval Date:	1/10/2023
P&T Revision Date:	9/9/2025, 1/10/2023

References

- Gilenya [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Co.; 2023
- Practice guideline: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Approved by the Guideline Development, Dissemination, and Implementation Subcommittee on October 9, 2017; by the Practice Committee on October 21, 2017; and by the AAN Institute Board of Directors on March 6, 2018.
- The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. A consensus Paper by the Multiple Sclerosis Coalition. Updated June 2019.

Fluorouracil, topical

Products Affected

- Fluorouracil 5% cream
- Fluorouracil 2% solution
- Fluorouracil 5% solution

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Superficial Basal Cell Carcinoma
Required Medical Information and Criteria	**<u>Basal Cell Carcinoma</u>** • Documentation confirming a diagnosis of superficial basal cell carcinoma with multiple lesions and/or difficult to treat areas.
Renewal Criteria	• Documented positive clinical response to therapy

Coverage Duration	• **Basal Cell Carcinoma:**
	  ○ Initial: 12 months
	  ○ Renewal: 12 months

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

References

- Efudex [package insert]. Sugar Land, TX: Bausch Health Inc.; 2021

Glatiramer

Products Affected

- Glatiramer 20mg/mL inj
- Glatiramer 40mg/mL inj

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of Multiple Sclerosis

Required Medical Information and Criteria	**<u>Multiple Sclerosis</u>**
	• Documented diagnosis of one of the following:
	  ○ A relapsing form of multiple sclerosis.
	  ○ A secondary progressive form of multiple sclerosis.
	• Medication is intended for use as monotherapy.

Renewal Criteria	• Positive clinical response to therapy
Prescriber Restriction	• **Multiple Sclerosis:** Neurologist
Coverage Duration	• **Multiple Sclerosis:** ○ Initial: lifetime

Effective Date:	11/1/2025
P&T Approval Date:	1/10/2023
P&T Revision Date:	9/9/2025, 1/10/2023

References

- Glatopa [package insert]. Princeton, NJ: Sandoz Inc.; 2023
- Practice guideline: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Approved by the Guideline Development, Dissemination, and Implementation Subcommittee on October 9, 2017; by the Practice Committee on October 21, 2017; and by the AAN Institute Board of Directors on March 6, 2018.
- The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. A consensus Paper by the Multiple Sclerosis Coalition. Updated June 2019.

Glucagon-Like Peptide-1 (GLP1) Receptor Agonist for Diabetes

Products Affected

- Trulicity Auto-Injector
- Rybelsus Tablet
- Ozempic Pen-Injector

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Type 2 Diabetes

Required Medical Information and Criteria	**<u>Type 2 Diabetes</u>**
	• Documentation of clinically diagnosed Type 2 Diabetes
	• One of the following:
	  ○ Documentation of all of the following:
	  ▪ Adequate trial of maximally tolerated dose of metformin
	  ▪ Documentation of trial and failure of sulfonylurea, pioglitazone, or insulin or contraindication to all
	  ▪ Documentation of trial and failure of one of the following (or contraindication to both):
	  • An SGLT-2 inhibitor (e.g. dapagliflozin)
	  • A DPP-4 inhibitor (e.g. saxagliptin or sitagliptin)
	  ○ Both of the following:
	  ▪ Documented diagnosis of ASCVD (MI, stroke, arterial revascularization, TIA, unstable angina) or CKD
	  ▪ Trial and failure of an SGLT2 inhibitor (dapagliflozin)
	• Documentation of trial and failure of liraglutide

Renewal Criteria	• Documented positive clinical response to therapy such as a decrease in A1c

Coverage Duration	• **Type 2 Diabetes:**
	  ○ Initial: 12 months
	  ○ Renewal: 12 months

Effective Date:	09/01/2026
P&T Approval Date:	09/12/2017

P&T Revision Date:	07/14/2026, 03/10/2026, 01/09/2024, 11/08/2022, 07/13/2021, 09/08/2020

References

- American Diabetes Association Professional Practice Committee. Standards of Care in Diabetes—2026. Diabetes Care. 2026;49(Suppl 1).
- Ozempic [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; 2026
- Trulicity [package insert]. Indianapolis, IN: Eli Lilly and Company; 2026
- Rybelsus [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; 2026

Golimumab (Simponi)

Products Affected

- Simponi Auto-Injector
- Simponi Aria (Specialty Fusion Drug)
- Simponi Prefilled Syringe

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Ankylosing Spondylitis/Axial Spondyloarthritis
	  ○ Juvenile Idiopathic Arthritis (IV only)
	  ○ Psoriatic Arthritis
	  ○ Rheumatoid Arthritis
	  ○ Ulcerative Colitis

Required Medical Information and Criteria	**<u>All diagnoses</u>**
	• Initial testing for latent TB and treatment, if necessary, before starting treatment.
	• No current active infection at initiation of therapy.
	• Risks and benefits documented in cases of chronic or recurrent infection.
	• Will NOT be used in combination with another biologic or Otezla.
	
	<u>Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA)</u>
	• Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by:
	  ○ Back pain and stiffness for more than 3 months AND
	  ○ Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive AND
	  ○ BASDAI score of >=4
	• One of the following:
	  ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
	  ○ Documented failure of conventional therapy with both of the following:
	  ▪ At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated AND
	  ▪ Physical therapy/exercise program
	• Trial and failure of infliximab and adalimumab or contraindication to both.

	Juvenile Idiopathic Arthritis (JIA)
	• Documentation of juvenile idiopathic arthritis with active systemic features of JIA, with a physician global assessment of 5 or higher (or any systemic activity in the absence of active joint involvement) or JIA without active systemic features
	• One of the following:
	  ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
	  ○ Documented trial and failure of the following:
	  ▪ NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND
	  ▪ At least 6 months of 2 of Methotrexate, leflunomide, sulfasalazine, hydroxychloroquine, or systemic corticosteroids
	• Documented intolerance or contraindication to DMARDs OR DMARD will be continued with adalimumab.
	• Trial and failure of infliximab and adalimumab or contraindication to both
	
	Psoriatic Arthritis (PsA):
	• Documentation of psoriatic arthritis based on at least 3 out of 5 of the following:
	  ○ Psoriasis (1 point for personal or family history, 2 points for current)
	  ○ Psoriatic nail dystrophy
	  ○ Negative test result for RF
	  ○ Dactylitis (current of history)
	  ○ Radiological evidence of juxta-articular new bone formation
	• One of the following:
	  ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
	  ○ Documented trial and failure of conventional therapy with both of the following:
	  ▪ NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND
	  ▪ Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine.
	• Trial and failure of infliximab, adalimumab, and ustekinumab or contraindication to all
	
	Rheumatoid Arthritis (RA):

	• Documentation of a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI)
	• One of the following:
	  ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
	  ○ Documented trial and failure of nonbiologic DMARD therapy: methotrexate (dosed at least 20mg per week for at least 8 weeks), leflunomide or sulfasalazine
	• Trial and failure of infliximab, adalimumab, and tocilizumab or contraindication to all
	
	<u>Ulcerative Colitis (UC):</u>
	• Documentation of moderate-to-severe ulcerative colitis
	• One of the following:
	  ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
	  ○ Documented trial and failure of at least 1 of the following: mesalamine, sulfasalazine, mercaptopurine, azathioprine, or corticosteroids (prednisone, methylprednisolone).
	• Trial and failure of infliximab, adalimumab, and ustekinumab or contraindication to all

Renewal Criteria	• **Ankylosing Spondylitis/Axial Spondyloarthritis:** Evidence of significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI. • **Juvenile Idiopathic Arthritis:** Evidence of 20% or greater improvement in tender joint count and swollen joint count or has there been an improvement in functional ability. • **Psoriatic Arthritis:** Evidence of a 20% or greater improvement in tender joint count and swollen joint count. • **Rheumatoid Arthritis:** Evidence of a 20% or greater improvement in tender joint count and swollen joint count. • **Ulcerative Colitis:** Evidence of a significant response such as a decrease in bloody stools per day or elimination of signs of toxicity.
Prescriber Restriction	• **Ankylosing Spondylitis**, **Axial Spondyloarthritis:** Rheumatologist. • **Juvenile Idiopathic Arthritis:** Rheumatologist. • **Psoriatic Arthritis:** Dermatologist or Rheumatologist.

	• **Rheumatoid Arthritis**: Rheumatologist. • **Ulcerative Colitis:** Gastroenterologist.
Coverage Duration	• **All diagnoses:** o Initial: 6 months o Renewal: 12 months

Effective Date:	07/01/2026
P&T Approval Date:	7/11/2023
P&T Revision Date:	05/12/2026, 7/11/2023

References

- 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.
- Ramiro S, Nikiphorou E, Sepriano A, et al. EULAR recommendations for the management of axial spondyloarthritis: 2022 update. *Ann Rheum Dis.* 2023;82(1):19-34.
- 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(4):1029-1072.
- Rubin DT, Ananthakrishnan AN, Siegel CA, Barnes EL, Long MD. ACG clinical guideline update: Ulcerative colitis in adults. *Am J Gastroenterol.* 2025;120(6):1187-1224.
- Singh S, Loftus EV Jr, Limketkai BN, et al. AGA living clinical practice guideline on pharmacological management of moderate-to-severe ulcerative colitis. *Gastroenterology.* 2024;167(7):1307-1343.
- Gossec L, Baraliakos X, Kerschbaumer A, et al.EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2023 update. *Ann Rheum Dis.* 2024;83(6):706-719.
- Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Care Res (Hoboken).* 2021;73(7):924-939.
- Onel KB, Horton DB, Lovell DJ, 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 (Hoboken).* 2019;71(6):717-734.
- Ringold S, Angeles-Han ST, Beukelman T, 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 Care Res (Hoboken).* 2022;74(4):521-537.

Gonadotropin-Releasing Hormone Agonists

Products Affected

- Lupron

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Endometriosis
	  ○ Uterine Leiomyomata (Fibroids) – For the reduction of the size of fibroids
	  ○ Uterine Leiomyomata (Fibroids) – Anemia
	  ○ Central Precocious Puberty (CPP)
	  ○ Prostate Cancer
	  ○ Gender Dysphoria/Gender Incongruence

Required Medical Information and Criteria	**<u>Endometriosis</u>**
	• One of the following:
	  ○ History of inadequate pain control response following and trial of at least 6 months or history of intolerance or contraindication to one of the following:
	  ▪ Danazol
	  ▪ Combination (estrogen/progestin) oral contraceptive
	  ▪ Progestins
	  ○ Patient has had surgical ablation to prevent recurrence
	
	<u>Uterine Leiomyomata (Fibroids) – For the reduction of the size of fibroids</u>
	• For use prior to surgery to reduce the size of fibroids to facilitate a surgical procedure (e.g., myomectomy, hysterectomy)
	
	<u>Uterine Leiomyomata (Fibroids) – Anemia</u>
	• Anemia is caused by uterine leiomyomata (fibroids)
	• Patient has tried and had an inadequate response to at least 1 month of monotherapy with iron
	• Used in combination with iron therapy
	• For use prior to surgery
	
	<u>Central Precocious Puberty (CPP)</u>
	• Diagnosis of central precocious puberty (idiopathic or neurogenic)
	• 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 • Advanced bone age of at least one year compared with chronological age • One of the following: ○ Patient has undergone gonadotropin-releasing hormone agonist (GnRHa) testing and peak luteinizing hormone (LH) level above pre-pubertal range ○ Patient has a random LH level in the pubertal range • One of the following: ○ 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) ○ Patient has no suspected tumors **<u>Prostate Cancer</u>** • Diagnosis of advanced or metastatic prostate cancer **<u>Gender Dysphoria/Gender Incongruence</u>** • Using gonadotropin for suppression of puberty • Diagnosis of gender dysphoria/gender incongruence
Renewal Criteria	• **Endometriosis:** Recurrence of symptoms following a trial of at least 6 months with leuprolide acetate AND used in combination with one of the following: Norethindrone 5mg daily, other "add-back" sex-hormones (e.g. estrogen, medroxyprogesterone), other bone-sparing agents (e.g., bisphosphonates). • **Central Precocious Puberty (CPP):** LH levels have been suppressed to pre-pubertal levels. • **Prostate Cancer:** Patient does not show evidence of progressive disease while on therapy.
Prescriber Restriction	• **Central Precocious Puberty (CPP):** Pediatric endocrinologist
Coverage Duration	• **Endometriosis:** ○ Initial: 6 months ○ Renewal: up to 6 months

	• **Uterine Leiomyomata (Fibroids Reduction):**
	  ○ Initial: 4 months
	
	• **Uterine Leiomyomata (Fibroids Anemia):**
	  ○ Initial: 3 months
	
	• **Central Precocious Puberty (CPP):**
	  ○ Initial: 12 months
	  ○ Renewal: up to 12 months
	
	• **Prostate Cancer:**
	  ○ Initial: 12 months
	  ○ Renewal: up to 12 months
	
	• **Gender Dysphoria:**
	  ○ Initial: 12 months

Effective Date:	7/1/2024
P&T Approval Date:	5/14/2024
P&T Revision Date:	5/14/2024, 1/10/2023

References
•

Grass Pollen Allergen Extract -Timothy Grass (Grastek)

Products Affected

- Grastek

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Grass pollen-induced allergic rhinitis
Required Medical Information and Criteria	**<u>Grass Pollen-Induced Allergic Rhinitis</u>** • Confirmed diagnosis of grass pollen induced allergic rhinitis
Renewal Criteria	• Documented positive clinical response to therapy
Prescriber Restriction	• **Grass Pollen-Induced Allergic Rhinitis:** Allergist or Immunologist

Coverage Duration	• **Grass Pollen-Induced Allergic Rhinitis:**
	  ○ Initial: 3 months
	  ○ Renewal: 3 months

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

References
•

Hepatitis C Antivirals

Products Affected

- Mavyret
- Vosevi
- Sofosbuvir-Velpatasvir

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of Hepatitis C Infection

Required Medical Information and Criteria	**<u>Hepatitis C Infection</u>**
	***PA for Mavyret and Sofosbuvir-Velpatasvir is only required if there is a history of prior treatment (treatment experienced). Vosevi requires PA in all cases. ***
	• All appropriate pre-treatment testing has been done:
	  ○ Genotype testing in the past 3 years is required if the patient has decompensated cirrhosis, prior treatment experience with DAA regimen, and if prescribed a regimen which is not pan-genotypic
	  ○ History of previous HCV treatment, viral load after treatment, and outcome are required only if there is documentation of treatment experience
	• Documentation of prior treatment history
	• Documentation of whether the patient achieved a sustained virological response (SVR) at week 12 or longer following the completion of their last DAA regimen
	• Documentation if this is likely a reinfection, indicated by at least one of the following:
	  ○ Does the patient have ongoing risk factors for hepatitis C reinfection (e.g. sexually active men who have sex with men, persons who inject drugs)
	  ○ Is the hepatitis C infection due a different genotype than previous
	• If the request is for elbasvir/grazoprevir for GT 1a, ledipasvir/sofosbuvir for GT 1a treatment experienced or sofosbuvir for GT 3 with cirrhosis or treatment experience has the patient had a baseline NS5a resistance test. (Note: baseline NS5A resistance testing is required per OHA in this situation)
	• The prescribed drug regimen a recommended regimen based on the patient's genotype, age, treatment status (retreatment or treatment naïve) and cirrhosis status (see table 1 and 2)?

**Per OHA: treatment experienced are patients who received more than 4 weeks of HCV DAA therapy.*

Table 1. Recommended Regimens for Adults and adolescents 12 years of age and older

Treatment History	Cirrhosis Status	Recommended Regimen
Treatment Naïve (Genotype 1-6)		
Treatment naïve	Non-cirrhotic	SOF/VEL x 12 weeks G/P x 8 weeks
	Compensated cirrhosis	G/P x 8 weeks SOF/VEL x 12 weeks (baseline resistance testing recommended for GT3)
	Decompensated cirrhosis	SOF/VEL + RBV x 12 weeks SOF/VEL x 24 weeks (if RBV ineligible)

Treatment Experienced (Genotype 1-6)		
Sofobuvir based regimen treatment failures, including: sofosbuvir + ribavirin Ledipasvir/Sofobuvir Velpatasvir/sofobuvir	Non-cirrhotic or compensated cirrhosis	SOF/VEL/VOX x 12 weeks G/P x16 weeks (except GT3)
Elbasvir/grazoprevir treatment failures	Non-cirrhotic or compensated cirrhosis	SOF/VEL/VOX x 12 weeks
Glecaprevir/pibrentasvir treatment failures	Non-cirrhotic or compensated cirrhosis	G/P + SOF + RBV x 16 weeks SOF/VEL/VOX x 12 weeks (plus RBV if compensated cirrhosis)
Multiple DAA Treatment Failures, including: Sofobuvir/velpatasvir/voxilaprevir Glecaprevir/pibrentasvir + sofobuvir	Non-Cirrhotic or compensated cirrhosis	G/P + SOF + RBV x 16-24 weeks SOF/VEL/VOX x24 weeks

<table>
<tr><td></td><td>
<u>Table 2. Recommended Regimens for children 3-12 years of age</u>
<table>
<tr><th>Treatment History</th><th>Cirrhosis Status</th><th>Recommended Regimen</th></tr>
<tr><td colspan="3">Treatment Naïve (Genotype 1-6)</td></tr>
<tr><td rowspan="2">Treatment Naive</td><td>Non-cirrhotic or compensated cirrhosis</td><td>SOF/VEL x 12 weeks
G/P x 8 weeks</td></tr>
<tr><td>Decompensated cirrhosis</td><td>SOF/VEL + RBV x 12 weeks</td></tr>
</table>
<table>
<tr><td>Abbreviations: DAA = direct acting antiviral; EBV/GZR = elbasvir/grazoprevir; G/P = glecaprevir and pibrentasvir; PEG = pegylated interferon; RBV = ribavirin; SOF = sofosbuvir; SOF/VEL = sofosbuvir/velpatasvir; SOF/VEL/VOX = sofosbuvir/velpatasvir/voxilaprevir</td></tr>
<tr><td>There is limited data supporting DAA regimens in treatment-experienced patients with decompensated cirrhosis. These patients should be handled on a case by case basis with the patient, prescriber, and CCO or FFS medical director</td></tr>
<tr><td>Ribavirin ineligible/intolerance may include: 1) neutrophils < 750 mm3, 2) hemoglobin < 10 g/dl, 3) platelets <50,000 cells/mm3, autoimmune hepatitis or other autoimmune condition, hypersensitivity or allergy to ribavirin</td></tr>
</table>
</td></tr>
<tr><td>Coverage Duration</td><td>

Hepatitis C Infection:

Initial: 8-24 weeks. Duration of approval depends on the specifics of the infection.

</td></tr>
</table>

Effective Date:	12/1/2022
P&T Approval Date:	11/8/2022
P&T Revision Date:	11/8/2022

References
•

Hereditary Angioedema (HAE) Agents

Products Affected

- Haegarda (C1 esterase inhibito)
- Orladeyo (Berotralstat)
- Icatibant

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Hereditary Angioedema, prophylaxis
	  ○ Hereditary Angioedema, acute attacks

Required Medical Information and Criteria	**<u>Hereditary Angioedema (both acute and prophylactic)</u>**
	• Diagnosis confirmed by genetic testing or normal C1q lab levels with levels below with levels below the lab's normal reference range for both C4 and C1IHN
	• History of HAE attacks that are considered severe with swelling of the face, throat, or gastrointestinal tract that significantly interrupts usual daily activity despite short-term symptomatic treatment
	• Patient has been evaluated for triggers of HAE attacks and is maximally managed for avoidance of those triggers (such as stress, hormonal changes, dental surgery, trauma, medications including ACE inhibitors and estrogen)
	• For acute treatment of HAE
	  ○ Request is for Icatibant
	  ○ Not used in combination with other approved treatments for acute HAE attacks
	• Prophylactic treatment of HAE
	  ○ Request is for Haegarda or Orladeyo
	  ○ Not used in combination with other approved treatments for prophylaxis against HAE

Renewal Criteria	• Documentation of at least 50% reduction in the number of HAE attacks, OR significant improvement in the severity and duration of attacks AND • Clinical documentation of functional improvement • For acute treatment of HAE ○ Not used in combination with other approved treatments for acute HAE attacks • Prophylactic treatment of HAE

	○ Not used in combination with other approved treatments for prophylaxis against HAE
Prescriber Restriction	• Allergist, immunologist, gastroenterologist, or HAE specialist; or in direct collaboration with one of the above specialists.
Coverage Duration	• **Hereditary Angioedema:** ○ Initial: 6 months ○ Renewal: 12 months

Effective Date:	03/01/2026
P&T Approval Date:	01/13/2026
P&T Revision Date:	01/13/2026

References

- Bloudek L, Jaksa A, McKenna A, Carlson J, Chen Y, Patrick A, Campbell JD. Observational Real-World Evidence Update; Prophylaxis of Hereditary Angioedema with Takhzyro and C1 Inhibitors: Effectiveness and Value. August 24, 2021.
- Busse PJ, et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema. J Allergy Clin Immunol Pract. 2021;9(1):132–150.e3.

Inclisiran (Leqvio)

Products Affected

- Leqvio Prefilled Syringe

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Established clinical ASCVD
	  ○ Primary or Familial Hyperlipidemia

Required Medical Information and Criteria	**<u>Established Clinical ASCVD</u>**
	• Documentation of very high risk ASCVD as evidenced by either:
	  ○ History of multiple major ASCVD events **OR**
	  ○ One major ASCVD event AND multiple high-risk conditions.
	• Documentation of a current LDL greater than or equal to 55 mg/dl.
	• Documentation of all the following:
	  ○ Patient is receiving maximally tolerated statin therapy (atorvastatin 40-80mg, rosuvastatin 20-40mg) or has a documented clinical intolerance to statins
	  ○ Is receiving ezetimibe or has a documented intolerance to ezetimibe.
	• Documentation of failure of PCSK9 inhibitor (Repatha or Praluent).
	
	<u>Primary or Familial Hyperlipidemia</u>
	• Documentation of an untreated (i.e., prior to lipid lowering therapy) LDL greater than 190 mg/dL.
	• Documentation of current LDL greater than 100 mg/dL.
	• Documentation of all the following:
	  ○ Patient is receiving maximally tolerated statin therapy (atorvastatin 40-80mg, rosuvastatin 20-40mg) or has a documented clinical intolerance to statins
	  ○ Is receiving ezetimibe or has a documented intolerance to ezetimibe.
	• Documentation of failure of PCSK9 inhibitor (Repatha or Praluent).

Renewal Criteria	• Documented positive clinical response to therapy (significant decrease in lipid levels).
Prescriber Restriction	• **All Diagnoses:** Cardiologist, Endocrinologist, or Lipid Specialist
Coverage Duration	• **All Diagnoses:**

	○ Initial: 6 months ○ Renewal: 12 months

Effective Date:	11/1/2024
P&T Approval Date:	9/10/2024
P&T Revision Date:	9/10/2024

References
•

Insulin Degludec

Products Affected

- Insulin Degludec Flextouch 100 unit/mL
- Insulin Degludec Flextouch 200 unit/mL

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Type 1 Diabetes
	  ○ Type 2 Diabetes

Required Medical Information and Criteria	**<u>All Diagnoses</u>**
	• Trial and failure of Insulin Glargine or documented intolerance or contraindication to Insulin Glargine
	• Documentation of significant barriers to standardized administration requiring flexibility in dose timing
	• For U-200 concentration only:
	  ○ Insulin requirements of greater than 160 units of insulin per dose
	  ○ Difficulty with multiple daily injections

Renewal Criteria	• Renewal criteria

Coverage Duration	• **All Diagnoses:**
	  ○ Initial: 12 months
	  ○ Renewal: 12 months

Effective Date:	5/1/2024
P&T Approval Date:	3/12/2024
P&T Revision Date:	3/12/2024

References
•

Insulin U-500 (Humulin R U-500)

Products Affected

- Humulin R U-500 Pens
- Humulin R U-500 Vials

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Type 1 Diabetes
	  ○ Type 2 Diabetes

Required Medical Information and Criteria	**<u>All Diagnoses</u>** • Attestation that the use of U-500 insulin is medically safe and appropriate
Coverage Duration	• **All Diagnoses:** ○ Initial: Lifetime

Effective Date:	3/1/2025
P&T Approval Date:	1/14/2025
P&T Revision Date:	1/14/2025

References
•

Interferon beta-1a (Avonex)

Products Affected

- Avonex Pen
- Avonex prefilled syringe

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of Multiple Sclerosis

Required Medical Information and Criteria	**<u>Multiple Sclerosis</u>**
	• Documented diagnosis of one of the following:
	  ○ A relapsing form of multiple sclerosis.
	  ○ A secondary progressive form of multiple sclerosis.
	• Medication is intended for use as monotherapy.
	• Trial and failure of all the following:
	  ○ Dimethyl fumarate
	  ○ Fingolimod
	  ○ Glatiramer

Renewal Criteria	• Documented positive clinical response to therapy
Prescriber Restriction	• **Multiple Sclerosis:** Neurologist

Coverage Duration	• **Multiple Sclerosis:**
	  ○ Initial: 12 months
	  ○ Renewal: 12 months

Effective Date:	11/1/2025
P&T Approval Date:	1/10/2023
P&T Revision Date:	9/9/2025, 1/10/2023

References

- Avonex [package insert]. Cambridge, MA: Biogen; 2023
- Practice guideline: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Approved by the Guideline Development, Dissemination, and Implementation Subcommittee on October 9, 2017; by the Practice

Committee on October 21, 2017; and by the AAN Institute Board of Directors on March 6, 2018.

- The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. A consensus Paper by the Multiple Sclerosis Coalition. Updated June 2019.

Interferon beta-1a (Rebif)

Products Affected

- Rebif Inj.
- Rebif Rebido

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of Multiple Sclerosis

Required Medical Information and Criteria	**<u>Multiple Sclerosis</u>**
	• Documented diagnosis of one of the following:
	  ○ A relapsing form of multiple sclerosis.
	  ○ A secondary progressive form of multiple sclerosis.
	• Medication is intended for use as monotherapy.
	• Trial and failure of all the following:
	  ○ Dimethyl fumarate
	  ○ Fingolimod
	  ○ Glatiramer
	  ○ Avonex

Renewal Criteria	• Documented positive clinical response to therapy
Prescriber Restriction	• **Multiple Sclerosis:** Neurologist

Coverage Duration	• **Multiple Sclerosis:**
	  ○ Initial: 12 months
	  ○ Renewal: 12 months

Effective Date:	11/1/2025
P&T Approval Date:	1/10/2023
P&T Revision Date:	9/9/2025, 1/10/2023

References

- Rebif [package insert]. Rockland, MA: EMD Serono Inc.; 2023
- Practice guideline: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Approved by the Guideline Development, Dissemination, and Implementation Subcommittee on October 9, 2017; by the Practice

Committee on October 21, 2017; and by the AAN Institute Board of Directors on March 6, 2018.

- The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. A consensus Paper by the Multiple Sclerosis Coalition. Updated June 2019.

Interferon beta-1b (Betaseron)

Products Affected

- Betaseron Inj.

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of Multiple Sclerosis

Required Medical Information and Criteria	**<u>Multiple Sclerosis</u>**
	• Documented diagnosis of one of the following:
	  ○ A relapsing form of multiple sclerosis.
	  ○ A secondary progressive form of multiple sclerosis.
	• Medication is intended for use as monotherapy.
	• Trial and failure of all the following:
	  ○ Dimethyl fumarate
	  ○ Fingolimod
	  ○ Glatiramer
	  ○ Avonex

Renewal Criteria	• Documented positive clinical response to therapy
Prescriber Restriction	• **Multiple Sclerosis:** Neurologist

Coverage Duration	• **Multiple Sclerosis:**
	  ○ Initial: 12 months
	  ○ Renewal: 12 months

Effective Date:	11/1/2025
P&T Approval Date:	1/10/2023
P&T Revision Date:	9/9/2025, 1/10/2023

References

- Betaseron [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; 2021
- Practice guideline: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Approved by the Guideline Development, Dissemination, and Implementation Subcommittee on October 9, 2017; by the Practice

Committee on October 21, 2017; and by the AAN Institute Board of Directors on March 6, 2018.

- The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. A consensus Paper by the Multiple Sclerosis Coalition. Updated June 2019.

Isotretinoin

Products Affected

- Amnesteem capsules
- Isotretinoin capsules
- Myorisan capsules
- Claravis capsules
- Zenetane capsules

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Severe nodulocystic acne
Required Medical Information and Criteria	**<u>Severe Nodulocystic Acne</u>** • Confirmed diagnosis of severe nodulocystic acne • Documentation of trial and failure, intolerance, or contraindication to combined therapy with an oral antibiotic and topical therapy (benzoyl peroxide or retinoid)
Renewal Criteria	• No Renewals
Age Restriction	• 12 years and older

Coverage Duration	• **Severe Nodulocystic Acne:**
	  ○ Initial: 20 weeks
	  ○ Renewal: No Renewals

Effective Date:	2/1/2023
P&T Approval Date:	1/10/2023
P&T Revision Date:	1/10/2023

Itraconazole

Products Affected

- Itraconazole Oral Solution

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Tinea Unguium

Required Medical Information and Criteria	**<u>Tinea Unguium</u>**
	• Documentation of one of the following:
	  ○ Patient is experiencing pain which limits normal activity (i.e, unable to wear shoes, difficulty walking, etc),
	  ○ Patient has diabetes,
	  ○ Patient has peripheral vascular disease,
	  ○ Patient is immunocompromised
	
	<u>All Other Diagnoses</u>
	• Diagnosis is supported by compendia and is an above the line condition

Renewal Criteria	• Documented positive clinical response to therapy

Coverage Duration	• **All Diagnoses:**
	  ○ Initial: 3 months
	  ○ Renewal: 3 months

Effective Date:	5/1/2024
P&T Approval Date:	3/12/2024
P&T Revision Date:	3/12/2024

References
•

Ivacaftor (Kalydeco)

Products Affected

- Kalydeco Tablets
- Kalydeco Packets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design. ○ Cystic Fibrosis
Required Medical Information and Criteria	**<u>Cystic Fibrosis</u>** • Confirmed diagnosis of cystic fibrosis with documentation showing at least one CFTR gene mutation that has shown to be responsive to Kalydeco • Not used in combination with other CFTR modulator treatments
Renewal Criteria	• Documented clinical response to therapy
Age Restriction	• 1 month of age and older
Prescriber Restriction	• **Cystic Fibrosis:** Pulmonologist

Coverage Duration	• **Cystic Fibrosis:**
	  ○ Initial: 3 months
	  ○ Renewal: 6 months

Effective Date:	05/01/2025
P&T Approval Date:	05/01/2021
P&T Revision Date:	09/01/2021, 03/11/2025

References
•

Ivermectin

Products Affected

- Ivermectin Tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical Information and Criteria	**All Diagnoses** • Clinical documentation of a diagnosis for which ivermectin is FDA approved or compendia supported
Renewal Criteria	• Documented reinfection
Coverage Duration	• **All Diagnoses:** o Initial: 6 months o Renewal: 6 months

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

References
•

Ixekizumab (Taltz)

Products Affected

- Taltz Auto-Injector
- Taltz Prefilled Syringe

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Ankylosing Spondylitis/Axial Spondyloarthritis
	  ○ Plaque Psoriasis
	  ○ Psoriatic Arthritis

Required Medical Information and Criteria	**<u>All diagnoses</u>**:
	• Initial testing for latent TB and treatment, if necessary, before starting treatment.
	• No current active infection at initiation of therapy.
	• Risks and benefits documented in cases of chronic or recurrent infection.
	• Will NOT be used in combination with another biologic or Otezla
	
	<u>Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA)</u>
	• Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by:
	  ○ Back pain and stiffness for more than 3 months AND
	  ○ Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive AND
	  ○ BASDAI score of >=4
	• One of the following:
	  ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
	  ○ Documented failure of conventional therapy with both of the following:
	  ▪ At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated AND
	  ▪ Physical therapy/exercise program
	• Trial and failure of infliximab and adalimumab or contraindication to both.
	
	<u>Plaque Psoriasis (PP):</u>

	• Documentation of severe plaque psoriasis, defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) = 11 or Children's Dermatology Life Quality Index (CDLQI) = 13 (or severe score on other validated tool) AND one or more of the following:
	  o At least 10% of body surface area involved
	  o Hand, foot, face, or mucous membrane involvement
	• One of the following:
	  o The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
	  o Documented trial and failure of all the following:
	  ▪ High-potency topical corticosteroids (augmented betamethasone, clobetasol, etc.)
	  ▪ At least one other topical agent (calcipotriene, tazarotene, anthralin, tar, etc.)
	  ▪ PUVA or UVB Phototherapy
	  ▪ Methotrexate
	  ▪ At least 1 other second line systemic agent such as cyclosporine or acitretin.
	• Trial and failure of infliximab, adalimumab, and ustekinumab or contraindication to all
	• Trial and failure of secukinumab (Cosentyx), apremilast (Otezla), Ilumya, Siliq, Sotyktu or contraindication to all
	• Trial and failure of, or contraindication to, Skyrizi
	
	<u>Psoriatic Arthritis (PsA):</u>
	• Documentation of psoriatic arthritis based on at least 3 out of 5 of the following:
	  o Psoriasis (1 point for personal or family history, 2 points for current)
	  o Psoriatic nail dystrophy
	  o Negative test result for RF
	  o Dactylitis (current of history)
	  o Radiological evidence of juxta-articular new bone formation
	• One of the following:
	  o The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
	  o Documented trial and failure of conventional therapy with both of the following:
	  ▪ NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND

	▪ Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine. • Trial and failure of infliximab, adalimumab, and ustekinumab or contraindication to all • Trial and failure of Cimzia, Cosentyx, Otezla, Orencia, Simponi, Xeljanz or contraindication to all
Renewal Criteria	• **Ankylosing Spondylitis/Axial Spondyloarthritis:** Evidence of significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI • **Plaque Psoriasis:** Evidence of positive clinical response to therapy as evidenced by ONE of the following: reduction of body surface area (BSA) involvement from baseline, improvement in symptoms (e.g. pruritus, inflammation) from baseline, or evidence of functional improvement. • **Psoriatic Arthritis:** Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
Prescriber Restriction	• **Ankylosing Spondylitis**, **Axial Spondyloarthritis:** Rheumatologist. • **Plaque Psoriasis:** Dermatologist. • **Psoriatic Arthritis:** Dermatologist or Rheumatologist.
Coverage Duration	• **All diagnoses:** o Initial: 6 months o Renewal: 12 months

Effective Date:	07/01/2026
P&T Approval Date:	07/11/2023
P&T Revision Date:	05/12/2026, 07/11/2023

References

- 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.
- Ramiro S, Nikiphorou E, Sepriano A, et al. EULAR recommendations for the management of axial spondyloarthritis: 2022 update. *Ann Rheum Dis.* 2023;82(1):19-34.

- 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(4):1029-1072.
- Gossec L, Baraliakos X, Kerschbaumer A, et al.EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2023 update. *Ann Rheum Dis.* 2024;83(6):706-719.

Lacosamide (Vimpat)

Products Affected

- Lacosamide Solution

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Focal Seizures
	  ○ Primary Generalized Tonic-Clonic Seizures

Required Medical Information and Criteria	**<u>Focal Seizures</u>** • Member under age 10 or unable to use tablets **<u>Primary Generalized Tonic-Clonic Seizures</u>** • Member under age 10 or unable to use tablets
Renewal Criteria	• Documentation of positive clinical response to therapy and continued inability to use tablets

Coverage Duration	• **All diagnoses:**
	  ○ Initial: 12 months
	  ○ Renewal: Lifetime

Effective Date:	01/01/2026
P&T Approval Date:	07/11/2023
P&T Revision Date:	11/11/2025, 03/11/2025, 03/12/2024

References

- Vimpat [package insert]. Smyrna, GA: UCB Inc.; 2023.

Lanthanum Carbonate

Products Affected

- Lanthanum Carbonate Chew Tabs

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Hyperphosphatemia in Chronic Kidney Disease

Required Medical Information and Criteria	**<u>Hyperphosphatemia in Chronic Kidney Disease</u>**
	• Confirmed diagnosis of hyperphosphatemia in chronic kidney disease
	• Trial and failure, contraindication, or intolerance (at least 6 weeks) to both of the following at maximally tolerated doses
	  ○ Calcium acetate
	  ○ Sevelamer carbonate

Age Restriction	• 6 years of age or older
Prescriber Restriction	• **Hyperphosphatemia in CKD:** Nephrologist
Coverage Duration	• **Hyperphosphatemia in CKD:** ○ Initial: Lifetime

Effective Date:	7/1/2023
P&T Approval Date:	5/9/2023
P&T Revision Date:	5/9/2023

References
•

Lasmiditan (Reyvow)

Products Affected

- Reyvow tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of acute migraine
Required Medical Information and Criteria	**<u>Acute Migraine</u>** • Confirmed diagnosis of migraine • Documentation showing the member is currently on preventative therapy • Trial and failure (defined as at least 6 weeks per agent) of: ○ At least 3 oral formulary triptans used at up to the maximally indicated dosing and in combination with NSAID therapy (e.g. naproxen).
Renewal Criteria	• Documented positive clinical response to therapy
Age Restriction	• 18 years of age or older
Prescriber Restriction	• **Acute Migraine:** Neurologist or headache specialist

Coverage Duration	• **Acute Migraine:**
	  ○ Initial: 3 months
	  ○ Renewal: 12 months

Effective Date:	9/1/2025
P&T Approval Date:	5/9/2023
P&T Revision Date:	7/8/2025, 5/9/2023

References
• Reyvow [package insert]. Indianapolis, IN: Eli Lilly and Co; 2022.

Lebrikizumab (Ebglyss)

Products Affected

- Ebglyss Prefilled Syringe
- Ebglyss Auto-Injector

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Atopic Dermatitis

Required Medical Information and Criteria	**<u>Atopic Dermatitis</u>**
	• Diagnosed with severe atopic dermatitis defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's Dermatology Life Quality Index (CDLQI) ≥ 13 (or severe score on another validated tool)
	• One or more of the following:
	  ○ At least 10% of body surface area involvement
	  ○ Hand, foot, or mucous membrane involvement
	• Documented contraindication or failed trial to ALL of the following:
	  ○ Moderate-high potency corticosteroid (e.g., clobetasol, fluocinonide, fluticasone)
	  ○ Topical calcineurin inhibitor (e.g. tacrolimus)
	  ○ Oral immunomodulator therapy (e.g. cyclosporine, methotrexate, azathioprine, mycophenolate mofetil) **OR** the member is oral corticosteroid dependent.

Renewal Criteria	• Documentation of positive clinical response to therapy
Prescriber Restriction	• **Atopic dermatitis**: Dermatologist

Coverage Duration	• **All Diagnoses:**
	  ○ Initial: 6 months
	  ○ Renewal: 12 months

Effective Date:	1/1/2025
P&T Approval Date:	11/12/2024
P&T Revision Date:	11/12/2024

References
•

Lenacapavir (Sunlenca)

Products Affected

- Sunlenca Therapy Pack
- Sunlenca Subcutaneous

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Multi-Drug-Resistant (MDR) HIV
Required Medical Information and Criteria	**<u>Multi-Drug-Resistant HIV</u>** • Diagnosis of MDR HIV-1 infection with resistance to at least two drugs in each of at least three of the following classes: NRTIs, NNRTIs, PIs, and INSTIs • Will be used in combination with an optimized baseline regimen (OBR) • Current ARV regimen has been stable for at least 2 months • HIV-1 RNA is ≥400 copies/mL
Renewal Criteria	• Continues to be used in combination with an optimized background regimen (OBR) • Provider states that patient continues to receive clinical benefit from the treatment
Prescriber Restriction	• **MDR HIV Infection:** HIV Specialist

Coverage Duration	• **MDR HIV Infection:**
	  ○ Initial: 6 months
	  ○ Renewal: 12 months

Effective Date:	4/1/2023
P&T Approval Date:	3/14/2023
P&T Revision Date:	3/14/2023

References

- U.S. Department of Health and Human Services (DHHS): ClinicalInfo.HIV.gov. Clinical Guidelines. https://clinicalinfo.hiv.gov/en/guidelines.

Lenacapavir (Yeztugo)

Products Affected

- Yeztugo Inj.
- Yeztugo Tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Pre-Exposure Prophylaxis to reduce the risk of HIV infection

Required Medical Information and Criteria	**<u>Pre-Exposure Prophylaxis (PrEP)</u>**
	• Confirmation the drug is being used for PrEP (a different product is used for treatment)
	• Submission of medical records documenting both of the following U.S. Food and Drug (FDA)-approved tests prior to use of Yeztugo:
	  ○ Negative HIV-1 antigen/antibody test
	  ○ Negative HIV-1 RNA assay
	• Trial and failure, contraindication, or intolerance to generic emtricitabine-tenofovir disoproxil fumarate 200/300mg.

Renewal Criteria	• Provider attests that patient is adherent to the testing appointments and scheduled injections of Yeztugo
	• Submission of medical records documenting both of the following U.S. Food and Drug (FDA)-approved tests prior to use of Yeztugo:
	  ○ Negative HIV-1 antigen/antibody test
	  ○ Negative HIV-1 RNA assay

Coverage Duration	• **Pre-Exposure Prophylaxis:**
	  ○ Initial: 12 months
	  ○ Renewal: 12 months

Effective Date:	11/1/2025
P&T Approval Date:	9/9/2025
P&T Revision Date:	9/9/2025

References
• Reference Yeztugo [package insert]. Foster City, CA: Gilead Sciences Inc.; 06/2025.

- Centers for Disease Control and Prevention. Expanding PrEP Coverage in the United States to Achieve EHE Goals. October 17, 2023.
- Centers for Disease Control and Prevention: US Public Health Service: Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 update: A Clinical Practice Guideline.
- IPD Analytics. HIV Pre-Exposure Prophylaxis: FDA approval of Yeztugo. Published July 2025.
- U.S. Department of Health and Human Services (DHHS): ClinicalInfo.HIV.gov. Clinical Guidelines. Accessed August 14, 2025. https://clinicalinfo.hiv.gov/en/guidelines.

Lidocaine Patch

Products Affected

- Lidocaine External Patch

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Post-Herpetic Neuralgia
Required Medical Information and Criteria	**<u>Post-Herpetic Neuralgia</u>** • Documentation confirming a diagnosis of post-herpetic neuralgia
Renewal Criteria	• Documented positive clinical response to therapy

Coverage Duration	• **Post-Herpetic Neuralgia:**
	  ○ Initial: 3 months
	  ○ Renewal: 3 months

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

References
•

Liraglutide

Products Affected

- Liraglutide Pen-Injector

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Type 2 Diabetes
	  ○ Secondary Prevention of Major Adverse Events (MACE)
	  ○ Obesity or Overweight (only applies to patients under age 21)
	  ○ Metabolic Dysfunction-Associated Steatohepatitis (MASH)

Required Medical Information and Criteria	**<u>Type 2 Diabetes</u>**
	• Documentation of clinically diagnosed Type 2 Diabetes
	• One of the following:
	  ○ Documentation of all of the following:
	  ▪ Adequate trial of maximally tolerated dose of metformin
	  ▪ Documentation of trial and failure of sulfonylurea, pioglitazone, or insulin or contraindication to all
	  ▪ Documentation of trial and failure of one of the following (or contraindication to both):
	  • An SGLT-2 inhibitor (e.g. dapagliflozin)
	  • A DPP-4 inhibitor (e.g. saxagliptin or sitagliptin)
	  ○ Both of the following:
	  ▪ Documented diagnosis of ASCVD (MI, stroke, arterial revascularization, TIA, unstable angina) or CKD
	  ▪ Trial and failure of an SGLT2 inhibitor (dapagliflozin)
	
	<u>Obesity or Overweight</u>
	• Patient is less than 21 years old or is eligible for EPSDT coverage through other means.
	• BMI at or above the 95th percentile or 27kg/m2.
	• Documentation of one of the following:
	  ○ Comorbidities (e.g., hypertension, dyslipidemia, fatty liver disease, depression, or sleep apnea).
	  ○ Trial and failure of at least 3 months of a diet/exercise plan administered by a health care provider in the last 6 months.
	• The patient is, or will be, engaged in a weight management lifestyle modification program in addition to pharmacotherapy.

	Secondary Prevention of Major Adverse Events • Liraglutide is being used to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight. • Liraglutide is being used as adjunct to lifestyle modification (e.g., dietary, or caloric restriction, exercise, behavioral support, community-based program). • Patient has established cardiovascular disease as evidenced by one of the following: o Prior myocardial infarction o Prior stroke o Peripheral arterial disease (e.g., intermittent claudication with ankle-brachial index <0.85, peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease) • BMI greater than or equal to 27 kg/m2 **Metabolic Dysfunction-Associated Steatohepatitis** • Clinical documentation of a diagnosis of MASH confirmed by one of the following: o FibroScan-aspartate aminotransferase (FAST) o MRI-aspartate aminotransferase (MAST) o Liver biopsy • Submission of medical records showing disease is fibrosis stage F2 or F3 as confirmed by one of the following: o FibroScan o Fibrosis-4 index (FIB-4) o Magnetic resonance Elastography (MRE) • Liraglutide is being used as adjunct to lifestyle modification (e.g., dietary, or caloric restriction, exercise, behavioral support, community-based program). • None of the following are present: o Cirrhosis o Viral hepatitis o Ongoing significant alcohol use (e.g. more than 21 drinks per week) • Presence of greater than or equal to 3 metabolic risk factors (e.g. obesity, hypertension, hypertriglyceridemia) • Member is currently treating 3 of the 5 metabolic risk factors (or treatment of at least 50% of the risk factors present) associated with MASH o Overweight or Obesity

	○ Hypertension ○ Type 2 diabetes ○ Hypertriglyceridemia ○ Decreased level of high-density lipoprotein (HDL)
Renewal Criteria	**Secondary Prevention of Major Adverse Events (MACE):** • Documentation of treatment success (BMI reduction of 5% or more). • Documentation of continuation of lifestyle modification program with reduced calorie diet and regular physical activity alongside continuous Liraglutide use (80% adherence). **Obesity or Overweight:** • Patient is less than 21 years old or is eligible for EPSDT coverage through other means. • Documentation of at least a 1% decrease in BMI from baseline. • Patient is continuing full weight loss plan (e.g., diet and exercise program, nutritional counseling). **Metabolic Dysfunction-Associated Steatohepatitis:** • Documentation of treatment success, e.g. lack of disease progression per fibrosis staging. **Type 2 Diabetes:** • Documented positive clinical response to therapy such as a decrease in A1c
Exclusion Criteria	• Coverage for weight loss is excluded for members aged 21 or older • Use in combination with any other GLP-1 or GIP medication
Coverage Duration	• **All Diagnoses:** ○ Initial: 12 months ○ Renewal: 12 months

Effective Date:	09/01/2026
P&T Approval Date:	09/12/2017
P&T Revision Date:	07/14/2026, 03/10/2026, 01/09/2024, 11/08/2022, 07/13/2021, 09/08/2020

References
• Liraglutide [package insert]. Parsippany, NJ: Teva Pharmaceuticals; 2026 • American Diabetes Association Professional Practice Committee. Standards of Care in Diabetes—2026. Diabetes Care. 2026;49(Suppl 1).

Lisdexamfetamine

Products Affected

- Lisdexamfetamine Capsules

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Attention Deficit Hyperactivity Disorder
	  ○ Binge Eating Disorder

Required Medical Information and Criteria	**<u>Attention Deficit Hyperactivity Disorder (ADHD)</u>**
	• Prior trial of at least 30 days of both of the following:
	  ○ An extended-release amphetamine product (amphetamine salts ER, dextroamphetamine ER, etc.)
	  ○ An extended-release methylphenidate product (dexmethylphenidate ER, methylphenidate ER, etc.)
	
	<u>Binge Eating Disorder (BED)</u>
	• Clinical documentation confirming a diagnosis of binge eating disorder per DSM-5 criteria
	• Trial and failure of 2 drugs from at least 2 of the following classes:
	  ○ Selective serotonin reuptake inhibitors (SSRI)
	  ○ Topiramate
	  ○ Methylphenidate

Renewal Criteria	• Documented positive clinical response to therapy
Age Restriction	• **Binge Eating Disorder:** 18 years of age or older

Coverage Duration	• **All diagnoses:**
	  ○ Initial: 12 months
	  ○ Renewal: 12 months

Effective Date:	3/1/2025
P&T Approval Date:	1/14/2025
P&T Revision Date:	1/14/2025

References

- www.columbiapsychiatry.org/news/effort-underway-develop-first-u-s-guidelines-adhd-adults
- www.cdc.gov/adhd/php/adults/index.html
- www.cdc.gov/adhd/diagnosis/index.html

Long-Acting Opiates

Products Affected

- Fentanyl Patch 12.5mcg, 25mcg, 50mcg, 75mcg, 100mcg
- Morphine Sulfate ER Tablets
- Oxycodone/Oxycontin ER
- Methadone

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Pain related to Cancer, Palliative Care, Severe Burns, Sickle Cell Disease
	  ○ Pain for conditions of the back and spine (guideline note 60)
	  ○ Pain for other funded conditions that meet criteria for medical appropriateness and medical necessity

Required Medical Information and Criteria	**<u>Pain Related to Cancer, severe burns, sickle cell disease, or Palliative Care</u>** • The member has pain associated with sickle cell disease, severe burn injury, cancer-related pain or under palliative care services with a life-threatening illness or severe advanced illness expected to progress towards dying. • Requests for fentanyl patches, methadone or Oxycontin ○ Trial and failure of, or contraindication to use of morphine sulfate ER tablets **<u>Pain Related to conditions of the Back and Spine (Guideline Note 60)</u>** • The request is for long-term opioid therapy more than 90 days after acute injury, acute flare or chronic pain, or surgery • Documented pain is severe enough to require around the clock analgesic therapy • Documentation includes a comprehensive individual treatment plan for chronic pain, taking into account the biological, behavioral, psychological and social factors which may influence each individual's experience of chronic pain as well as any current and past treatments. • Member's function has been improved with opioid therapy. • Opioids have been prescribed with a plan to keep active (home or prescribed exercise regimen) and additional therapies such as spinal manipulation, PT, yoga, or acupuncture when available.

	• Prescriber is enrolled in the Oregon Prescription Drug Monitoring Program (PDMP) and has verified that the opioid prescribing is appropriate
	• All the following risks have been assessed, and the prescriber has determined that the benefits outweigh the risks
	  o Risk of abuse
	  o Risk of respiratory adverse events
	  o Menta health/Depression screening
	  o PDMP report
	  o Urine drug screen, after acute phase of treatment
	• Documented trial and failure of scheduled short-acting opioid therapy
	• Requests for fentanyl patches, methadone or Oxycontin
	  o Trial and failure of, or contraindication to use of morphine sulfate ER tablets
	
	<u>Other Pain</u>
	• Medication is intended for use for the treatment of pain for a funded condition or there is an applicable comorbid condition
	• Documented use of current and/or recent usage of opioid therapy for at least 15 days (considered treatment experienced) and the member's function has been improved while on opioid therapy
	• Documented pain that is severe enough to require around the clock analgesic therapy
	• The prescriber is enrolled in the Oregon Prescription Drug Monitoring Program (PDMP) and has verified that opioid prescribing is appropriate
	• All of the following risks have been assessed, and the prescriber has determined that the benefits outweigh the risks:
	  o Risk of abuse
	  o Risk of respiratory adverse events
	  o Mental health/depression screening
	  o Urine drug screen
	• Appropriate non-pharmacologic and non-opioid therapies have been maximized for submitted condition (NSAID, muscle relaxants, anticonvulsant, DMARD, PT, etc.)
	• Total cumulative opioid daily dose does not exceed 90MED
	• Documented trial and failure of scheduled short-acting opioid therapy
	• Requests for fentanyl patches, methadone or Oxycontin
	  o Trial and failure of, or contraindication to morphine sulfate ER tablets

Renewal Criteria	**<u>Pain Related to Cancer, severe burns, sickle cell disease, or Palliative Care</u>**

	• Documented continued need for requested opioid therapy
	
	<u>Pain Related to conditions of the Back and Spine (Guideline Note 60)</u>
	• Opioids have been prescribed with a plan to keep active (home or prescribed exercise regimen) and additional therapies such as spinal manipulation, PT, yoga, or acupuncture, when available
	• Member's function has been improved while on opioid therapy
	• Member's risk has been assessed for ALL of the following
	  ○ Risk of abuse
	  ○ Risk of respiratory adverse events
	  ○ Mental Health/Depression screening
	  ○ Urine drug screen
	  ○ PDMP report
	• Total cumulative dose ≤90MED
	
	<u>Other Pain</u>
	• Documentation shows provider monitoring of PDMP
	• Documentation that the member's function has improved and there is continued need for requested therapy
	• Total cumulative dose ≤90MED
	• Continued use of both non-pharmacologic and non-opioid therapies

Exclusion Criteria	• Request for any condition for which chronic opioid use is not supported
	  ○ Migraine
	  ○ Fibromyalgia
	  ○ Central pain syndrome
	• For pain related to conditions of the back and spine: intended for use within first 90 days for the treatment of acute injury, acute flare of chronic pain, or surgery (per Guideline Note 60—short acting opioid therapy only is covered)
	• Conditional exclusion: used in combination with benzodiazepine or other CNS depressant

Coverage Duration	**<u>Pain Related to Cancer, severe burns, sickle cell disease, or Palliative Care</u>** • Initial: 12 months—No maximum MED • Renewal: 12 months—No maximum MED **<u>Pain Related to conditions of the Back and Spine (Guideline Note 60)</u>** • Initial: 12 months—Max MED 90mg unless exception

	• Renewal: 12 months—Max MED 90mg unless exception **<u>Other Pain</u>** • Initial: 12 months—Max MED 90mg unless exception • Renewal: 12 months—Max MED 90mg unless exception

Effective Date:	07/01/2026
P&T Approval Date:	05/12/2026
P&T Revision Date:	05/12/2026

References
• 2022 CDC Opioid Treatment Guidelines • Oregon Chronic Opioid Prescribing Guidelines • Guideline Note 60 of the Prioritized List • 2022 VA Opioid Treatment Guidelines

Lotilaner (Xdemvy)

Products Affected

- Xdemvy 0.25% Ophthalmic solution

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Demodex Blepharitis
Required Medical Information and Criteria	**<u>Demodex Blepharitis</u>** • Documentation of at least mild erythema of the upper eyelid margin • Presence of mites upon examination of eyelashes by light microscopy or presence of collarettes on slit lamp examination
Renewal Criteria	• N/A
Age Restriction	• 18 years of age and older
Prescriber Restriction	• **Demodex Blepharitis:** Optometrist or Ophthalmologist

Coverage Duration	• **Demodex Blepharitis:**
	  ○ Initial: 6 weeks
	  ○ Renewal: Renewals are not allowed

Effective Date:	5/1/2024
P&T Approval Date:	3/12/2024
P&T Revision Date:	3/12/2024

References
•

Lubiprostone

Products Affected

- Lubiprostone capsules

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Chronic idiopathic constipation in adults (in presence of above the line comorbid condition or if age under 21)
	  ○ Irritable bowel syndrome in females (assigned at birth) > 18 YO (in presence of above the line comorbid condition or if age under 21)
	  ○ Opioid induced constipation (in presence of above the line comorbid condition or if age under 21)

Required Medical Information and Criteria	**<u>Chronic Idiopathic Constipation (CIC)</u>**
	• Documentation of a funded comorbid condition that would be improved with the treatment of CIC
	• Documentation of failure to have benefit with recommended conventional first-line treatments (or contraindication to all first-line treatments):
	  ○ Dietary Modification: Increased dietary fiber (25 grams/day) and increased fluid consumption
	  ○ Bulk-forming Laxatives: Psyllium
	  ○ Osmotic Laxatives: Polyethylene glycol, lactulose, magnesium hydroxide, milk of magnesia
	  ○ Stool Softener: Docusate
	  ○ Stimulant Laxatives: Senna, bisacodyl.
	
	<u>Irritable Bowel Syndrome with Constipation (IBS-C) in females (assigned at birth)</u>
	• Documentation of a funded comorbid condition that would be improved with the treatment of IBS-C
	• Documentation of failure to have benefit with recommended conventional first-line treatments (or contraindication to all first-line treatments):
	  ○ Dietary Modification: Increased dietary fiber (25 grams/day) and increased fluid consumption
	  ○ Bulk-forming Laxatives: Psyllium
	  ○ Osmotic Laxatives: Polyethylene glycol, lactulose, magnesium hydroxide, milk of magnesia
	  ○ Stool Softener: Docusate

	○ Stimulant Laxatives: Senna, bisacodyl. **<u>Opioid Induced Constipation (OIC)</u>** • Documentation of a funded comorbid condition that would be improved with the treatment of OIC • Documentation of failure to have benefit with recommended conventional first-line treatments (or contraindication to all first-line treatments): ○ Dietary Modification: Increased dietary fiber (25 grams/day) and increased fluid consumption ○ Osmotic Laxatives: Polyethylene glycol, lactulose, magnesium hydroxide, milk of magnesia ○ Stool Softener: Docusate ○ Stimulant Laxatives: Senna, bisacodyl. • The patient is not using methadone.
Renewal Criteria	• Documentation of efficacy and continued need
Age Restriction	• 18 years of age and older
Prescriber Restriction	• **Chronic Idiopathic Constipation and Irritable Bowel Syndrome with Constipation:** Gastroenterologist, other provider after patient consultation with a dietician • **Opioid Induced Constipation:** Gastroenterologist, pain management specialist, other provider after patient consultation with a dietician
Coverage Duration	• **All diagnoses:** ○ Initial: 12 months ○ Renewal: 12 months

Effective Date:	9/1/2025
P&T Approval Date:	7/8/2025
P&T Revision Date:	7/8/2025

References

- Change L, et al. American Gastroenterological Association-American College of Gastroenterology Clinical Practice Guideline: Pharmacological Management of Chronic Idiopathic Constipation. *Gastroenterology* 2023;164:1086–1106.
- Davids JS, et al. Clinical Practice Guidelines. The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management of Anal Fissures. *Dis Colon Rectum* 2022; 66: 190–199.

- Paquette IM, et al. The American Society of Colon and Rectal Surgeons' Clinical Practice Guideline for the Evaluation and Management of Constipation. *Dis Colon Rectum* 2016; 59: 479–492.
- Tabbers MM, et al. Evaluation and Treatment of Functional Constipation in Infants and Children: Evidence-Based Recommendations from ESPGHAN and NASPGHAN. JPGN 2014;58: 258–274.
- Wald A, et al. ACG Clinical Guidelines: Management of Benign Anorectal Disorders. *Am J Gastroenterol* 2021;116:1987–2008.

Lumacaftor-Ivacaftor (Orkambi)

Products Affected

- Orkambi Granules
- Orkambi Tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design. ○ Cystic Fibrosis
Required Medical Information and Criteria	**<u>Cystic Fibrosis</u>** • Documentation of cystic fibrosis diagnosis with homozygous F508del mutation • Not used in combination with other CFTR modulator treatments
Renewal Criteria	• Documented clinical response to therapy
Age Restriction	• 1 years of age and older
Prescriber Restriction	• **Cystic Fibrosis:** Pulmonologist

Coverage Duration	• **Cystic Fibrosis:**
	  ○ Initial: 6 months
	  ○ Renewal: 12 months

Effective Date:	5/1/2025
P&T Approval Date:	5/1/2021
P&T Revision Date:	9/1/2021, 3/11/2025

References
•

Mefloquine

Products Affected

- Mefloquine Tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of Malaria
Required Medical Information and Criteria	**<u>Malarial Treatment</u>** • Confirmed diagnosis of malaria
Renewal Criteria	• N/A

Coverage Duration	• **Malaria:**
	  ○ Initial: 1 months
	  ○ Renewal: N/A

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

References
•

Mesalamine Step Therapy

Products Affected

- Mesalamine DR tablet 1.2 gm

Step Therapy Criteria	• Trial and failure of ○ Mesalamine 0.375gm caps

Effective Date:	11/1/2025
P&T Approval Date:	9/9/2025
P&T Revision Date:	9/9/2025

Mirabegron (Myrbetriq)

Products Affected

- Mirabegron ER tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Overactive Bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency
	  ○ Neurogenic detrusor overactivity in pediatric members

Required Medical Information and Criteria	**<u>Overactive Bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency</u>**
	• Documented trial and failure of at least 3 of the following, or contraindication to all:
	  ○ Oxybutynin IR or ER
	  ○ Fesoterodine
	  ○ Solifenacin
	  ○ Tolterodine IR or ER
	  ○ Trospium IR or ER (requires step therapy through oxybutynin)
	
	<u>Neurogenic Detrusor Overactivity in pediatric members</u>
	• Is there documented trial and failure, intolerance, or contraindication to both of the following:
	  ○ Oxybutynin IR or ER
	  ○ Solifenacin

Renewal Criteria	• Documentation of positive clinical response to therapy
Age Restriction	• 3 years of age and older

Coverage Duration	• **All Diagnoses:**
	  ○ Initial: 12 months
	  ○ Renewal: 12 months

Effective Date:	7/1/2025
P&T Approval Date:	5/13/2025
P&T Revision Date:	5/13/2025

References

- Cameron AP, Chung DE, Dielubanza EJ, et al. The AUA/SUFU guideline on the diagnosis and treatment of idiopathic overactive bladder. J Urol. Published online April 23, 2024.
- Myrbetriq [package insert]. Northbrook, IL: Astellas.; 2021.

Mitapivat (Pyrukynd)

Products Affected

- Pyrukind Tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Hemolytic Anemia
Required Medical Information and Criteria	**<u>Hemolytic Anemia</u>** • Diagnosis of pyruvate kinase deficiency with at least two mutations within the PKLR gene, including a missense mutation • Confirmation of current hemoglobin ≤ 10mg/dL • Patient is not homozygous for the R479H mutation • Patient does not have two non-missense variants in the PKLR gene, without the presence of another missense variant • Patient has had at least 6 RBC transfusions within the previous year for hemolytic anemia due to PKD • Prescriber confirmed concomitant use of daily folic acid • Confirmation that the patient does not have moderate or severe hepatic dysfunction.
Renewal Criteria	• Clinical documentation showing an increase in Hb at least 1.5 mg/dL over baseline and/or a reduction in frequency of transfusions.
Age Restriction	• 18 years of age or older
Prescriber Restriction	• **Hemolytic Anemia:** Hematologist

Coverage Duration	• **Hemolytic Anemia:**
	  ○ Initial: 3 months
	  ○ Renewal: 6 months

Effective Date:	8/01/2022
P&T Approval Date:	7/12/2022
P&T Revision Date:	7/12/2022

References
•

Mometasone Nasal Spray

Products Affected

- Mometasone Furoate Nasal Spray

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Nasal Congestion or Rhinitis

Required Medical Information and Criteria	**<u>Nasal Congestion or Rhinitis</u>**
	• Diagnosis of asthma or an above the line comorbid condition that may worsen if not treated
	• Inadequate treatment response, intolerance, or contraindication to all the following
	  ○ Fluticasone nasal spray
	  ○ Budesonide nasal spray
	  ○ Triamcinolone nasal spray

Renewal Criteria	• Documented positive clinical response to therapy

Coverage Duration	• **All Diagnoses:**
	  ○ Initial: 12 months
	  ○ Renewal: 12 months

Effective Date:	12/1/2022
P&T Approval Date:	11/8/2022
P&T Revision Date:	11/8/2022

References
•

Naltrexone (Vivitrol)

Products Affected

- Vivitrol Injection

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical Information and Criteria	**<u>All Diagnoses</u>** ○ The drug will be dispensed directly to the provider and not the member.
Coverage Duration	• **All Diagnoses:** ○ Initial: 12 months ○ Renewal: 12 months

Effective Date:	5/1/2024
P&T Approval Date:	3/12/2024
P&T Revision Date:	7/12/2022

References
•

Nasal Steroids

Products Affected

- Budesonide 32 mcg/act nasal spray
- Triamcinolone 55 mcg/act nasal spray

Step Therapy Criteria	• Trial and failure of ○ Fluticasone 50 mcg/act nasal spray

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

Nemolizumab (Nemluvio)

Products Affected

- Nemluvio Auto-Injector

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Atopic Dermatitis
	  ○ Prurigo Nodularis

Required Medical Information and Criteria	**<u>Atopic Dermatitis</u>**
	• Diagnosed with severe atopic dermatitis defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's Dermatology Life Quality Index (CDLQI) ≥ 13 (or severe score on another validated tool)
	• One or more of the following:
	  ○ At least 10% of body surface area involvement
	  ○ Hand, foot, or mucous membrane involvement
	• Documented contraindication or failed trial to ALL of the following:
	  ○ Moderate-high potency corticosteroid (e.g., clobetasol, fluocinonide, fluticasone)
	  ○ Topical calcineurin inhibitor (e.g. tacrolimus)
	  ○ Oral immunomodulator therapy (e.g. cyclosporine, methotrexate, azathioprine, mycophenolate mofetil) **OR** the member is oral corticosteroid dependent.
	
	<u>Prurigo Nodularis</u>
	• Funded condition (as defined by guideline note 21 of the prioritized list) or age under 21.
	• Diagnosis of PN verified by a dermatologist and the patient has had the diagnosis for at least 3 months.
	• Severe or very severe itch (WI-NRS score ≥7) reported within the past week.
	• At least 20 PN lesions in total on both legs and/or both arms and/or trunk
	• Trial and failure (inadequate efficacy after 4-week trial, intolerable side effects) or contraindication to recommended first line agents for the treatment of PN including:
	  ○ High potency topical steroids
	  ○ Phototherapy

	○ At least one systemic agent (immunosuppressant, gabapentinoid, or antidepressant). • Trial and failure of dupilumab (Dupixent)
Renewal Criteria	**<u>Atopic Dermatitis</u>** • Documentation of positive clinical response to therapy • Dosing has been decreased to 30mg every 8 weeks as recommended by FDA label **<u>Prurigo Nodularis</u>** • Documentation of positive clinical response to therapy
Age Restriction	• **Atopic Dermatitis:** 12 years and older • **Prurigo Nodularis:** 18 years and older
Prescriber Restriction	• **Atopic dermatitis**: Dermatologist • **Prurigo Nodularis**: Dermatologist
Coverage Duration	• **All Diagnoses:** ○ Initial: 6 months ○ Renewal: 12 months

Effective Date:	7/1/2026
P&T Approval Date:	5/12/2026
P&T Revision Date:	5/12/2026

References

- Nemluvio [package insert]. Dallas, TX: Galderma Laboratories, L.P.; 2025.

Nitroglycerin ointment

Products Affected

- Nitroglycerin 0.4% ointment

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Anal Fissure
Required Medical Information and Criteria	**<u>Anal Fissure</u>** • Diagnosis of moderate to severe pain associated with chronic anal fissure.
Renewal Criteria	• N/A
Prescriber Restriction	• None

Coverage Duration	• **Anal Fissure:**
	  ○ Initial: 2 months
	  ○ Renewal: N/A

Effective Date:	9/1/2025
P&T Approval Date:	7/8/2025
P&T Revision Date:	7/8/2025

References

- Davids JS, et al. Clinical Practice Guidelines. The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management of Anal Fissures. *Dis Colon Rectum* 2022; 66: 190–199.
- Wald A, et al. ACG Clinical Guidelines: Management of Benign Anorectal Disorders. *Am J Gastroenterol* 2021;116:1987–2008.

Non-Formulary Criteria

Products Affected

- All Non-Formulary Medications

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design

Required Medical Information and Criteria	**<u>All FDA Approved Conditions</u>**
	• One of the following:
	  ○ The requested medication is being used to treat an above the line diagnosis on the OHA Prioritized list
	  ○ The member has an above the line comorbid condition that will be treated indirectly by the requested medication
	  ○ The member under the age of 21
	• One of the following:
	  ○ The requested medication is being used for an FDA-approved indication:
	  ○ The requested medication is being used for an off-label indication with well-established, clinical evidence supporting its use.
	• All appropriate formulary alternatives have been tried and failed or are contraindicated.
	<u>Non-Formulary alternative dosage form (e.g. a request for NF oral solution when tablets are on formulary)</u>
	• One of the following:
	  ○ Member is age 10 or younger
	  ○ Member has clinically documented inability to swallow tablets/capsules
	• One of the following:
	  ○ The formulary equivalent tablet/capsule does not require PA
	  ○ The formulary equivalent tablet/capsule requires PA and the PA criteria has been met

Renewal Criteria	• Clinical documentation of follow-up indicating safety, efficacy and medication adherence over previous approval duration. • There are not any newly added formulary alternatives, or newly added formulary alternatives have been tried and failed or are contraindicated.

Age Restriction	• FDA labeled limits
Prescriber Restriction	• **All Diagnoses:** Appropriate Specialist will vary by drug and condition
Coverage Duration	• **All Diagnoses:** o Initial: 6 months or shorter if appropriate for the drug/condition o Renewal: 12 months or shorter if appropriate for the drug/condition

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

References
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Omalizumab (Xolair)

Products Affected

- Xolair Prefilled Syringe
- Xolair Auto-Injector

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Moderate to Severe Asthma
	  ○ Chronic Rhinosinusitis with Nasal Polyps
	  ○ Chronic Idiopathic Urticaria - Refractory
	  ○ IgE-Mediated Food Allergy

Required Medical Information and Criteria	**<u>Severe Asthma</u>**
	• Confirmed diagnosis of moderate to severe persistent asthma.
	• Positive skin test or RAST to a perennial aeroallergen.
	• Baseline IgE serum level within FDA label.
	• Documentation of steps taken to avoid, within reason, environmental allergens and other triggers environmental allergens and other triggers.
	• Documented trial and failure, with claims history of adherence to**:**
	  ○ High dose inhaled corticosteroid with a long-acting beta agonist (e.g., Advair),
	  ○ Long acting anti-muscarinic (e.g., Spiriva)**,**
	  ○ Leukotriene Inhibitor (e.g., Singulair).
	• Documented trial and failure of, or contraindication to allergen immunotherapy.
	
	Chronic Rhinosinusitis with Nasal Polyps (CRSwNP):
	• Confirmed diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP).
	• Documentation of recurrent nasal polyps after prior sinus surgery.
	• Documented risk of another sinus surgery, or a statement why sinus surgery is not medically appropriate.
	• Documented trial and failure, with claims history of adherence to**:**
	  ○ At least 2 intranasal corticosteroids (e.g., fluticasone, mometasone),
	  ○ Sinuva.
	• Documentation that Xolair is intended as adjunct therapy with nasal corticosteroids.

	<u>Chronic Idiopathic Urticaria - refractory (CIU)</u> • Documentation of chronic spontaneous or idiopathic urticaria**.** • Age under 21, or a comorbid condition which would make chronic urticaria coverable under the prioritized list. • Documented trial and failure of at least 6 weeks of maximally tolerated doses of all the following: o 1st generation antihistamine – (e.g., doxepin, hydroxyzine) o 2nd generation antihistamine – (e.g., cetirizine, levocetirizine, fexofenadine, loratadine, desloratadine) o Histamine Type-2 Receptor Antagonists (e.g., famotidine, cimetidine) o Leukotriene inhibitor (e.g., montelukast, zafirlukast) **<u>IgE-Mediated Food Allergy</u>** • Diagnosis of IgE Mediated Food Allergy as evidenced by one of the following: o Positive skin prick test (defined as greater than or equal to 4 mm wheal greater than saline control) to food, o Positive food specific IgE (greater than or equal to 6 kUA/L), o Positive oral food challenge, defined as experiencing dose-limiting symptoms at a single dose of less than or equal to 300 mg of food protein. • Clinical history of IgE mediated food allergy. • Used in conjunction with food allergen avoidance. • Both of the following: o Baseline (pre-Xolair treatment) serum total IgE level is greater than or equal to 30 IU/mL and less than or equal to 1850 IU/mL, o Dosing is according to serum total IgE levels and body weight. • Xolair will not be used concomitantly with Palforzia. • Attestation that the member is co-prescribed epinephrine or has epinephrine at home.
Renewal Criteria	**IgE Mediated Food Allergy:** • Patient demonstrates positive clinical response to therapy (e.g., reduction of type 1 allergic reactions, including anaphylaxis, following accidental exposure to one or more foods). • Used in conjunction with food allergen avoidance. • Dosing will continue to be based on body weight and pretreatment IgE serum levels. **All Other Diagnoses:**

	• Documentation of clinically significant improvement in symptoms.
Exclusion Criteria	• Specific criteria we want reviewed. This should be blank in many cases. Do not include things like "allergy to the drug you are asking for"; this is obvious and doesn't need to be part of the criteria.
Age Restriction	• **Asthma**: 6 years of age and older • **CIU:** 12 years of age and older • **CRSwNP:** 18 years of age and older • **IgE Mediated Food Allergy:** 1 year of age and older
Prescriber Restriction	• **Asthma:** Prescribed by or in consultation with a pulmonologist or immunologist. • **CIU:** Prescribed by or in consultation with an immunologist. • **CRSwNP**: Prescribed by or in consultation with an allergist or ENT. • **IgE Mediated Food Allergy:** Prescribed by or in consultation with an allergist or immunologist.
Coverage Duration	• **Asthma:** o Initial: 6 months o Renewal: 12 months • **CRSwNP:** o Initial: 6 months o Renewal: 12 months • **CIU:** o Initial: 4 months o Renewal: 6 months • **IgE Mediated Food Allergy:** o Initial: 6 months o Renewal: 12 months

Effective Date:	9/1/2024
P&T Approval Date:	7/9/2024
P&T Revision Date:	7/9/2024

References
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General Oncology (Chemotherapy)

Products Affected

- Abemaciclib (Verzenio)
- Abiraterone
- Acalabrutinib (Calquence)
- Adagrasib (Krazati)
- Alectinib (Alecensa)
- Alpelisib (Piqray)
- Ascinimib (Scemblix)
- Asparaginase Erwinia (Rylaze)
- Avutometinib/Defactinib (Avmapki/Fazynja Pak)
- Belzutifan (Welireg)
- Binimetinib (Mektovi)
- Bosutinib (Bosulif)
- Brigatinib (Alunbrig)
- Busulfan (Myleran)
- Cabozantinib (Cabometyx)
- Capivasertib (Truqap)
- Capmatinib (Tabrecta)
- Ceritinib (Zykadia)
- Chlorambucil (Leukeran)
- Crizotinib (Xalkori)
- Dabrafenib (Tafinlar)
- Dasatinib
- Darolutamide (Nubeqa)
- Dordaviprone (Modeyso)
- Elacestrant (Orserdu)
- Encorafenib (Braftovi)
- Entrectinib (Rozlytrek)
- Erlotinib
- Estramustine (Emcyt)
- Everolimus
- Fruquintinib (Fruzaqla)
- Futibatinib (Lytgobi)
- Gefitinib
- Ibrutinib (Imbruvica)
- Imlunestrant (Inluriyo)
- Mobocertinib (Exkivity)
- Nilotinib (Tasigna)
- Niraparib/Abiraterone (Akeega)
- Nirogacestat (Ogsiveo)
- Olaparib (Lynparza)
- Olutasidenib (Rezlidhia)
- Osimertinib (Tagrisso)
- Pacritinib (Vonjo)
- Palbociclib (Ibrance)
- Pazopanib
- Pemigatinib (Pemazyre)
- Pexidartinib (Turalio)
- Pirtobrutinib (Jaypirca)
- Ponatinib (Iclusig)
- Procarbazine (Matulane)
- Quizartinib (Vanflyta)
- Relacorilant (Lifyorli)
- Repotrectinib (Augtyro)
- Ribociclib (Kisqali)
- Sargramostim (Leukine)
- Selpercatinib (Retevmo)
- Sevabertinib (Hyrnuo)
- Sorafenib
- Sotorasib (Lumakras)
- Sunitinib
- Sunvozertinib (Zegfrovy)
- Talazoparib (Talzenna)
- Taletrectinib (Ibtrozi)
- Temozolomide
- Tepotinib (Tepmetko)
- Thioguanine (Tabloid)
- Tivozanib (Fotivda)
- Topotecan (Hycamtin)
- Tovorafenib (Ojemda)
- Trametinib (Mekinist)

- Inavolisib (Itovebi)
- Infigratinib (Truseltiq)
- Ivosidenib (Tibsovo)
- Lazertinib (Lazcluze)
- Lenvatinib (Lenvima)
- Lomustine (Gleostine)
- Lorlatinib (Lobrena)
- Midostaurin (Rydapt)
- Mitotane (Lysodren)
- Trifluridine/Tipiracil (Lonsurf)
- Tucatinib (Tukysa)
- Vepdegestrant (Veppanu)
- Vimseltinib (Romvimza)
- Vorasidinib (Voranigo)
- Vorinostat (Zolinza)
- Zanubrutinib (Brukinsa)
- Ziftomenib (Komzifti)
- Zongertinib (Hernexeos)

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design

Required Medical Information and Criteria	**All Diagnoses**
	• One of the following is true:
	  ○ The requested drug is being used for an FDA approved indication.
	  ○ The requested medication is being used according to National Comprehensive Cancer Network (NCCN) guidelines.

Renewal Criteria	Submission of clinical documentation supporting provider follow-up that indicates safety and efficacy of the medication and adherence to treatment.
Age Restriction	• Refer to FDA indication and NCCN guidelines
Prescriber Restriction	• **All Diagnoses:** Oncologist or hematologist

Coverage Duration	• **All Diagnoses:**
	  ○ Initial: 3 months
	  ○ Renewal: up to 6 months

Effective Date:	09/01/2026
P&T Approval Date:	10/01/2022
P&T Revision Date:	07/14/2026, 05/12/2026, 01/13/2026, 11/11/2025, 09/09/2025, 07/08/2025, 05/13/2025, 03/11/2025, 05/14/2024, 03/01/2024, 01/09/2024, 11/1/2023, 09/01/2023, 07/11/2023, 05/09/2023, 03/14/2023, 01/10/2023, 10/01/2022

Oral Antifungal Agents

Products Affected

- Griseofulvin Ultramicrosize Tabs
- Ketoconazole Tabs
- Griseofulvin Microsize Susp

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical Information and Criteria	**<u>All Diagnoses</u>** • The medication is being used for an FDA-approved indication OR being used for an off-label indication with well-established, clinical evidence supporting its use, including the dose being requested • For suspension only: ○ Is there a reason that a tablet form can't be used
Renewal Criteria	• Documentation of positive clinical response to therapy • Evidence of continued need for the medication

Coverage Duration	• **All diagnoses:**
	  ○ Initial: 3 months
	  ○ Renewal (non-immunocompromised): 3 months
	  ○ Renewal (immunocompromised): 6 months

Effective Date:	1/1/2025
P&T Approval Date:	11/12/2024
P&T Revision Date:	11/12/2024

References

- Ketoconazole tablets [package insert]. Toronto, Ontario: Apotex Inc.; 2021.
- Griseofulvin [package insert]. Bridgewater, GA: Valent LLC.; 2016.

Oral Nutrition Supplements

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design

Required Medical Information and Criteria	**<u>All Diagnoses</u>**
	• Documentation showing the prescribed oral nutritional formula and/or nutritional supplements are an integral part of treatment/medically necessary for a nutritional deficiency.
	• Documentation including assessment by treating practitioner or registered dietitian that member is unable to meet their recommended caloric/protein or micronutrient needs through regular, liquified, blenderized, or pureed foods in any modified texture or form.
	OR
	• For age under 21
	  ○ Documented delayed growth or failure to thrive.
	  ○ Documentation showing the prescribed formula/nutritional supplement is for the prevention of nutritional deficiency or malnutrition.

Renewal Criteria	• Documentation of continued positive response for the requested enteral nutrition/formula with a continued need for requested supplement.
Exclusion Criteria	• Supplement is to be administered via enteral tube feeding (e.g. G-tube, NG-tube). • For tube feedings please submit via a DME vendor through the DME benefit

Coverage Duration	• **All Diagnoses:**
	  ○ Initial: 6 months
	  ○ Renewal: 12 months

Effective Date:	1/1/2025
P&T Approval Date:	11/12/2024
P&T Revision Date:	11/12/2024

References

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Pancrelipase (Creon, Pancreaze)

Products Affected

- Creon Capsules
- Pancreaze Capsules

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Exocrine Pancreatic Insufficiency

Required Medical Information and Criteria	**<u>Exocrine Pancreatic Insufficiency</u>**
	• Clinical documentation of one of the following:
	  ○ Confirmed diagnosis of cystic fibrosis
	  ○ History of pancreatectomy
	  ○ Diagnosis of exocrine pancreatic cancer
	  ○ Diagnosis of chronic pancreatitis confirmed by imaging
	  ○ Confirmed diagnosis of pancreatic insufficiency confirmed with one of the following methods:
	  ▪ Steatorrhea with fecal fat determination
	  ▪ Measurement of fecal elastase
	  ▪ Secretin or CCK pancreatic function testing
	  ▪ Two of the following CFTR mutations (G542X, W1282X, R553X, 621+1G>T, 1717–1G>A, 3120+1G>A , R1162X, 3659delC, 1898+1G>A, 2184delA, 711+1G>T, F508del, I507del, G551D, N1303K, R560T)

Renewal Criteria	• Documented positive clinical response to therapy

Coverage Duration	• **Exocrine Pancreatic Insufficiency:**
	  ○ Initial: 12 months
	  ○ Renewal: 12 months

Effective Date:	2/1/2022
P&T Approval Date:	1/11/2022
P&T Revision Date:	1/11/2022

References
•

Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors

Products Affected

- Repatha SureClick
- Repatha Prefilled Syringe
- Repatha Pushtronex
- Praluent Auto-Injector
- Lerochol Prefilled Syringe

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Established clinical ASCVD (Secondary Prevention)
	  ○ ASCVD Primary Prevention
	  ○ Primary or Familial Hyperlipidemia

Required Medical Information and Criteria	**<u>Established Clinical ASCVD (Secondary Prevention)</u>**
	• Documentation of very high risk ASCVD as evidenced by either:
	  ○ History of multiple major ASCVD events
	  ○ One major ASCVD event AND multiple high-risk conditions.
	• Documentation of a current LDL greater than or equal to 55 mg/dl.
	• Documentation of all the following:
	  ○ Patient is receiving maximally tolerated statin therapy (atorvastatin 40-80mg, rosuvastatin 20-40mg) or has a documented clinical intolerance to statins
	  ○ Is receiving ezetimibe or has a documented intolerance to ezetimibe.
	
	<u>ASCVD Primary Prevention</u>
	• Documentation of no prior ischemic events (myocardial infarction, ischemic stroke, or unstable angina requiring revascularization)
	  ○ *For patient with a history of ischemic events use the Established ASCVD criteria
	• Documentation of high or very high risk by one of the following:
	  ○ Current ASCVD
	  ○ High Risk Diabetes
	• Documentation of a current LDL greater than or equal to 90 mg/dl.
	• Documentation of all the following:
	  ○ Patient is receiving maximally tolerated statin therapy (atorvastatin 40-80mg, rosuvastatin 20-40mg) or has a documented clinical intolerance to statins
	  ○ Is receiving ezetimibe or has a documented intolerance to

	ezetimibe.
	
	<u>Primary or Familial Hyperlipidemia</u>
	• Documentation of an untreated (i.e., prior to lipid lowering therapy) LDL greater than 190 mg/dL.
	• Documentation of current LDL greater than 100 mg/dL.
	• Documentation of all the following:
	  ○ Patient is receiving maximally tolerated statin therapy (atorvastatin 40-80mg, rosuvastatin 20-40mg) or has a documented clinical intolerance to statins
	  ○ Is receiving ezetimibe or has a documented intolerance to ezetimibe.

Renewal Criteria	• Documented positive clinical response to therapy (significant decrease in lipid levels).
Prescriber Restriction	• **All Diagnoses:** Cardiologist, Endocrinologist, or Lipid Specialist

Coverage Duration	• **All Diagnoses:**
	  ○ Initial: 6 months
	  ○ Renewal: 12 months

Effective Date:	07/01/2026
P&T Approval Date:	01/11/2022
P&T Revision Date:	05/12/2026, 01/15/2026, 9/10/2024, 1/11/2022

References

- Lerochol [package insert]. Cincinnati, OH: LIB Therapeutics Inc. 2025.
- Praluent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals Inc. 2022.
- Repatha [package insert]. Thousand Oaks, CA: Amgen Inc. 2025.

Peanut Powder (Palforzia)

Products Affected

- Palforzia Capsule and Powder

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Peanut Allergy
Required Medical Information and Criteria	**<u>Peanut Allergy</u>** • Confirmed positive skin test or peanut-specific serum IgE greater than 0.35 kUA/L • Concurrent prescription with injectable epinephrine • Medical justification supports necessity for oral immunotherapy despite peanut avoidance.
Renewal Criteria	• Currently receiving medication by way of previously approved SHP authorization or documents showing **Initial** approval criteria was or has been met. • For patients who required use of injectable epinephrine while on Palforzia, must have medical justification that supports continued need for Palforzia. • If 18 years or older, must have medical justification that supports continued need for oral immunotherapy despite peanut avoidance and documentation that **Initial** dose escalation happened between age 4 and 17.
Age Restriction	• Patient must be between 4 and 17 at therapy initiation
Prescriber Restriction	• **Peanut Allergy:** Allergist or Immunologist enrolled in Palforzia REMS program

Coverage Duration	• **Peanut Allergy:**
	  ○ Initial: 12 months
	  ○ Renewal: 12 months

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

References
•

Phosphodiesterase Type 5 (PDE5) inhibitors

Products Affected

- Sildenafil 20mg tablet
- Tadalafil 20mg tablet

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Pulmonary Arterial Hypertension
Required Medical Information and Criteria	**<u>Pulmonary Arterial Hypertension</u>** • Clinically documented diagnosis of Pulmonary Arterial Hypertension (WHO group 1 pulmonary hypertension)
Renewal Criteria	• Documented positive clinical response to therapy
Exclusion Criteria	• Treatment of erectile dysfunction
Age Restriction	• Tadalafil: 18 years of age and over
Prescriber Restriction	• **Pulmonary Arterial Hypertension:** Cardiologist or Pulmonologist

Coverage Duration	• **Pulmonary Arterial Hypertension:**
	  ○ Initial: 6 months
	  ○ Renewal: 12 months

Effective Date:	9/1/2025
P&T Approval Date:	7/13/2021
P&T Revision Date:	7/8/2025, 7/13/2021

References

- Adcirca (tadalafil). Prescribing information. Eli Lilly and Co. Indianapolis, IN 2020.
- Revatio (sildenafil). Prescribing information. Viatris Specialty LLC. Morgantown, WV 2024

Phytonadione (Vitamin K) Step Therapy

Products Affected

- Phytonadione 5mg tab

Step Therapy Criteria	• Concurrent use of warfarin

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

Pitolisant (Wakix)

Products Affected

- Wakix Tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Cataplexy and Narcolepsy
	  ○ Excessive Somnolence - Narcolepsy

Required Medical Information and Criteria	**<u>Cataplexy and Narcolepsy</u>**
	• Confirmation of diagnosis of narcolepsy based on both:
	  ○ Polysomnography
	  ○ A multiple sleep latency test
	• Documentation that CYP2D6 testing has been done, and the dosing will be adjusted if the patient is a poor metabolizer.
	• Diagnosis of Cataplexy confirmed by a specialist.
	• Trial and failure or contraindication to ALL the following:
	  ○ SSRI antidepressant (e.g. fluoxetine)
	  ○ SNRI antidepressant (e.g. venlafaxine and duloxetine)
	  ○ Tricyclic antidepressant (e.g. clomipramine)
	  ○ Sodium oxybate product titrated to maximally tolerated dose.
	
	<u>Excessive Somnolence - Narcolepsy</u>
	• Confirmation of diagnosis of narcolepsy based on both:
	  ○ Polysomnography
	  ○ A multiple sleep latency test
	• Documentation that CYP2D6 testing has been done, and the dosing will be adjusted if the patient is a poor metabolizer.
	• Documentation of fatigue severity using a validated measure (e.g. Epworth score, Brief Fatigue Inventory, or other validated measure
	• Trial and failure or contraindication to ALL the following:
	  ○ Modafinil (at least 200mg dose) AND armodafinil
	  ○ Mixed amphetamine salts, methylphenidate or dexmethylphenidate, AND dextroamphetamine
	  ○ Sunosi (solriamfetol)
	  ○ A sodium oxybate product

Renewal Criteria	• Documentation of positive clinical response to therapy
Exclusion Criteria	• Severe renal or hepatic impairment

	• Pregnant or actively trying to conceive
Prescriber Restriction	• **All Diagnoses:** Sleep Specialist or Neurologist
Coverage Duration	• **All Diagnoses:** o Initial: 3 months o Renewal: 6 months

Effective Date:	3/1/2025
P&T Approval Date:	1/14/2025
P&T Revision Date:	1/14/2025

References
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Plozasiran (Redemplo)

Products Affected

- Redemplo PFS

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Familial chylomicronemia syndrome (FCS)

Required Medical Information and Criteria	**<u>Familial Chylomicronemia Syndrome (FCS)</u>**
	• Diagnosis of FCS confirmed by one of the following:
	  ○ Genetic diagnosis of FCS (mutations in LPL (post-resin)), apoCII, glycosylphosphatidylinositol (GPIHBP1), apolipoprotein A-V (ApoA5) or Lipase Maturation Factor 1 (LMF1)
	  ○ All of the following:
	  ▪ Documented history of fasting TG level >10mmol/L or 880mg/dL refractory to standard triglyceride therapies (observed on 3 separate labs)
	  ▪ Other causes of elevated TG have been ruled out (e.g. EtOH excess, poor diet, medications and medical conditions known to raise TG [oral estrogen, exogenous glucocorticoids, SGA, isotretinoin, antiretrovirals/PI, bile-acid binding resins, HIV, Cushing syndrome, uncontrolled T2DM, nephrotic syndrome, renal insufficiency])
	  ▪ One of the following:
	  • Absent or low Lipoprotein Lipase activity (<20% of normal value), history of acute pancreatitis not caused by alcohol or cholelithiasis, recurrent hospitalizations for severe abdominal pain without another identified cause, childhood pancreatitis, or a family history of hypertriglyceridemia-induced pancreatitis
	  • History of acute pancreatitis (in the absence of gallstones and alcoholism)
	  • History of recurrent abdominal pain without other known cause
	• Trial and failure of the following therapies for lowering triglycerides with adherence at maximally tolerated dosing:
	  ○ Very low-fat diet
	  ○ Fibrates
	  ○ Niacin

	○ Prescription Omega-3 ○ High intensity statins • Medication will be used with concomitant lifestyle modifications, including low-fat diet of ≤20g of fat per day and avoidance of alcohol
Renewal Criteria	• Continued adherence to low-fat diet and medications for triglyceride management • Documentation of positive clinical response to therapy
Age Restriction	• Age ≥18 years old
Prescriber Restriction	• Endocrinologist, lipid specialist, cardiologist, gastroenterologist, pancreatologist
Coverage Duration	• **Familial Chylomicronemia Syndrome (FCS):** ○ Initial: 6 months ○ Renewal: 12 months:

Effective Date:	03/01/2026
P&T Approval Date:	01/13/2026
P&T Revision Date:	01/13/2026

References

- Watts, G.F., et al. Plozasiran for Managing Persistent Chylomicronemia and Pancreatitis Risk. N Eng J Med 2025;392:127-37.

Potassium Binders

Products Affected

- Lokelma Powder
- Veltassa Packet

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Hyperkalemia

Required Medical Information and Criteria	**<u>Hyperkalemia</u>**
	• Being used for the treatment of hyperkalemia based on current potassium labs
	• Failed all the following:
	  ○ Dietary changes (potassium restriction)
	  ○ Dose modification/discontinuation of ACE-inhibitor, ARB, or other hyperkalemia causing agents
	  ○ Diuretics titrated to maximum tolerated dose
	• If the request is for Veltassa:
	  ○ Trial and failure or contraindication to Lokelma

Renewal Criteria	Documented positive clinical response to therapy by either of the following: • Potassium level returning to normal on therapy • Significant drop in potassium level from baseline on therapy

Coverage Duration	• **Hyperkalemia:**
	  ○ Initial: 6 months
	  ○ Renewal: 12 months

Effective Date:	7/1/2024
P&T Approval Date:	5/14/2024
P&T Revision Date:	9/13/2022

References
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Pretomanid

Products Affected

- Pretomanid tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Pulmonary tuberculosis
Required Medical Information and Criteria	**<u>Pulmonary tuberculosis</u>** • Evidence of extensively drug-resistant active pulmonary tuberculosis (XDR-TB) caused by mycobacterium tuberculosis. ○ XDR-TB is defined as TB that is resistant to rifampicin and isoniazid, at least one fluoroquinolone (levofloxacin or moxifloxacin) and a second-line injectable (amikacin, capreomycin, and kanamycin) OR Isoniazid, rifampin a fluoroquinolone AND bedaquiline or linezolid. • Pretomanid is prescribed as part of a guideline recommended multi-drug treatment regimen.
Renewal Criteria	• N/A
Exclusion Criteria	• Use outside of recognized treatment guidelines. • Medication is being received through a county clinic with a state funded TB program.
Age Restriction	• Age of 14 or greater.
Prescriber Restriction	• Infectious Disease
Coverage Duration	• **Pulmonary tuberculosis:** 24 weeks

Effective Date:	5/1/2025
P&T Approval Date:	3/11/2025
P&T Revision Date:	3/11/2025

References

- Pretomanid [package insert]. Morgantown, WV: Mylan Specialty L.P.; 2024.

Prostacyclin Agonists

Products Affected

- Orenitram tablets
- Treprostinil
- Remodulin
- Tyvaso

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Pulmonary Arterial Hypertension

Required Medical Information and Criteria	**<u>Pulmonary Arterial Hypertension</u>**
	• Clinically documented diagnosis of Pulmonary Arterial Hypertension (WHO group 1 pulmonary hypertension)
	• Clinical documentation of WHO functional class III or IV
	• Evidence of an unfavorable response or intolerance to all of the following:
	  ○ Phosphodiesterase Type 5 inhibitor (sildenafil, tadalafil)
	  ○ Endothelin Receptor Antagonist (ambrisentan, bosentan)
	  ○ Combination therapy with a Phosphodiesterase Type 5 inhibitor + Endothelin Receptor Antagonist (ambrisentan + tadalafil)
	• The requested medication will be an add on to an already established first line agent or agents (sildenafil, tadalafil, ambrisentan, bosentan)

Renewal Criteria	• Documentation of positive clinical response to therapy
Age Restriction	• Age 16 or older
Prescriber Restriction	• **Pulmonary Arterial Hypertension:** Cardiologist or Pulmonologist

Coverage Duration	• **Pulmonary Arterial Hypertension:**
	  ○ Initial: 6 months
	  ○ Renewal: 12 months

Effective Date:	9/1/2025
P&T Approval Date:	7/13/2021
P&T Revision Date:	7/8/2025, 7/13/2021

References

- Orenitram [package insert]. Research Triangle Park, NC: United Therapeutics Corp; 2023.

- Remodulin [package insert]. Research Triangle Park, NC: United Therapeutics Corp; 2023.
- Tyvaso [package insert]. Research Triangle Park, NC: United Therapeutics Corp; 2022.

Quantity Limit Exception Criteria

Products Affected

- All Drugs with Quantity Limits

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design

Required Medical Information and Criteria	**<u>All FDA Approved Conditions</u>**
	• One of the following:
	  ○ The requested medication is being used to treat an above the line diagnosis on the OHA Prioritized list
	  ○ The member has an above the line comorbid condition that will be treated indirectly by the requested medication
	  ○ The member under the age of 21
	• One of the following:
	  ○ The requested medication is being used for an FDA-approved indication:
	  ○ The requested medication is being used for an off-label indication with well-established, clinical evidence supporting its use.
	• Documentation of failure of the requested medication within quantity limits, including failure of different strengths of the requested medication.
	• All appropriate formulary alternatives have been tried and failed or are contraindicated.

Renewal Criteria	• Documented positive clinical response to therapy
Exclusion Criteria	• Specific criteria we want reviewed. This should be blank in many cases. Do not include things like “allergy to the drug you are asking for”; this is obvious and doesn’t need to be part of the criteria.
Age Restriction	• FDA labeled limits
Prescriber Restriction	• **All Diagnoses:** Appropriate Specialist will vary by drug and condition

Coverage Duration	• **All Diagnoses:**
	  ○ Initial: 6 months or shorter if appropriate for the drug/condition
	  ○ Renewal: 12 months or shorter if appropriate for the drug/condition

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

References
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Resmetirom (Rezdiffra)

Products Affected

- Rezdiffra Tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Metabolic Dysfunction-Associated Steatohepatitis

Required Medical Information and Criteria	**<u>Metabolic Dysfunction-Associated Steatohepatitis</u>**
	• Clinical documentation confirming a diagnosis of metabolic dysfunction-associated steatohepatitis (MASH), formulary known as nonalcoholic steatohepatitis (NASH)
	• Patient does not have cirrhosis (e.g. decompensated cirrhosis)
	• Submission of medical records (e.g. chart notes) showing diagnosis has been confirmed by one of the following:
	  ○ FibroScan-aspartate aminotransferase (FAST)
	  ○ MRI-aspartate aminotransferase (MAST)
	  ○ Liver biopsy
	• Submission of medical records (e.g. chart notes) showing disease is fibrosis stage F2 or F3 as confirmed by one of the following:
	  ○ FibroScan
	  ○ Fibrosis-4 index (FIB-4)
	  ○ Magnetic resonance Elastography (MRE)
	• Presence of greater than or equal to 3 metabolic risk factors (e.g., Type 2 diabetes, hypertension, obesity)
	• Submission of medical records (e.g. chart notes) confirming drug is used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program

Renewal Criteria	• Patient demonstrates positive response to therapy (e.g., MASH resolution, fibrosis stage improvement, etc.) • Submission of medical records (e.g., chart notes) confirming drug will continue to be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program)
Age Restriction	• !8 years of age or older
Prescriber Restriction	• **Metabolic Dysfunction-Associated Steatohepatitis:** Gastroenterologist, Hepatologist

Coverage Duration	• **Metabolic Dysfunction-Associated Steatohepatitis:** ○ Initial: 6 months ○ Renewal: 12 months

Effective Date:	7/1/2024
P&T Approval Date:	5/14/2024
P&T Revision Date:	5/14/2024

References
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Rifapentine (Priftin)

Products Affected

- Priftin tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Latent tuberculosis
	  ○ Active tuberculosis

Required Medical Information and Criteria	**<u>Latent tuberculosis</u>** • Used in combination with isoniazid (INH). **<u>Active tuberculosis</u>** • Used as part of a multi-drug regimen.
Renewal Criteria	• N/A
Exclusion Criteria	• Medication is being received through a county clinic with a state funded TB program.
Age Restriction	• Age ≥ 2 years old with latent TB • Age ≥ 12 years old with active TB
Prescriber Restriction	• **Latent TB:** Not limited by specialty • **Active TB:** Infectious disease specialist required for multidrug resistant cases only
Coverage Duration	• **Latent TB:** 3 months • **Active TB:** 6 months

Effective Date:	5/1/2025
P&T Approval Date:	3/12/2024
P&T Revision Date:	3/11/2025, 3/12/2024

References

- Priftin [package insert]. Bridgewater, NJ: Sanofi-Aventis.; 2021.

Risankizumab (Skyrizi)

Products Affected

- Skyrizi IV Solution
- Skyrizi Cartridge
- Skyrizi Prefilled Syringe
- Skyrizi Pen

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Crohn's Disease
	  ○ Plaque Psoriasis
	  ○ Psoriatic Arthritis
	  ○ Ulcerative Colitis

Required Medical Information and Criteria	**<u>All diagnoses</u>**
	• Initial testing for latent TB and treatment, if necessary, before starting treatment.
	• No current active infection at initiation of therapy.
	• Risks and benefits documented in cases of chronic or recurrent infection.
	• Will NOT be used in combination with another biologic or Otezla.
	
	<u>Crohn's Disease (CD)</u>
	• Documentation of moderate-to-severe Crohn's Disease
	• Trial and failure of infliximab, adalimumab, and ustekinumab (dosed every 4 weeks) or contraindication to all
	• Trial and failure of vedolizumab (Entyvio) and Rinvoq (upadacitinib) or contraindication to both
	
	<u>Plaque Psoriasis (PP):</u>
	• Documentation of severe plaque psoriasis, defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) = 11 or Children's Dermatology Life Quality Index (CDLQI) = 13 (or severe score on other validated tool) AND one or more of the following:
	  ○ At least 10% of body surface area involved
	  ○ Hand, foot, face, or mucous membrane involvement
	• One of the following:

	○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR ○ Documented trial and failure of all the following: ▪ High-potency topical corticosteroids (augmented betamethasone, clobetasol, etc.) ▪ At least one other topical agent (calcipotriene, tazarotene, anthralin, tar, etc.) ▪ PUVA or UVB Phototherapy ▪ Methotrexate ▪ At least 1 other second line systemic agent such as cyclosporine or acitretin. • Trial and failure of infliximab, adalimumab, and ustekinumab or contraindication to all • Trial and failure of secukinumab (Cosentyx), apremilast (Otezla), tildrakizumab (Ilumya), brodalumab (Siliq), deucravacitinib (Sotyktu) or contraindication to all **<u>Psoriatic Arthritis (PsA):</u>** • Documentation of psoriatic arthritis based on at least 3 out of 5 of the following: ○ Psoriasis (1 point for personal or family history, 2 points for current) ○ Psoriatic nail dystrophy ○ Negative test result for RF ○ Dactylitis (current of history) ○ Radiological evidence of juxta-articular new bone formation • One of the following: ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR ○ Documented trial and failure of conventional therapy with both of the following: ▪ NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND ▪ Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine. • Trial and failure of infliximab, adalimumab, and ustekinumab or contraindication to all • Trial and failure of certolizumab (Cimzia), secukinumab (Cosentyx), apremilast (Otezla), abatacept (Orencia), golimumab (Simponi), tofacitinib (Xeljanz), upadacitinib (Rinvoq), ixekizumab (Taltz), and Bimekizumab (Bimzelx) or contraindication to all

	<u>Ulcerative Colitis (UC):</u>
	• Documentation of moderate-to-severe ulcerative colitis
	• One of the following:
	  ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
	  ○ Documented trial and failure of at least 1 of the following: mesalamine, sulfasalazine, mercaptopurine, azathioprine, or corticosteroids (prednisone, methylprednisolone).
	• Trial and failure of infliximab, adalimumab, and ustekinumab (dosed every 4 weeks) or contraindication to all
	• Trial and failure of vedolizumab (Entyvio), golimumab (Simponi), tofacitinib (Xeljanz), etrasimod (Velsipity) or contraindication to all

Renewal Criteria	• **Crohn's Disease:** Evidence of a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission. • **Plaque Psoriasis:** Evidence of positive clinical response to therapy as evidenced by ONE of the following: reduction of body surface area (BSA) involvement from baseline, improvement in symptoms (e.g. pruritus, inflammation) from baseline, or evidence of functional improvement. • **Psoriatic Arthritis:** Evidence of a 20% or greater improvement in tender joint count and swollen joint count. • **Ulcerative Colitis:** Evidence of a significant response such as a decrease in bloody stools per day or elimination of signs of toxicity.
Prescriber Restriction	• **Crohn's Disease and Ulcerative Colitis:** Gastroenterologist. • **Plaque Psoriasis:** Dermatologist. • **Psoriatic Arthritis:** Dermatologist or Rheumatologist.

Coverage Duration	• **All diagnoses:**
	  ○ Initial: 6 months
	  ○ Renewal: 12 months

Effective Date:	07/01/2026
P&T Approval Date:	05/12/2026
P&T Revision Date:	05/12/2026

References

- Lichtenstein GR, Loftus EV Jr, Afzali A, et al. ACG clinical guideline: Management of Crohn's disease in adults. *Am J Gastroenterol.* 2025;120(6):1225-1264.
- 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(4):1029-1072.
- Rubin DT, Ananthakrishnan AN, Siegel CA, Barnes EL, Long MD. ACG clinical guideline update: Ulcerative colitis in adults. *Am J Gastroenterol.* 2025;120(6):1187-1224.
- Singh S, Loftus EV Jr, Limketkai BN, et al. AGA living clinical practice guideline on pharmacological management of moderate-to-severe ulcerative colitis. *Gastroenterology.* 2024;167(7):1307-1343.
- Gossec L, Baraliakos X, Kerschbaumer A, et al.EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2023 update. *Ann Rheum Dis.* 2024;83(6):706-719.

Risdiplam (Evrysdi)

Products Affected

- Evrysdi Solution

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Spinal Muscular Atrophy
Required Medical Information and Criteria	**<u>Spinal Muscular Atrophy</u>** • Confirmed (via genetic testing) diagnosis of 5q-autosomal recessive SMA (type 1, 2 or 3) • Patient is not dependent on invasive ventilation or tracheostomy or use of non-invasive ventilation beyond uses for sleeping • Patient is not receiving concomitant chronic SMN modifying therapy such as Spinraza • Patient has not previously received gene replacement therapy for the treatment of SMA (e.g. Zolgensma)
Renewal Criteria	• Documentation of clinical improvement from baseline in motor functionality confirmed by standard exams (e.g. BSID-III, CHOP INTEND, HINE-2, RULM test)
Prescriber Restriction	• **Spinal Muscular Atrophy:** Neurologist with expertise in the treatment of spinal muscular atrophy

Coverage Duration	• **Spinal Muscular Atrophy:**
	  ○ Initial: 12 months
	  ○ Renewal: 12 months

Effective Date:	9/1/2023
P&T Approval Date:	7/11/2023
P&T Revision Date:	7/11/2023

References
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Roflumilast

Products Affected

- Roflumilast Tablet

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Chronic Obstructive Pulmonary Disorder (COPD)
Required Medical Information and Criteria	**<u>Chronic Obstructive Pulmonary Disorder (COPD)</u>** • Diagnosis of moderate to severe COPD and chronic bronchitis • Trial and failure of at least 2 previous treatments for COPD
Renewal Criteria	• Documentation of positive clinical response to roflumilast therapy.

Coverage Duration	• **COPD:**
	  ○ Initial: 12 months
	  ○ Renewal:12 months

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

References
•

Sacubitril/Valsartan (Entresto)

Products Affected

- Entresto tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Heart Failure

Required Medical Information and Criteria	**<u>Heart Failure</u>**
	• Diagnosis of New York Heart Association class II to IV heart failure
	• The patient meets one of the following:
	  ○ Receiving concomitant therapy with one of the following beta blockers: carvedilol, bisoprolol, sustained release metoprolol OR
	  ○ Beta-blockers are contraindicated or the member has been unable to tolerate them
	• The patient will discontinue use of any ACE inhibitor or ARB before initiating therapy with Entresto.

Renewal Criteria	• Documented positive response to therapy.
Prescriber Restriction	• Cardiologist, or in consultation with a cardiologist
Coverage Duration	• **Heart Failure:** ○ Initial: Lifetime

Effective Date:	9/1/2025
P&T Approval Date:	4/25/2016
P&T Revision Date:	7/8/2025

References

- Entresto [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; 2024.

Secukinumab (Cosentyx)

Products Affected

- Cosentyx Pen 300mg Dose
- Cosentyx IV Solution (Specialty Fusion Drug)
- Cosentyx Prefilled Syringe 300mg Dose

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Ankylosing Spondylitis/Axial Spondyloarthritis
	  ○ Hidradenitis Suppurativa
	  ○ Juvenile Idiopathic Arthritis
	  ○ Plaque Psoriasis
	  ○ Psoriatic Arthritis

Required Medical Information and Criteria	**<u>All diagnoses</u>**
	• Initial testing for latent TB and treatment, if necessary, before starting treatment.
	• No current active infection at initiation of therapy.
	• Risks and benefits documented in cases of chronic or recurrent infection.
	• Will NOT be used in combination with another biologic or Otezla.
	
	<u>Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA)</u>
	• Loading dose will not be approved.
	• Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by:
	  ○ Back pain and stiffness for more than 3 months AND
	  ○ Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive AND
	  ○ BASDAI score of >=4
	• One of the following:
	  ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
	  ○ Documented failure of conventional therapy with both of the following:
	  ▪ At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated AND
	  ▪ Physical therapy/exercise program

	• Trial and failure of infliximab and adalimumab or contraindication to both
	
	<u>Hidradenitis Suppurativa (HS)</u>
	• Documentation of a diagnosis of moderate to severe hidradenitis suppurativa (Hurley Stage II or Hurley Stage III)
	• One of the following:
	  ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
	  ○ Documented failure of conventional therapy (e.g. oral antibiotics).
	• Trial and failure of infliximab, adalimumab, and ustekinumab or contraindication to all.
	
	<u>Juvenile Idiopathic Arthritis (JIA)</u>
	• Documentation of juvenile idiopathic arthritis with active systemic features of JIA, with a physician global assessment of 5 or higher (or any systemic activity in the absence of active joint involvement) or JIA without active systemic features
	• One of the following:
	  ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
	  ○ Documented trial and failure of the following:
	  ▪ NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND
	  ▪ At least 6 months of 2 of Methotrexate, leflunomide, sulfasalazine, hydroxychloroquine, or systemic corticosteroids
	• Documented intolerance or contraindication to DMARDs OR DMARD will be continued with Cosentyx
	• Trial and failure of infliximab and adalimumab or contraindication to both
	
	<u>Plaque Psoriasis (PP):</u>
	• Documentation of severe plaque psoriasis, defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) = 11 or Children's Dermatology Life Quality Index (CDLQI) = 13 (or severe score on other validated tool) AND one or more of the following:
	  ○ At least 10% of body surface area involved
	  ○ Hand, foot, face, or mucous membrane involvement
	• One of the following:
	  ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR

	○ Documented trial and failure of all the following: ▪ High-potency topical corticosteroids (augmented betamethasone, clobetasol, etc.) ▪ At least one other topical agent (calcipotriene, tazarotene, anthralin, tar, etc.) ▪ PUVA or UVB Phototherapy ▪ Methotrexate ▪ At least 1 other second line systemic agent such as cyclosporine or acitretin. • Trial and failure of infliximab, adalimumab, and ustekinumab or contraindication to all **<u>Psoriatic Arthritis (PsA):</u>** • Loading dose will not be approved. • Documentation of psoriatic arthritis based on at least 3 out of 5 of the following: ○ Psoriasis (1 point for personal or family history, 2 points for current) ○ Psoriatic nail dystrophy ○ Negative test result for RF ○ Dactylitis (current of history) ○ Radiological evidence of juxta-articular new bone formation • One of the following: ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR ○ Documented trial and failure of conventional therapy with both of the following: ▪ NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND ▪ Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine. • Trial and failure of infliximab, adalimumab, and ustekinumab or contraindication to all
Renewal Criteria	• **Ankylosing Spondylitis**, **Axial Spondyloarthritis:** Evidence of significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI. • **Juvenile Idiopathic Arthritis:** Evidence of 20% or greater improvement in tender joint count and swollen joint count or has there been an improvement in functional ability.

	• **Hidradenitis Suppurativa:** Evidence of a reduction of 25% or more of the total abscess and inflammatory nodule count and no increase in abscesses and draining fistulas. • **Plaque Psoriasis:** Evidence of positive clinical response to therapy as evidenced by ONE of the following: reduction of body surface area (BSA) involvement from baseline, improvement in symptoms (e.g. pruritus, inflammation) from baseline, or evidence of functional improvement. • **Psoriatic Arthritis:** Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
Prescriber Restriction	• **Ankylosing Spondylitis, Axial Spondyloarthritis**: Rheumatologist. • **Hidradenitis Suppurativa, Plaque Psoriasis:** Dermatologist. • **Juvenile Idiopathic Arthritis**: Rheumatologist. • **Psoriatic Arthritis:** Dermatologist or Rheumatologist.
Coverage Duration	• **All Diagnoses:** o Initial: 6 months o Renewal: 12 months

Effective Date:	07/01/2026
P&T Approval Date:	01/11/2022
P&T Revision Date:	05/12/2026, 05/14/2024, 9/1/2023, 07/11/2023, 01/11/2022

References

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- Ramiro S, Nikiphorou E, Sepriano A, et al. EULAR recommendations for the management of axial spondyloarthritis: 2022 update. *Ann Rheum Dis.* 2023;82(1):19-34.
- Alikhan A, Sayed C, Alavi A, et al. Practical guidelines for managing patients with hidradenitis suppurativa: An update. *J Am Acad Dermatol.* 2022;86(4):861-891.
- 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(4):1029-1072.

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- Ringold S, Angeles-Han ST, Beukelman T, 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 Care Res (Hoboken).* 2022;74(4):521-537.

Seladelpar (Livdelzi)

Products Affected

- Livdelzi Capsules

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Primary Biliary Cholangitis

Required Medical Information and Criteria	**<u>Primary Biliary Cholangitis</u>**
	• Diagnosis of primary biliary cholangitis (PBC) confirmed by two of the following:
	  ○ Biochemical evidence of cholestasis based on ALP elevation
	  ○ Presence of AMA or other PBC-specific autoantibodies
	  ○ Histology confirmation after biopsy
	• Documentation of at least 12 months of inadequate response to ursodiol
	• No current decompensated cirrhosis

Renewal Criteria	• Documented adherence to medication regimen and clinical benefit
Age Restriction	• Age 18 or older
Prescriber Restriction	• **Primary Biliary Cholangitis:** Hepatologist or Gastroenterologist

Coverage Duration	• **Primary Biliary Cholangitis:**
	  ○ Initial: 6 months
	  ○ Renewal: 12 months

Effective Date:	1/1/2025
P&T Approval Date:	11/12/2024
P&T Revision Date:	11/12/2024

References
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Semaglutide (Wegovy)

Products Affected

- Wegovy Injection

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Secondary Prevention of Major Adverse Events (MACE)
	  ○ Obesity or Overweight (only applies to patients under age 21)
	  ○ Metabolic Dysfunction-Associated Steatohepatitis (MASH)

Required Medical Information and Criteria	**<u>Secondary Prevention of Major Adverse Events</u>**
	• Wegovy is being used to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight.
	• Wegovy is being used as adjunct to lifestyle modification (e.g., dietary, or caloric restriction, exercise, behavioral support, community-based program).
	• Patient has established cardiovascular disease as evidenced by one of the following:
	  ○ Prior myocardial infarction
	  ○ Prior stroke
	  ○ Peripheral arterial disease (e.g., intermittent claudication with ankle-brachial index <0.85, peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease)
	• BMI greater than or equal to 27 kg/m2
	
	<u>Obesity or Overweight</u>
	• Patient is less than 21 years old or is eligible for EPSDT coverage through other means.
	• BMI at or above the 95th percentile or 27kg/m2.
	• Documentation of one of the following:
	  ○ Comorbidities (e.g., hypertension, dyslipidemia, fatty liver disease, depression, or sleep apnea).
	  ○ Trial and failure of at least 3 months of a diet/exercise plan administered by a health care provider in the last 6 months.
	• The patient is, or will be, engaged in a weight management lifestyle modification program in addition to pharmacotherapy.
	• Trial and failure of liraglutide

	<u>Metabolic Dysfunction-Associated Steatohepatitis</u>
	• Clinical documentation of a diagnosis of MASH confirmed by one of the following:
	  ○ FibroScan-aspartate aminotransferase (FAST)
	  ○ MRI-aspartate aminotransferase (MAST)
	  ○ Liver biopsy
	• Submission of medical records showing disease is fibrosis stage F2 or F3 as confirmed by one of the following:
	  ○ FibroScan
	  ○ Fibrosis-4 index (FIB-4)
	  ○ Magnetic resonance Elastography (MRE)
	• Wegovy is being used as adjunct to lifestyle modification (e.g., dietary, or caloric restriction, exercise, behavioral support, community-based program).
	• None of the following are present:
	  ○ Cirrhosis
	  ○ Viral hepatitis
	  ○ Ongoing significant alcohol use (e.g. more than 21 drinks per week)
	• Presence of greater than or equal to 3 metabolic risk factors (e.g. obesity, hypertension, hypertriglyceridemia)
	• Member is currently treating 3 of the 5 metabolic risk factors (or treatment of at least 50% of the risk factors present) associated with MASH
	  ○ Overweight or Obesity
	  ○ Hypertension
	  ○ Type 2 diabetes
	  ○ Hypertriglyceridemia
	  ○ Decreased level of high-density lipoprotein (HDL)

Renewal Criteria	**Secondary Prevention of Major Adverse Events (MACE):** • Documentation of treatment success (BMI reduction of 5% or more). • Documentation of continuation of lifestyle modification program with reduced calorie diet and regular physical activity alongside continuous Wegovy use (80% adherence). **Obesity or Overweight:** • Patient is less than 21 years old or is eligible for EPSDT coverage through other means. • Documentation of at least a 1% decrease in BMI from baseline.

	• Patient is continuing full weight loss plan (e.g., diet and exercise program, nutritional counseling). **Metabolic Dysfunction-Associated Steatohepatitis:** • Documentation of treatment success, e.g. lack of disease progression per fibrosis staging.
Exclusion Criteria	• Coverage for weight loss is excluded for members aged 21 or older • Use in combination with any other GLP-1 or GIP medication
Age Restriction	• **Secondary Prevention of Major Adverse Events (MACE):** 12 years or older • **Obesity or overweight:** Age 12 to under 21 years of age • **Metabolic Dysfunction-Associated Steatohepatitis:** Age 18 or older
Prescriber Restriction	• **Secondary Prevention of Major Adverse Events (MACE):** Cardiologist • **Metabolic Dysfunction-Associated Steatohepatitis:** Hepatologist, Endocrinologist or Gastroenterologist
Coverage Duration	• **Secondary Prevention of Major Adverse Events (MACE):** o Initial: 6 months o Renewal: 12 months • **Obesity or Overweight:** o Initial: 6 months o Renewal: 12 months or until age 21, whichever is less • **Metabolic Dysfunction-Associated Steatohepatitis:** o Initial: 6 months o Renewal: 12 months

Effective Date:	5/1/2026
P&T Approval Date:	7/9/2024
P&T Revision Date:	3/10/2026,11/11/2025, 7/9/2024, 5/13/2024

References
• Wegovy [package insert]. Plainsboro, NJ: Novo Nordisk INC.; 2025.

Sirolimus Solution

Products Affected

- Sirolimus Oral Solution

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Age Restriction	• Patient is under age 10 or unable to use tablets
Coverage Duration	• **All Diagnoses:** o Initial: 12 months o Renewal: 12 months

Effective Date:	5/1/2024
P&T Approval Date:	3/12/2024
P&T Revision Date:	3/12/2024

References
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Sodium Oxybate

Products Affected

- Sodium oxybate 500mg/mL

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Cataplexy and narcolepsy
	  ○ Excessive somnolence due to narcolepsy

Required Medical Information and Criteria	**<u>Cataplexy and Narcolepsy</u>**
	• Confirmation of diagnosis of narcolepsy based on polysomnography AND a multiple sleep latency test with cataplexy
	• Trial and failure or contraindication to ALL the following
	  ○ SSRI antidepressant (e.g. fluoxetine)
	  ○ SNRI antidepressant (e.g. venlafaxine or duloxetine)
	  ○ Tricyclic antidepressant (e.g. clomipramine)
	
	<u>Excessive Somnolence due to Narcolepsy</u>
	• Confirmation of diagnosis of narcolepsy based on BOTH:
	  ○ Polysomnography
	  ○ A multiple sleep latency test
	• Baseline documentation of fatigue severity using a validated measure (e.g. Epworth score, Brief Fatigue Inventory, or other validated tool).
	• Trial and failure or contraindication to ALL the following:
	  ○ Modafinil (maximum recommended/tolerated dose)
	  ○ At least 2 stimulant medications (amphetamine, methylphenidate, dextroamphetamine, etc.)
	  ○ Sunosi (maximum recommended/tolerated dose)

Renewal Criteria	• Request for a continued maintenance dose within FDA approved limits based on indication. • Documented clinical efficacy and tolerability to therapy compared to baseline (for Epworth Sleepiness scale—improvement of at least 3 points is considered clinically significant).
Exclusion Criteria	• Currently pregnant or plan to conceive during treatment.
Age Restriction	• Age ≥7 years old and weight ≥20kg
Prescriber Restriction	• **All diagnoses:** Sleep specialist, Neurologist, Pulmonologist

Coverage Duration	• **All diagnoses:** o Initial: 3 months o Renewal: 12 months

Effective Date:	11/1/2025
P&T Approval Date:	9/9/2025
P&T Revision Date:	9/9/2025

References

- Xyrem [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; 2025
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- Mehra R, et al. Current Management of Residual Excessive Daytime Sleepiness Due to Obstructive Sleep Apnea: Insights for Optimizing Patient Outcomes. Neurol Ther (2021) 10:661-672.
- Servid and Shirley. Drug Class Review with New Drug Evaluation: Narcolepsy Agents. Drug Use Research & Management Program. July 2029.
- Epstein LJ, et al. Clinical Guideline for the Evaluation, Management, and Long-term Care of Obstructive Sleep Apnea in Adults. Journal of Clinical Sleep Medicine, Vol.5, No. 3, 2009.

Sodium-Glucose Co-Transporter 2 (SGLT-2) Inhibitors

Products Affected

- Dapagliflozin Tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Type 2 Diabetes
	  ○ Chronic Kidney Disease
	  ○ Heart Failure

Required Medical Information and Criteria	**<u>Type 2 Diabetes</u>**
	• One of the following:
	  ○ Both of:
	  ▪ Trial and failure of, or contraindication to metformin.
	  ▪ Trial and failure of sulfonylurea or pioglitazone, or contraindication to both.
	  ○ Established ASCVD (MI, stroke, arterial revascularization, TIA, unstable angina)
	
	<u>Chronic Kidney Disease</u>
	• Concurrent therapy with an ACEi or ARB at maximum tolerated doses, or documented contraindication to both
	• Stage 2-4 CKD (eGFR <60 mL/min/1.73 m^2 or albuminuria >30mg/g or 3mg/mmol)
	
	<u>Heart Failure</u>
	• Diagnosis of NYHA Class II to IV heart failure

Prescriber Restriction	• **Heart Failure:** Prescribed by, or in consultation with, a Cardiologist or documentation of consultation for HF evaluation and treatment has been done.
Coverage Duration	• **All Diagnoses:** ○ Initial: Lifetime

Effective Date:	09/01/2026
P&T Approval Date:	03/08/2022

P&T Revision Date:	07/14/2026, 07/07/2024, 03/08/2022

References

- American Diabetes Association Professional Practice Committee. Standards of Care in Diabetes—2026. Diabetes Care. 2026;49(Suppl 1).
- Farxiga [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP. 2026.

Somatropin (Growth Hormone)

Products Affected

- Nutropin AQ
- Zomacton Inj
- Omnitrope inj 5.8mg

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Growth Hormone Deficiency (GHD)
	  ○ Prader-Willi Syndrome
	  ○ Noonan Syndrome
	  ○ Turner Syndrome
	  ○ Idiopathic Short Stature
	  ○ Growth Failure secondary to chronic kidney disease (CKD)
	  ○ Small for gestational age
	  ○ Short stature homeobox-containing (SHOX) gene deficiency
	  ○ HIV Associated Cachexia

Required Medical Information and Criteria	**<u>All Diagnoses</u>**
	• Documentation of goals of therapy and objective baseline assessment (e.g., quality of life, exercise capacity, height, body composition
	
	<u>Patient Under Age 18</u>
	• Confirmation of one of the following:
	  ○ Growth Hormone Deficiency (GHD) as noted by one of the following:
	  ▪ Growth hormone deficiency is confirmed by a negative response to a growth hormone stimulation test (e.g., serum GH levels of <5 ng/mL on stimulation testing with either of the following: glucagon or insulin)
	  ▪ Patient has had the pituitary removed or destroyed or has had panhypopituitarism since birth
	  ○ Diagnosis of Prader-Willi Syndrome and patient does not have concurrent severe obesity nor history of upper airway obstruction nor sleep apnea nor severe respiratory impairment
	  ○ Diagnosis of Noonan Syndrome
	  ○ Diagnosis of Turner Syndrome
	  ○ Diagnosis of Idiopathic Short Stature
	  ○ Diagnosis of Growth Failure secondary to chronic kidney disease (CKD)
	  ○ Diagnosis of Small for gestational age

	○ Diagnosis of Short stature homeobox-containing (SHOX) gene deficiency ○ Diagnosis of HIV Associated Cachexia **<u>Patients Aged 18 and Older</u>** • Confirmation of one of the following: ○ Confirmation of all the following: ▪ Growth Hormone Deficiency (GHD) as noted by one of the following: ▪ Growth hormone deficiency is confirmed by a negative response to a growth hormone stimulation test (e.g., serum GH levels of <5 ng/mL on stimulation testing with either of the following: glucagon or insulin) ▪ Patient has had the pituitary removed or destroyed or has had panhypopituitarism since birth ▪ The prescriber certifies that the growth hormone is not being prescribed for anti-aging therapy or to enhance athletic ability or body building ○ HIV associated cachexia ○ Short Bowel Syndrome (SBS)
Renewal Criteria	• Treatment with agent initiated in a patient prior to reaching adulthood (<18 years of age) was to improve growth velocity or height and one of the following: ○ Growth velocity greater than 2.5 cm per year ○ Growth velocity less than 2.5 cm per year • Documentation that benefits of therapy continue to outweigh risks • Documentation of improvement from baseline as assessed by the prescribing provider
Prescriber Restriction	• **Under 18:** Pediatric Endocrinologist or Nephrologist • **18 and Older:** Endocrinologist
Coverage Duration	• **All Diagnoses:** ○ Initial: 12 months ○ Renewal: up to 12 months

Effective Date:	5/1/2026
P&T Approval Date:	3/14/2023
P&T Revision Date:	3/10/2026, 3/14/2023

References
• Omnitrope [package insert]. Princeton, NJ: Sandoz Inc.; 2025 • Nutropin [package insert]. South San Francisco, CA: Genentech Inc.; 2025 • Zomacton [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; 2025

Sotatercept (Winrevair)

Products Affected

- Winrevair Injection

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Pulmonary Arterial Hypertension (PAH)

Required Medical Information and Criteria	**<u>Pulmonary Arterial Hypertension (PAH)</u>**
	• Diagnosis of symptomatic PAH (WHO Group 1 PH) confirmed by right heart catheterization.
	• WHO functional class II or III symptoms.
	• On a stable dose of both
	  ○ Endothelin-1 receptor antagonists (ERA) **and**
	  ○ Phosphodiesterase type 5 inhibitors **or** guanylate cyclase stimulant
	• Current PAH background therapies (ERA, PDE5i, etc.) will be continued unless not tolerated.
	• Baseline platelet count >500,000

Renewal Criteria	• Documented positive clinical response to therapy
Prescriber Restriction	• **Pulmonary Arterial Hypertension:** Pulmonologist or Cardiologist

Coverage Duration	• **Pulmonary Arterial Hypertension:**
	  ○ Initial: 6 months
	  ○ Renewal: 12 months

Effective Date:	11/1/2024
P&T Approval Date:	9/10/2024
P&T Revision Date:	9/10/2024

References
•

Sparsentan (Filspari)

Products Affected

- Filspari Tablets

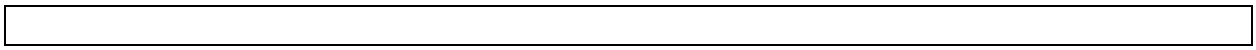
Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Primary Immunoglobulin A Nephropathy.
Required Medical Information and Criteria	**<u>Primary Immunoglobulin A Nephropathy</u>** • Urine protein-to-creatine ratio (UPCR) ≥ 1.5 and eGFR ≥ 30 mL/min?1.73 m2 • Biopsy-verified primary IgA nephropathy • No history of kidney transplant and not currently receiving dialysis • Member has failed to achieve a reduction in proteinuria to under 1 gram/day while receiving maximally tolerated doses of an ACE inhibitor or ARB for at least 12 weeks
Renewal Criteria	• Documentation of improved or stable kidney function compared to baseline or reduction in proteinuria
Age Restriction	• Age 18 or older
Prescriber Restriction	• **Primary Immunoglobulin A Nephropathy:** Nephrologist.

Coverage Duration	• **Primary Immunoglobulin A Nephropathy:**
	  ○ Initial: 6 months
	  ○ Renewal: 12 months

Effective Date:	07/01/2026
P&T Approval Date:	07/11/2023
P&T Revision Date:	05/12/2026, 07/11/2023

References

- IPD analytics. Nephrology: IgA Nephropathy. Accessed March 30, 2026.
- Kidney Disease: Improving Global Outcomes (KDIGO) IgAN and IgAV Work Group. KDIGO 2025 Clinical Practice Guideline for the Management of Immunoglobulin A Nephropathy (IgAN) and Immunoglobulin A Vasculitis (IgAV). Kidny Int. 2025; 108 (4S):S1-S71.
- Stoneman S, et al. IgA Nephropathy in Adults A Review. JAMA. 2026;335 (9):799-813.



Sumatriptan Nasal Spray Step Therapy

Products Affected

- Sumatriptan Nasal Spray

Step Therapy Criteria	• Trial and failure of ○ Formulary triptan tablet

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

Suzetrigine (Journavx)

Products Affected

- Journavx tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Acute, moderate to severe pain

Required Medical Information and Criteria	**<u>Acute moderate to severe pain</u>**
	• Clinical documentation of post-operative use following one of the following:
	  ○ Abdominoplasty
	  ○ Bunionectomy
	• Documentation of one of the following:
	  ○ Diagnosis of opioid use disorder
	  ○ Prescriber has a specific concern for opioid abuse.

Renewal Criteria	• Not eligible for renewal, patients will need to meet initial criteria with new surgery to be eligible for a new prescription.
Exclusion Criteria	• Use for more than 14 days. • Any use outside of acute post-procedural pain.
Age Restriction	• Age 18 or older.

Coverage Duration	• **Acute moderate to severe pain:**
	  ○ Initial: 14 days
	  ○ Renewal: N/A

Effective Date:	7/1/2025
P&T Approval Date:	5/13/2025
P&T Revision Date:	5/13/2025

References

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- Dowel D, Ragan KR, Jones CM, Baldwin GT, Chou R. Center for Disease Control and Prevention. CDC Clinical Practice Guideline for Prescribing Opioids for Pain, United States, 2022. CDC Morbidity and Mortality Weekly Report. Recommendations and Reports; Nov 4, 2022: 71 (3); 1-95. Found at: CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022 | MMWR
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- Herzig SJA, Mosher HJR, Calcaterra SLN, Jena ABA, Nuckols TKL. Improving the Safety of Opioid Use for Acute Noncancer Pain in Hospitalized Adults: A Consensus Statement From the Society of Hospital Medicine.J Hosp Med. 2018 Apr;13(4):263-71. https://pubmed.ncbi.nlm.nih.gov/29624189. doi:10.12788/jhm.2980.
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- Journavx (suzetrigine) [Package Insert]. Vertex Pharmaceuticals, Inc; Boston, MA: 2025. Accessed at: https://pi.vrtx.com/files/uspi_suzetrigine.pdf.
- Vertex Pharmaceuticals. Evaluation of Efficacy and Safety of VX-548 for Acute Pain After a Bunionectomy. NCT05553366. Updated March 26, 2025.Accessed March 26, 2025. https://www.clinicaltrials.gov/study/NCT05553366.
- Vertex Pharmaceuticals. Evaluation of Efficacy and Safety of VX-548 for Acute Pain After an Abdominoplasty. NCT05558410. Updated August 27, 2024, Accessed March 26, 2025. https://www.clinicaltrials.gov/study/NCT05558410.

Synthroid Step Therapy

Products Affected

- Synthroid

Step Therapy Criteria	• Trial and failure of ○ Generic levothyroxine

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

Tacrolimus Ointment

Products Affected

- Tacrolimus 0.1% Ointment
- Tacrolimus 0.03% Ointment

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Atopic Dermatitis
	  ○ Psoriasis

Required Medical Information and Criteria	**<u>Atopic Dermatitis</u>**
	• Clinical documentation of diagnosis of moderate to severe atopic dermatitis
	  ○ At least 10% of body surface area involved
	  ○ Hand, foot, face, or mucous membrane involvement
	• Trial and failure of all the following (or a reason they are not appropriate):
	  ○ High potency topical steroids
	
	<u>Psoriasis</u>
	• Diagnosis of moderate to severe psoriasis as indicated by a validated tool such as the Dermatology Life Quality Index and one of the following:
	  ○ At least 10% of body surface area involved
	  ○ Hand, foot, face, or mucous membrane involvement
	• Trial and failure of all the following (or a reason they are not appropriate):
	  ○ High potency topical steroids

Renewal Criteria	• Documented positive clinical response to therapy

Coverage Duration	• **All Diagnoses:**
	  ○ Initial: 12 months
	  ○ Renewal: 12 months

Effective Date:	09/01/2026
P&T Approval Date:	11/09/2021
P&T Revision Date:	07/14/2026, 11/09/2021

References

- Oregon Health Authority, Health Evidence Review Commission. *Prioritized List of Health Services, Guideline Note 21 (Severe Inflammatory Skin Disease).* Salem, OR: Oregon Health Authority.
- Davis DMR, et al. Guidelines of care for the management of atopic dermatitis in pediatric patients. *Journal of the American Academy of Dermatology*. 2026;95(1):121.e1-121.e26.
- Menter A, et al. Joint AAD–NPF Guidelines of Care for the Management and Treatment of Psoriasis with Topical Therapy. *J Am Acad Dermatol.* 2021;84(2):432-470.

Tafluprost Ophth Step Therapy

Products Affected

- Tafluprost 0.0015% solution (BAK free)

Step Therapy Criteria	• Trial and failure of
	  ○ Latanoprost 0.005% ophthalmic solution
	  ○ Travoprost 0.004% ophthalmic solution (BAK free)

Effective Date:	03/01/2026
P&T Approval Date:	01/13/2026
P&T Revision Date:	01/13/2026

Tazarotene

Products Affected

- Tazarotene 0.1% Cream

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Psoriasis
	  ○ Acne

Required Medical Information and Criteria	**<u>Psoriasis</u>**
	• Diagnosis of moderate to severe psoriasis as indicated by a validated tool such as the Dermatology Life Quality Index and one of the following:
	  ○ At least 10% of body surface area involved
	  ○ Hand, foot, face, or mucous membrane involvement
	
	<u>Acne</u>
	• Confirmation that the diagnosis is one of the following:
	  ○ Above the line (severe acne)
	  ○ The member is under the 21 and acne is substantially interfering with daily life
	• Trial and Failure of at least 2 other formulary alternatives used to treat acne

Renewal Criteria	• Documented positive clinical response to therapy

Coverage Duration	• **All Diagnoses:**
	  ○ Initial: 12 months
	  ○ Renewal: 12 months

Effective Date:	3/1/2023
P&T Approval Date:	1/10/2023
P&T Revision Date:	1/10/2023

References
•

Tenofovir Alafenamide (Descovy)

Products Affected

- Descovy Tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of HIV Infection
	  ○ Pre-Exposure Prophylaxis of HIV Infection (PrEP)

Required Medical Information and Criteria	**<u>Treatment of HIV Infection</u>** • Clinical contraindication to generic Truvada • Documentation that the drug will be used in combination with other HIV drugs as part of a complete treatment regimen **<u>Pre-Exposure Prophylaxis of HIV Infection (PrEP)</u>** • Clinical contraindication to generic Truvada
Coverage Duration	• **All Diagnoses:** ○ Initial: Lifetime

Effective Date:	9/1/2024
P&T Approval Date:	7/11/2024
P&T Revision Date:	7/11/2024

References
•

Testosterone

Products Affected

- Testosterone 1% Gel (25mg & 50mg)
- Testosterone 1% Gel pump

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Gender Dysphoria.
	  ○ AIDS Wasting Syndrome.
	  ○ Post-Menopausal Breast Cancer.
	  ○ Hypogonadism.

Required Medical Information and Criteria	**<u>Gender Dysphoria</u>** • Diagnosis of gender dysphoria • Trial and failure or contraindication to injectable testosterone **<u>AIDS Wasting Syndrome</u>** • Diagnosis of AIDS wasting syndrome • Trial and failure or contraindication to injectable testosterone **<u>Post-Menopausal Breast Cancer</u>** • Diagnosis of post-menopausal breast cancer • Trial and failure or contraindication to injectable testosterone **<u>Hypogonadism</u>** • Diagnosis of hypogonadism • Trial and failure or contraindication to injectable testosterone
Renewal Criteria	• Documented positive clinical response to therapy

Coverage Duration	• **Gender Dysphoria, AIDS Wasting Syndrome, Post-Menopausal Breast Cancer:**
	  ○ Initial: Lifetime
	
	• **Hypogonadism:**
	  ○ Initial: 12 months
	  ○ Renewal: 12 months

Effective Date:	7/1/2024
P&T Approval Date:	9/13/2022
P&T Revision Date:	5/14/2024, 9/13/2022

References
•

Tezacaftor-Ivacaftor (Symdeko)

Products Affected

- Symdeko Tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design. ○ Cystic Fibrosis
Required Medical Information and Criteria	**<u>Cystic Fibrosis</u>** • Documentation of cystic fibrosis diagnosis with homozygous F508del mutation • Not used in combination with other CFTR modulator treatments
Renewal Criteria	• Documented clinical response to therapy
Age Restriction	• 1 years of age and older
Prescriber Restriction	• **Cystic Fibrosis:** Pulmonologist

Coverage Duration	• **Cystic Fibrosis:**
	  ○ Initial: 6 months
	  ○ Renewal: 12 months

Effective Date:	05/01/2025
P&T Approval Date:	05/01/2021
P&T Revision Date:	09/01/2021, 03/11/2025

References
•

Thickener (Thick-It)

Products Affected

- Thick-It
- Thick-It #2

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Swallowing Disorder

Required Medical Information and Criteria	**<u>Swallowing Disorder</u>**
	• Documented swallowing study/evaluation for the treatment of swallowing disorder due to one of the following medical conditions:
	  ○ Diagnosis of dysphagia which negatively impacts the ability to swallow
	  ○ Chronic diseases such as, but not limited to, Parkinson's, dementia, reflux disease, stroke, neuromuscular disease/disorder, and spinal cord injury
	  ○ Treatment of head, neck, or throat cancer
	  ○ Documented aspiration of food or liquid associated with chronic illness or disease

Renewal Criteria	• Documentation of appointment in the last 12 months confirming effectiveness of the requested thickener and continued need

Coverage Duration	• **Swallowing Disorder:**
	  ○ Initial: 6 months
	  ○ Renewal: 12 months

Effective Date:	1/1/2025
P&T Approval Date:	11/12/2024
P&T Revision Date:	11/12/2024

References
• Oregon administrative rule 410-148-0260 (7)(a)(A-D)(b)

Tiagabine

Products Affected

- Tiagabine Tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Partial (Focal) Seizures
Required Medical Information and Criteria	**<u>Partial Seizures</u>** • Confirmation of diagnosis of Partial Seizures
Renewal Criteria	• Documented positive clinical response to therapy

Coverage Duration	• **Partial Seizures:**
	  ○ Initial: 12 months
	  ○ Renewal: 12 months

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

References
•

Ticagrelor

Products Affected

- Ticagrelor tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Acute Coronary Syndrome
	  ○ Minor Ischemic Stroke
	  ○ Etc.

Required Medical Information and Criteria	**<u>Acute Coronary Syndrome</u>**
	• Member has:
	  ○ Either non-ST-elevation acute coronary syndrome (NSTE-ACS) or ST-elevation myocardial infarction (STEMI) AND
	  ○ Has had percutaneous coronary intervention (PCI) AND
	  ○ Has a contraindication to prasugrel
	OR
	• Member has NSTE-ACS and is treated with medical therapy alone (has not had PCI)
	
	<u>Minor Ischemic Stroke</u>
	• Member has had a minor non-cardioembolic ischemic stroke (NIHSS score ≤5) in the immediate past
	• Did not receive IV alteplase
	• Has a reason that clopidogrel can't be used

Renewal Criteria	• **Acute Coronary Syndrome:** Documentation of positive clinical response to therapy and continued need for treatment • **Minor ischemic stroke:** Renewal not appropriate
Age Restriction	• 18 years of age and older
Prescriber Restriction	• **Acute Coronary Syndrome:** Cardiologist • **Minor Ischemic Stroke:** Cardiologist, Neurologist

Coverage Duration	• **Acute Coronary Syndrome:**
	  ○ Initial: 12 months
	  ○ Renewal: 12 months
	
	• **Minor Ischemic Stroke:**
	  ○ Initial: 1 month
	  ○ Renewal: N/A

Effective Date:	9/1/2025
P&T Approval Date:	7/11/2023
P&T Revision Date:	7/8/2025, 7/11/2023

References

- Brilinta [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2024.
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- Powers WJ,et al.; on behalf of the American Heart Association Stroke Council. Guidelines for the early management of patients with acute ischemic stroke: 2019 update to the 2018 guidelines for the early management of acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2019;50:e344–e418

Tildrakizumab (Ilumya)

Products Affected

- Ilumya Subcutaneous PFS

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Plaque Psoriasis

Required Medical Information and Criteria	**<u>All diagnoses</u>**
	• Initial testing for latent TB and treatment, if necessary, before starting treatment.
	• No current active infection at initiation of therapy.
	• Risks and benefits documented in cases of chronic or recurrent infection.
	• Will NOT be used in combination with another biologic or Otezla.
	
	<u>Plaque Psoriasis (PP):</u>
	• Documentation of severe plaque psoriasis, defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) = 11 or Children's Dermatology Life Quality Index (CDLQI) = 13 (or severe score on other validated tool) AND one or more of the following:
	  ○ At least 10% of body surface area involved
	  ○ Hand, foot, face, or mucous membrane involvement
	• One of the following:
	  ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
	  ○ Documented trial and failure of all the following:
	  ▪ High-potency topical corticosteroids (augmented betamethasone, clobetasol, etc.)
	  ▪ At least one other topical agent (calcipotriene, tazarotene, anthralin, tar, etc.)
	  ▪ PUVA or UVB Phototherapy
	  ▪ Methotrexate
	  ▪ At least 1 other second line systemic agent such as cyclosporine or acitretin.
	• Trial and failure of infliximab, adalimumab, and ustekinumab or contraindication to all

Renewal Criteria	• **Plaque Psoriasis:** Evidence of positive clinical response to therapy as evidenced by ONE of the following: reduction of body surface area (BSA) involvement from baseline, improvement in symptoms (e.g. pruritus, inflammation) from baseline, or evidence of functional improvement.
Prescriber Restriction	• **Plaque Psoriasis:** Dermatologist.
Coverage Duration	• **All diagnoses:** o Initial: 6 months o Renewal: 12 months

Effective Date:	07/01/2026
P&T Approval Date:	05/12/2026
P&T Revision Date:	05/12/2026

References

- Ilumya [package insert]. Whitehouse Station, NJ: Merck and Co. Inc. 2025.
- 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(4):1029-1072.

Tobramycin Solution

Products Affected

- Tobramycin Nebulization Solution

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Cystic Fibrosis
Required Medical Information and Criteria	**<u>Cystic Fibrosis</u>** • Confirmed diagnosis of cystic fibrosis **<u>All Other Diagnoses</u>** • Confirmed diagnosis of an FDA approved or compendia supported indication
Renewal Criteria	• Confirmed diagnosis with clinical evidence supporting chronic use
Prescriber Restriction	• **Cystic Fibrosis:** Prescribed by or in consultation with Infectious Disease Specialist, Pulmonologist, or Cystic Fibrosis Specialist • **All Other Diagnoses:** Prescribed by or in consultation with Infectious Disease Specialist, or Pulmonologist

Coverage Duration	• **Cystic Fibrosis:**
	  ○ Initial: Lifetime
	
	• **All Other Diagnoses:**
	  ○ Initial: 3 months
	  ○ Renewal: 12 months

Effective Date:	1/1/2025
P&T Approval Date:	11/12/2024
P&T Revision Date:	11/12/2024

References

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- Mogayzel, Jr, PJ, et al. Cystic Fibrosis Foundation Pulmonary Guidelines. Chronic Medications for Maintenance of Lung Health. Am J Respir Crit Care Med 2013; 18 (7): 680–689.

Tocilizumab (Actemra, Tyenne)

Products Affected

- Actemra Prefilled Syringe
- Actemra ActPen
- Tyenne Prefilled Syringe
- Tyenne Auto-Injector
- Tyenne IV Solution

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Cytokine Release Syndrome (CRS) Risk due to CAR T-Cell Therapy
	  ○ Giant Cell Arteritis
	  ○ Juvenile Idiopathic Arthritis
	  ○ Rheumatoid Arthritis
	  ○ Systemic Sclerosis-Associated Interstitial Lung Disease

Required Medical Information and Criteria	**<u>All diagnoses</u>**
	• Initial testing for latent TB and treatment, if necessary, before starting treatment.
	• No current active infection at initiation of therapy.
	• Risks and benefits documented in cases of chronic or recurrent infection.
	• Will NOT be used in combination with another biologic or Otezla.
	
	<u>Cytokine Release Syndrome (CRS) Risk due to CAR T-Cell Therapy:</u>
	• Member will receive or is receiving chimeric antigen receptor (CAR) T-cell immunotherapy
	
	<u>Giant Cell Arteritis:</u>
	• Clinical documentation confirming diagnosis of Giant Cell Arteritis
	• Trial and failure of glucocorticoid treatment
	
	<u>Juvenile Idiopathic Arthritis (JIA)</u>
	• Documentation of juvenile idiopathic arthritis with active systemic features of JIA, with a physician global assessment of 5 or higher (or any systemic activity in the absence of active joint involvement) or JIA without active systemic features
	• One of the following:
	  ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
	  ○ Documented trial and failure of the following:

	▪ NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND ▪ At least 6 months of 2 of Methotrexate, leflunomide, sulfasalazine, hydroxychloroquine, or systemic corticosteroids • Documented intolerance or contraindication to oral disease-modifying antirheumatic drugs (DMARD) such as methotrexate, leflunomide, etc. or DMARDs will be continued • Trial and failure of infliximab and adalimumab or contraindication to both. **<u>Rheumatoid Arthritis (RA):</u>** • Documentation of a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI) • One of the following: o The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR o Documented trial and failure of nonbiologic DMARD therapy: methotrexate (dosed at least 20mg per week for at least 8 weeks), leflunomide or sulfasalazine • Trial and failure of infliximab and adalimumab or contraindication to both. **<u>Systemic Sclerosis-Associated Interstitial Lung Disease:</u>** • Confirmed diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) • Trial and failure of mycophenolate mofetil
Renewal Criteria	• **Juvenile Idiopathic Arthritis:** Evidence of 20% or greater improvement in tender joint count and swollen joint count or has there been an improvement in functional ability. • **Rheumatoid Arthritis:** Evidence of a 20% or greater improvement in tender joint count and swollen joint count. • **Giant Cell Arteritis:** Demonstrated positive clinical response to therapy. • **Systemic Sclerosis-Associated Interstitial Lung Disease:** Demonstrated positive clinical response to therapy.
Prescriber Restriction	• **Cytokine Release Syndrome (CRS) Risk due to CAR T-Cell Therapy:** Oncologist or Hematologist • **Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Giant Cell Arteritis:** Rheumatologist

	• **Systemic Sclerosis-Associated Interstitial Lung Disease:** Rheumatologist or Pulmonologist
Coverage Duration	• **Cytokine Release Syndrome:** o Initial: 2 months o Renewal: N/A • **All Other Diagnoses:** o Initial: 6 months o Renewal: 12 months

Effective Date:	07/01/2026
P&T Approval Date:	07/11/2023
P&T Revision Date:	05/12/2026, 07/09/2024, 07/11/2023

References

- Actemra [package insert]. South San Francisco, CA: Genentech, Inc. 2025.
- Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Care Res (Hoboken).* 2021;73(7):924-939.
- Onel KB, Horton DB, Lovell DJ, 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 (Hoboken).* 2019;71(6):717-734.
- Ringold S, Angeles-Han ST, Beukelman T, 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 Care Res (Hoboken).* 2022;74(4):521-537.

Tofacitinib (Xeljanz)

Products Affected

- Xeljanz XR tablets
- Xeljanz Tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Ankylosing Spondylitis/Axial Spondyloarthritis
	  ○ Juvenile Idiopathic Arthritis
	  ○ Psoriatic Arthritis
	  ○ Rheumatoid Arthritis
	  ○ Ulcerative Colitis

Required Medical Information and Criteria	**<u>Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA)</u>**
	• Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by:
	  ○ Back pain and stiffness for more than 3 months AND
	  ○ Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive AND
	  ○ BASDAI score of >=4
	• One of the following:
	  ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
	  ○ Documented failure of conventional therapy with both of the following:
	  ▪ At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated AND
	  ▪ Physical therapy/exercise program
	• Trial and failure of infliximab and adalimumab or contraindication to both.
	
	<u>Juvenile Idiopathic Arthritis (JIA)</u>
	• Documentation of juvenile idiopathic arthritis with active systemic features of JIA, with a physician global assessment of 5 or higher (or any systemic activity in the absence of active joint involvement) or JIA without active systemic features
	• One of the following:
	  ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
	  ○ Documented trial and failure of the following:

	▪ NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND ▪ At least 6 months of 2 of Methotrexate, leflunomide, sulfasalazine, hydroxychloroquine, or systemic corticosteroids • Documented intolerance or contraindication to DMARDs OR DMARD will be continued with Xeljanz. • Trial and failure of infliximab and adalimumab or contraindication to both **Psoriatic Arthritis (PsA):** • Documented of psoriatic arthritis based on at least 3 out of 5 of the following: o Psoriasis (1 point for personal or family history, 2 points for current) o Psoriatic nail dystrophy o Negative test result for RF o Dactylitis (current of history) o Radiological evidence of juxta-articular new bone formation • One of the following: o The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR o Documented trial and failure of conventional therapy with both of the following: ▪ NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND ▪ Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine. • Trial and failure of infliximab, adalimumab, and ustekinumab or contraindication to all **Rheumatoid Arthritis (RA):** • Documentation of a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI) • One of the following: o The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR o Documented trial and failure of nonbiologic DMARD therapy: methotrexate (dosed at least 20mg per week for at least 8 weeks), leflunomide or sulfasalazine • Trial and failure of infliximab, adalimumab, and tocilizumab or contraindication to all

	<u>Ulcerative Colitis (UC):</u>
	• Documentation of moderate-to-severe ulcerative colitis
	• One of the following:
	  ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
	  ○ Documented trial and failure of at least 1 of the following: mesalamine, sulfasalazine, mercaptopurine, azathioprine, or corticosteroids (prednisone, methylprednisolone).
	• Trial and failure of infliximab, adalimumab, and ustekinumab or contraindication to all

Renewal Criteria	• **Ankylosing Spondylitis/Axial Spondyloarthritis:** Evidence of significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI. • **Juvenile Idiopathic Arthritis:** Evidence of 20% or greater improvement in tender joint count and swollen joint count or has there been an improvement in functional ability. • **Psoriatic Arthritis:** Evidence of a 20% or greater improvement in tender joint count and swollen joint count. • **Rheumatoid Arthritis:** Evidence of a 20% or greater improvement in tender joint count and swollen joint count. • **Ulcerative Colitis:** Evidence of a significant response such as a decrease in bloody stools per day or elimination of signs of toxicity.
Prescriber Restriction	• **Ankylosing Spondylitis**, **Axial Spondyloarthritis:** Rheumatologist. • **Psoriatic Arthritis:** Dermatologist or Rheumatologist. • **Juvenile Idiopathic Arthritis:** Rheumatologist • **Rheumatoid Arthritis**: Rheumatologist. • **Ulcerative Colitis:** Gastroenterologist.

Coverage Duration	• **All Diagnoses:**
	  ○ Initial: 6 months
	  ○ Renewal: 12 months

Effective Date:	07/01/2026
P&T Approval Date:	7/11/2023
P&T Revision Date:	05/12/2026, 07/11/2023, 01/11/2022

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- Singh S, Loftus EV Jr, Limketkai BN, et al. AGA living clinical practice guideline on pharmacological management of moderate-to-severe ulcerative colitis. *Gastroenterology.* 2024;167(7):1307-1343.
- Gossec L, Baraliakos X, Kerschbaumer A, et al.EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2023 update. *Ann Rheum Dis.* 2024;83(6):706-719.
- Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Care Res (Hoboken).* 2021;73(7):924-939.
- Onel KB, Horton DB, Lovell DJ, 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 (Hoboken).* 2019;71(6):717-734.
- Ringold S, Angeles-Han ST, Beukelman T, 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 Care Res (Hoboken).* 2022;74(4):521-537.

Topical Antifungal Agents

Products Affected

- Ciclopirox 8% Solution
- Econazole 1% Cream
- Selenium Sulfide 2.5% Lotion
- Ketoconazole 2% Cream and Shampoo

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical Information and Criteria	**<u>All Diagnoses</u>** • All the following have been tried and failed or are not appropriate for use: o Clotrimazole 1% cream o Miconazole 2% (cream, aerosol, or powder), o Terbinafine 1%, cream, terbinafine tablets o Nystatin 100,000 units/gram (ointment, cream, or powder)
Renewal Criteria	• Documented positive clinical response to therapy
Coverage Duration	• **All Diagnoses:** o Initial: 3 months o Renewal: 12 months

Effective Date:	9/1/2023
P&T Approval Date:	7/11/2023
P&T Revision Date:	7/11/2023, 1/11/2022

References
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Toujeo Step Therapy

Products Affected

- Toujeo Max Solostar
- Toujeo Solostar

Step Therapy Criteria	• Trial and failure of ○ Any non-concentrated basal insulin product

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

Tranexamic Acid

Products Affected

- Tranexamic Acid Tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Hemophilia – Hemorrhage Prophylaxis; Tooth Extraction
	  ○ Menorrhagia

Required Medical Information and Criteria	**<u>Hemophilia – Hemorrhage Prophylaxis</u>**
	  ○ Documentation that use is intended for hemorrhage prophylaxis for tooth extraction
	
	<u>Menorrhagia</u>
	• Documentation of abnormal uterine bleeding
	• Trail and failure of, current use of, or contraindication to all of the following:
	  ○ Combined Oral Contraceptive therapy
	  ○ Progestin therapy (oral or LM) or Levonorgestrel IUD
	  ○ NSAID therapy

Renewal Criteria	• Documentation of positive clinical response to therapy
Prescriber Restriction	• **Hemorrhage Prophylaxis:** Hematologist, Hemophilia Specialist, Dentist • **Menorrhagia:** Gynecologist

Coverage Duration	• **All Diagnoses:**
	  ○ Initial: 12 months
	  ○ Renewal: 12 months

Effective Date:	7/1/2024
P&T Approval Date:	5/14/2024
P&T Revision Date:	5/14/2024

References
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Tretinoin, Topical

Products Affected

- Tretinoin **0.025% cream**
- Tretinoin **0.05% cream**
- Tretinoin **0.1% cream**
- Tretinoin **0.01% gel**
- Tretinoin **0.025% gel**

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Acne
Required Medical Information and Criteria	**Acne** • Documentation of trial and failure, intolerance, or contraindication to a topical product containing benzoyl peroxide.
Renewal Criteria	• Documentation of positive clinical response to therapy.

Coverage Duration	• **All Diagnosis**
	  ○ Initial: 12 months
	  ○ Renewal: 12 months

Effective Date:	02/01/2023
P&T Approval Date:	01/10/2023
P&T Revision Date:	01/10/2023

Ubrogepant (Ubrelvy)

Products Affected

- Ubrelvy tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of acute migraine
	  ○

Required Medical Information and Criteria	**<u>Acute Migraine</u>** • Confirmed diagnosis of migraine • Documentation showing the member is currently on preventative therapy • Trial and failure (defined as at least 6 weeks per agent) of: ○ At least 3 oral formulary triptans used at up to the maximally indicated dosing and in combination with NSAID therapy (e.g. naproxen).
Renewal Criteria	• Documented positive clinical response to therapy
Age Restriction	• 18 years of age or older
Prescriber Restriction	• **Acute Migraine:** Neurologist or headache specialist

Coverage Duration	• **Acute Migraine:**
	  ○ Initial: 3 months
	  ○ Renewal: 12 months

Effective Date:	9/1/2025
P&T Approval Date:	5/9/2023
P&T Revision Date:	7/8/2025, 5/9/2023

References
• Ubrelvy [package insert]. North Chicago, IL: Abbvie Inc; 2025.

Upadacitinib (Rinvoq)

Products Affected

- Rinvoq Tablets
- Rinvoq LQ Solution

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Ankylosing Spondylitis/Axial Spondyloarthritis
	  ○ Atopic Dermatitis
	  ○ Crohn's Disease
	  ○ Psoriatic Arthritis
	  ○ Rheumatoid Arthritis
	  ○ Ulcerative Colitis

Required Medical Information and Criteria	**<u>Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA)</u>**
	• Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by:
	  ○ Back pain and stiffness for more than 3 months AND
	  ○ Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive AND
	  ○ BASDAI score of >=4
	• One of the following:
	  ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
	  ○ Documented failure of conventional therapy with both of the following:
	  ▪ At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated AND
	  ▪ Physical therapy/exercise program
	• Trial and failure of infliximab and adalimumab or contraindication to both.
	• Trial and failure of Cimzia, Cosentyx, Simponi, Taltz, and Xeljanz/Xeljanz XR, or contraindication to all.
	
	<u>Atopic Dermatitis</u>
	• Diagnosed with severe atopic dermatitis defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's Dermatology Life Quality Index (CDLQI) ≥ 13 (or severe score on another validated tool)
	• One or more of the following:

	○ At least 10% of body surface area involvement ○ Hand, foot, or mucous membrane involvement • Documented contraindication or failed trial to ALL of the following: ○ Moderate-high potency corticosteroid (e.g., clobetasol, fluocinonide, fluticasone) ○ Topical calcineurin inhibitor (e.g. tacrolimus) ○ Oral immunomodulator therapy (e.g. cyclosporine, methotrexate, azathioprine, mycophenolate mofetil) **OR** the member is oral corticosteroid dependent. • Trial and failure of, or contraindication to nemolizumab (Nemluvio) • Trial and failure of dupilumab (Dupixent) and lebrikizumab (Ebglyss) or contraindication to both **Crohn's Disease (CD)** • Documentation of moderate-to-severe Crohn's Disease • Trial and failure of infliximab, adalimumab, and ustekinumab (dosed every 4 weeks) or contraindication to all **Psoriatic Arthritis (PsA):** • Documentation of psoriatic arthritis based on at least 3 out of 5 of the following: ○ Psoriasis (1 point for personal or family history, 2 points for current) ○ Psoriatic nail dystrophy ○ Negative test result for RF ○ Dactylitis (current of history) ○ Radiological evidence of juxta-articular new bone formation • One of the following: ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR ○ Documented trial and failure of conventional therapy with both of the following: ▪ NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND ▪ Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine. • Trial and failure of infliximab, adalimumab, and ustekinumab or contraindication to all • Trial and failure of Cimzia, Cosentyx, Otezla, Orencia, Simponi, Xeljanz or contraindication to all

	<u>Rheumatoid Arthritis (RA):</u>
	• Documentation of a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI)
	• One of the following:
	  ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
	  ○ Documented trial and failure of nonbiologic DMARD therapy: methotrexate (dosed at least 20mg per week for at least 8 weeks), leflunomide or sulfasalazine
	• Trial and failure of infliximab, adalimumab, and tocilizumab or contraindication to all
	• Trial and failure of Cimzia, Kineret, Orencia, rituximab, Simponi, Olumiant, Xeljanz, and Kevzara or contraindication to all
	
	<u>Ulcerative Colitis (UC):</u>
	• Documentation of moderate-to-severe ulcerative colitis
	• One of the following:
	  ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
	  ○ Documented trial and failure of at least 1 of the following: mesalamine, sulfasalazine, mercaptopurine, azathioprine, or corticosteroids (prednisone, methylprednisolone).
	• Trial and failure of infliximab, adalimumab, and ustekinumab or contraindication to all
	• Trial and failure of Entyvio, Simponi, Xeljanz, Velsipity or contraindication to all

Renewal Criteria	• **Ankylosing Spondylitis/Axial Spondyloarthritis:** Evidence of significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI. • **Atopic Dermatitis:** Evidence of positive clinical response to therapy as evidenced by ONE of the following: reduction of body surface area (BSA) involvement from baseline, improvement in symptoms (e.g. pruritus, inflammation) from baseline, or evidence of functional improvement. • **Crohn's Disease:** Evidence of a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission.

	• **Psoriatic Arthritis:** Evidence of a 20% or greater improvement in tender joint count and swollen joint count. • **Rheumatoid Arthritis:** Evidence of a 20% or greater improvement in tender joint count and swollen joint count. • **Ulcerative Colitis:** Evidence of a significant response such as a decrease in bloody stools per day or elimination of signs of toxicity.
Prescriber Restriction	• **Ankylosing Spondylitis**, **Axial Spondyloarthritis:** Rheumatologist. • **Atopic Dermatitis:** Dermatologist. • **Crohn's Disease and Ulcerative Colitis:** Gastroenterologist. • **Psoriatic Arthritis:** Dermatologist or Rheumatologist. • **Rheumatoid Arthritis**: Rheumatologist.
Coverage Duration	• **All Diagnoses:** o Initial: 6 months o Renewal: 12 months

Effective Date:	07/01/2026
P&T Approval Date:	07/11/2023
P&T Revision Date:	05/12/2026, 07/11/2023, 01/11/2022

References

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- Gossec L, Baraliakos X, Kerschbaumer A, et al.EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2023 update. *Ann Rheum Dis.* 2024;83(6):706-719.
- Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Care Res (Hoboken).* 2021;73(7):924-939.

Ustekinumab

Products Affected

- Selarsdi IV and SC solution
- Yesintek IV and SC solution
- Steqeyma IV and SC solution
- Starjemza IV and SC solution

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Crohn's Disease
	  ○ Plaque Psoriasis
	  ○ Psoriatic Arthritis
	  ○ Ulcerative Colitis
	• Compendia supported uses
	  ○ Hidradenitis Suppurativa

Required Medical Information and Criteria	**<u>All diagnoses</u>**
	• Initial testing for latent TB and treatment, if necessary, before starting treatment.
	• No current active infection at initiation of therapy.
	• Risks and benefits documented in cases of chronic or recurrent infection.
	• Will NOT be used in combination with another biologic or Otezla
	
	<u>Crohn's Disease (CD)</u>
	• Documentation of moderate-to-severe Crohn's Disease
	
	<u>Hidradenitis Suppurativa (HS)</u>
	• Documentation of a diagnosis of moderate to severe hidradenitis suppurativa (Hurley Stage II or Hurley Stage III)
	• One of the following:
	  ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
	  ○ Documented failure of conventional therapy (e.g. oral antibiotics).
	
	<u>Plaque Psoriasis (PP)</u>
	• Documentation of severe plaque psoriasis, defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) = 11 or Children's Dermatology Life Quality Index (CDLQI) = 13

	(or severe score on other validated tool) AND one or more of the following: ○ At least 10% of body surface area involved ○ Hand, foot, face, or mucous membrane involvement • The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of all the following: ○ High-potency topical corticosteroids (augmented betamethasone, clobetasol, etc.) ○ At least one other topical agent (calcipotriene, tazarotene, anthralin, tar, etc.) ○ PUVA or UVB Phototherapy ○ Methotrexate ○ At least 1 other second line systemic agent such as cyclosporine or acitretin **Psoriatic Arthritis (PsA)** • Documentation of psoriatic arthritis based on at least 3 out of 5 of the following: ○ Psoriasis (1 point for personal or family history, 2 points for current) ○ Psoriatic nail dystrophy ○ Negative test result for RF ○ Dactylitis (current of history) ○ Radiological evidence of juxta-articular new bone formation • The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of conventional therapy with both of the following: ○ NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND ○ Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine **Ulcerative Colitis (UC)** • Documentation of moderate-to-severe ulcerative colitis • The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of at least 1 of the following: ○ Mesalamine, sulfasalazine OR ○ Mercaptopurine, azathioprine, OR ○ Corticosteroids (prednisone, methylprednisolone)

Renewal Criteria	• **Crohn's Disease:** Evidence of a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission. • **Hidradenitis Suppurativa:** Evidence of a reduction of 25% or more of the total abscess and inflammatory nodule count and no increase in abscesses and draining fistulas. • **Plaque Psoriasis:** Evidence of positive clinical response to therapy as evidenced by ONE of the following: reduction of body surface area (BSA) involvement from baseline, improvement in symptoms (e.g. pruritus, inflammation) from baseline, or evidence of functional improvement. • **Psoriatic Arthritis:** Evidence of a 20% or greater improvement in tender joint count and swollen joint count. • **Ulcerative Colitis:** Evidence of a significant response such as a decrease in bloody stools per day or elimination of signs of toxicity.
Exclusion Criteria	• Not to be used in combination with other biologics for the same indication.
Prescriber Restriction	• **Crohn's Disease and Ulcerative Colitis:** Gastroenterologist. • **Plaque Psoriasis, Hidradenitis Suppurativa:** Dermatologist. • **Psoriatic Arthritis:** Dermatologist or Rheumatologist.
Coverage Duration	• **All diagnoses:** o Initial: 6 months o Renewal: 12 months

Effective Date:	07/01/2026
P&T Approval Date:	07/11/2023
P&T Revision Date:	05/12/2026, 03/11/2025, 07/11/2023

References

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- Yesintek [package insert]. Cambridge, MA: Biocon Biologics; 2024.
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- Lichtenstein GR, Loftus EV Jr, Afzali A, et al. ACG clinical guideline: Management of Crohn's disease in adults. *Am J Gastroenterol.* 2025;120(6):1225-1264.
- Alikhan A, Sayed C, Alavi A, et al. Practical guidelines for managing patients with hidradenitis suppurativa: An update. *J Am Acad Dermatol.* 2022;86(4):861-891.
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- Gossec L, Baraliakos X, Kerschbaumer A, et al.EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2023 update. *Ann Rheum Dis.* 2024;83(6):706-719.

Valacyclovir Step Therapy

Products Affected

- Valacyclovir tablets

Step Therapy Criteria	• Trial and failure of ○ Acyclovir tablets

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

Vanzacaftor-tezacaftor-deutivacaftor (Alyftrek)

Products Affected

- Alyftrek Tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design. ○ Cystic Fibrosis

Required Medical Information and Criteria	**<u>Cystic Fibrosis</u>**
	• Presence of at least one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected by a U.S. Food and Drug Administration (FDA)-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA):
	  ○ F508del mutation
	  ○ A mutation in the CFTR gene that is responsive based on clinical, in vitro, or extrapolated data.
	• Not to be used in combination with other CFTR modulator treatments

Renewal Criteria	• Demonstrated positive clinical response to therapy.
Age Restriction	• Age 6 and older.
Prescriber Restriction	• Pulmonologist or Specialist affiliated with a CF care center.
Coverage Duration	• Initial: 6 months • Renewal: 12 months

Effective Date:	05/01/2025
P&T Approval Date:	03/11/2025
P&T Revision Date:	03/11/2025

References
• Alyftrek [package insert]. Boston, MA: Vertx Pharmaceuticals Inc.; 2025.

Vonoprazan (Voquezna)

Products Affected

- Voquezna 10mg and 20mg tablets

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Erosive esophagitis
	  ○ H. Pylori infection
	  ○ Non-Erosive Esophagitis

Required Medical Information and Criteria	**<u>Erosive Esophagitis</u>**
	• Imaging confirmed LA Classification Grade C/D erosive esophagitis AND
	• Documented contraindication, intolerance, or inadequate response to 2 or more PPIs (i.e., lansoprazole, omeprazole, esomeprazole, etc.) at maximum tolerated twice-daily dosing for at least 8 weeks each.
	
	<u>H. Pylori Infection</u>
	• Confirmed H. pylori positive infection
	• Documented contraindication, intolerance, or inadequate response to:
	  ○ Standard first-line therapies for H.pylori infection
	  ▪ Bismuth quadruple therapy
	  ▪ Rifabutin triple therapy (rifabutin, amoxicillin, omeprazole)
	• Co-prescribed with antibiotics
	
	<u>Non-Erosive Esophagitis</u>
	• Documented contraindication, intolerance, or inadequate response to 2 or more PPIs (i.e., lansoprazole, omeprazole, esomeprazole, etc.) at maximum tolerated twice-daily dosing for at least 8 weeks each.

Renewal Criteria	• Renewals past the initial approved timelines are not allowed
Age Restriction	• 18 years of age or older.
Prescriber Restriction	• **Erosive or Non-Erosive Esophagitis:** Gastroenterologist

Coverage Duration	• **Initial healing of Erosive Esophagitis:**
	  ○ Initial: 2 months
	  ○ Renewal: n/a
	
	• **Maintenance of healing of Erosive Esophagitis:**

	○ Initial: 6 months ○ Renewal: n/a • **H. Pylori infection:** ○ Initial: 14 days ○ Renewal: n/a • **Non-Erosive Esophagitis:** ○ Initial: 4 weeks ○ Renewal: n/a

Effective Date:	09/01/2026
P&T Approval Date:	1/9/2024
P&T Revision Date:	07/14/2026, 01/09/2024

References

- Voquezna [package insert]. Buffalo Grove, IL: Phatham Pharmaceuticals; 2025.

Voriconazole

Products Affected

- Voriconazole tablets
- Voriconazole suspension

Covered Uses	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of invasive aspergillosis
	  ○ Treatment of serious fungal infections

Required Medical Information and Criteria	**<u>All diagnoses</u>** • Documentation of one of the approved conditions
Renewal Criteria	• Documented positive clinical response and continued need
Age Restriction	• **Suspension only:** Member is under age 10 or unable to use tablets

Coverage Duration	• **All diagnoses:**
	  ○ Initial: 3 months
	  ○ Renewal: 3 months

Effective Date:	5/1/2024
P&T Approval Date:	3/12/2024
P&T Revision Date:	3/12/2024

References
• Vfend [package insert]. New York, NY: Pfizer.; 2025.

Zafirlukast Step Therapy

Products Affected

- Zafirlukast tablets

Step Therapy Criteria	○ Trial and failure of montelukast

Effective Date:	9/1/2025
P&T Approval Date:	7/8/2025
P&T Revision Date:	7/8/2025