Samaritan Health Plans

Prior Authorization Criteria

InterCommunity Health Network

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

Updated on 05/01/2025. 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**
- **ORENCIA CLICKJECT**

PA Criteria	Criteria Details
Required Medical Information	**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. **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 both infliximab and adalimumab **Psoriatic Arthritis (PsA):** • 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 • 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: o NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND

PA Criteria	Criteria Details
	○ Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine • Trial and failure of both infliximab and adalimumab **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 both infliximab and adalimumab
Age Restrictions	
Prescriber Restrictions	**Psoriatic Arthritis:** Dermatologist or Rheumatologist. **Rheumatoid Arthritis, Juvenile Idiopathic Arthritis**: Rheumatologist.
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
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.

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

Acne Combo Products

Products Affected

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

PA Criteria	Criteria Details
Required Medical Information	Documentation of trial and failure, intolerance, or contraindication to clindamycin/benzoyl peroxide 1.2-5% gel
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 12 months; **Renewal**: 12 months
Renewal Criteria	Documentation of positive clinical response to therapy

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

Acne Medication – Isotretinoin

Products Affected

- Amnesteem **capsules 10mg, 20mg, 40mg**
- Claravis **capsules 10mg, 20mg, 30mg 40mg**
- Isotretinoin **capsules 10mg, 20mg, 25mg, 30mg, 35mg, 40mg**
- Myorisan **capsules 10mg, 20mg, 30mg, 40mg**
- Zenetane **capsules 10mg, 20mg, 30mg, 40mg**

PA Criteria	Criteria Details
Required Medical Information	Diagnosis of Severe nodulocystic acne **AND** documentation of trial and failure, intolerance, or contraindication to oral antibiotic with topical combination therapy (BP + Abx, retinoid + BP, or retinoid + BP + Abx)
Age Restrictions	12 years and older
Prescriber Restrictions	
Coverage Duration	**Initial**: 20 weeks
Renewal Criteria	No Renewals

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

Acne Medication – Tretinoin

Products Affected

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

PA Criteria	Criteria Details
Required Medical Information	Documentation of trial and failure, intolerance, or contraindication to a topical product containing benzoyl peroxide.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 12 months, **Renewal**: 12 months
Renewal Criteria	Documentation of positive clinical response to therapy.

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

Adalimumab

Products Affected

- Adalimumab-adaz **40mg/0.4mL (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**

PA Criteria	Criteria Details
Required Medical Information	**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: o Back pain and stiffness for more than 3 months AND o Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive AND o 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: o At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated **AND** o Physical therapy/exercise program **Crohn's Disease (CD):** • Documentation of moderate-to-severe Crohn's Disease • 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: 6-mercaptopurine, azathioprine, corticosteroid, methotrexate **Hidradenitis Suppurativa (HS):**

PA Criteria	Criteria Details
	• Documentation of a diagnosis of moderate to severe hidradenitis suppurativa (Hurley Stage II or Hurley Stage III) • 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) **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 with adalimumab **Plaque Psoriasis (PP):** • 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 • 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 o At least 1 other second line systemic agent such as cyclosporine or acitretin **Psoriatic Arthritis (PsA):**

PA Criteria	Criteria Details

	• 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
	
	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
	
	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)
	
	Uveitis:
	• Documentation of non-infectious, intermediate-, posterior- or pan-uveitis
	• Documented failure of all the following:
	  ○ Topical glucocorticoids for at least 1 month OR periocular steroid injection, AND
	  ○ Oral corticosteroids, AND

PA Criteria	Criteria Details
	○ At least one of the following: mycophenolate, tacrolimus, cyclosporine, azathioprine, or methotrexate
Age Restrictions	
Prescriber Restrictions	**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	**Initial**: 6 months. **Renewal**: 12 months.
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. **HS:** Evidence of a reduction of 25% or more of the total abscess and inflammatory nodule count and no increase in abscesses and draining fistulas. **JIA:** Evidence of 20% or greater improvement in tender joint count and swollen joint count or has there been an improvement in functional ability. **PP:** 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. **UC:** Evidence of a significant response such as a decrease in bloody stools per day or elimination of signs of toxicity.

PA Criteria	Criteria Details
	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.

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

Alpelisib (VIJOICE)

Products Affected

- Vijoice TAB

PA Criteria	Criteria Details
Required Medical Information	• Confirmed diagnosis of PROS **AND** • At least one severe clinical manifestation of PROS **AND** • A PIK3CA mutation that is confirmed by genetic testing
Age Restrictions	At least 2 years of age.
Prescriber Restrictions	Prescribed by or in consultation with a provider who specializes in treatment of genetic disorders.
Coverage Duration	**Initial**: 24 weeks. **Renewal**: 6 months.
Renewal Criteria	Documentation of a reduction in volume from baseline in at least one lesion **AND** an improvement in at least one symptom of PROS from baseline

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

Ambrisentan (LETAIRIS)

Products Affected

- AMBRISENTAN

PA Criteria	Criteria Details
Required Medical Information	• Diagnosis of pulmonary arterial hypertension (PAH) World Health Organization (WHO Group 1) confirmed by right heart catheterization **OR** patient is currently on any therapy for the diagnosis of PAH. • Documented failure or incomplete response to tadalafil or ambrisentan is being co-prescribed with tadalafil.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist.
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
Renewal Criteria	Documentation of positive clinical response to therapy. **Note:** Letairis (ambrisentan) has a black box warning for embryo-fetal toxicity. Because of the risks of birth defects, Letairis is available for females only through a special restricted distribution program under a Risk Evaluation and Mitigation Strategy (REMS).

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

Anakinra (KINERET)

Products Affected

- KINERET **100 MG/0.67ML**

PA Criteria	Criteria Details
Required Medical Information	**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 **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 both infliximab and adalimumab
Age Restrictions	
Prescriber Restrictions	**Rheumatoid Arthritis**: Rheumatologist.
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
Renewal Criteria	**RA:** Evidence of a 20% or greater improvement in tender joint count and swollen joint count.

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

Apremilast (OTEZLA)

Products Affected

- OTEZLA **TAB 30MG, TAB 10/20/30**

PA Criteria	Criteria Details

Required Medical Information	**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
	
	Plaque Psoriasis (PP):
	• 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
	• Trial and failure of both infliximab and adalimumab
	
	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

PA Criteria	Criteria Details
	○ 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 both infliximab and adalimumab
Age Restrictions	
Prescriber Restrictions	**Plaque Psoriasis:** Dermatologist. **Psoriatic Arthritis:** Dermatologist or Rheumatologist.
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
Renewal Criteria	**PP:** 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.

Effective Date:	9/1/2023
P&T Approval Date:	7/11/2023
P&T Revision Date:	07/11/2023, 01/11/2022

Aprepitant (EMEND)

Products Affected

- APREPITANT

PA Criteria	Criteria Details
Required Medical Information	Prevention of acute nausea and vomiting associated with initial and repeat courses of highly emetogenic chemotherapy in conjunction with other antiemetic agents, such as dexamethasone and ondansetron. Prevention of delayed nausea and vomiting associated with highly emetogenic chemotherapy in conjunction with dexamethasone. Documentation of patient receiving treatment with a moderate to highly emetogenic chemotherapy agent. Documentation patient is receiving concurrent treatment with IV or oral ondansetron (Zofran), granisetron (Kytril) or palonosetron (Aloxi) and dexamethasone.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

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

Atovaquone-proguanil (MALARONE)

Products Affected

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

PA Criteria	Criteria Details
Required Medical Information	**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 CDC
Age Restrictions	FDA label
Prescriber Restrictions	
Coverage Duration	**Prevention**: 3 months **Treatment**: 1 month
Renewal Criteria	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 **TAB 1MG, 2MG, 4MG,**

PA Criteria	Criteria Details
Required Medical Information	**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 **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 both infliximab and adalimumab • Trial and failure of Actemra, Cimzia, Kineret, Orencia, and rituximab
Age Restrictions	
Prescriber Restrictions	**Rheumatologist**
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
Renewal Criteria	Evidence of a 20% or greater improvement in tender joint count and swollen joint count.

Effective Date:	9/1/2023
P&T Approval Date:	7/11/2023
P&T Revision Date:	07/11/2023, 01/11/2022

Bedaquiline (Sirturo)

Products Affected

- Sirturo tablets

PA Criteria	Criteria Details
Required Medical Information	**<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.
Exclusions	Medication is being received through a county clinic with a state funded TB program.
Age Restrictions	5 years of age or older
Prescriber Restrictions	Infectious Disease
Coverage Duration	**Pulmonary tuberculosis:** 24 weeks
Renewal Criteria	N/A

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

Belzutifan (WELIREG)

Products Affected

- **WELIREG**

PA Criteria	Criteria Details
Required Medical Information	Confirmed diagnosis of Von Hippel-Lindau disease with VHL alteration confirmation **AND** require therapy for either associated renal cell carcinoma, associated pancreatic neuroendocrine tumors, or associated CNS hemangioblastoma **AND** confirmation that patient is not eligible currently for surgery **AND** Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by oncologist
Coverage Duration	**Initial**: 3 months. **Renewal**: 3 months
Renewal Criteria	Documented positive clinical response to therapy

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

Bempedoic acid (NEXLETOL)

Products Affected

- Nexletol tablets
- Nexlizet tablets

PA Criteria	Criteria Details

Required Medical Information	**Established clinical ASCVD:**
	• 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 that:
	  ○ Patient is receiving maximally tolerated statin therapy (atorvastatin 40-80mg, rosuvastatin 20-40mg) or has a documented clinical intolerance to statins **AND**
	  ○ Is receiving ezetimibe or has a documented intolerance to ezetimibe.
	• Documentation of failure of PCSK9 inhibitor (Repatha or Praluent).
	
	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 that:
	  ○ Patient is receiving maximally tolerated statin therapy (atorvastatin 40-80mg, rosuvastatin 20-40mg) or has a documented clinical intolerance to statins **AND**
	  ○ Is receiving ezetimibe or has a documented intolerance to ezetimibe.
	• Documentation of failure of PCSK9 inhibitor (Repatha or Praluent).

Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist.
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months
Renewal Criteria	Documented positive clinical response to therapy (significant decrease in lipid levels).

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

Belumosudil (REZUROCK)

Products Affected

- **Rezurock**

PA Criteria	Criteria Details
Required Medical Information	Diagnosed with chronic graft-versus-host disease (cGVHD) **AND** who have tried and failed of at least two prior lines of systemic therapy for cGVHD **AND** not currently taking Imbruvica (ibrutinib)
Age Restrictions	Patient must be 12 years or older.
Prescriber Restrictions	Prescribed by an oncologist or transplant specialist
Coverage Duration	**Initial**: 3 months. **Renewal**: 6 months.
Renewal Criteria	**Renewal Criteria**: Documented positive clinical response to therapy

Effective Date:	04/01/2022
P&T Approval Date:	03/08/2022
P&T Revision Date:	03/08/2022

Bimekizumab-bkzx (BIMZELX)

Products Affected

- **Bimzelx**

PA Criteria	Criteria Details
Required Medical Information	○ 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: • At least 10% of body surface area involved • Hand, foot, face, or mucous membrane involvement OR • 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 ○ The patient tried and failed BOTH first line agents (infliximab or biosimilar AND Humira or biosimilar)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
Renewal Criteria	**Renewal Criteria**: Documentation of positive clinical response to therapy as evidenced by ONE of the following: • Reduction of body surface area (BSA) involvement from baseline

PA Criteria	Criteria Details
	• Improvement in symptoms (e.g. pruritus, inflammation) from baseline • Evidence of functional improvement

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

Bosentan (TRACLEER)

Products Affected

- BOSENTAN

PA Criteria	Criteria Details
Required Medical Information	**Pulmonary arterial hypertension (PAH):** Diagnosed with PAH WHO Group 1 confirmed by right heart catheterization **AND** documentation of NYHA Functional Classification II, III, or IV symptoms **AND** documented normal liver function tests prior to initiation.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist.
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Bosutinib (Bosulif)

Products Affected

- Bosulif capsules
- Bosulif tablets

PA Criteria	Criteria Details

Required Medical Information	**Chronic Myelogenous/Myeloid Leukemia:**
	• Diagnosis of Philadelphia chromosome-positive chronic myelogenous/myeloid leukemia (Ph+ CML) AND
	• One of the following:
	  ○ Disease is in the accelerated or blast phase OR
	  ○ Disease is in the chronic phase and patient is 1 year of age or older
	• One of the following:
	  ○ Trial and failure or intolerance to generic imatinib
	  ○ Continuation of prior therapy

Age Restrictions	
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Patient does not show evidence of progressive disease while on therapy

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

BUPRENORPHINE PATCH

Products Affected

- BUPRENORPHINE PATCH

PA Criteria	Criteria Details
Required Medical Information	**Cancer or End-of-Life Care:** Patient is being treated for cancer related pain or pain associated with end-of-life **AND** documented trial and failure of scheduled short-acting opioid therapy **AND** documented trial and failure of, contraindication to long-acting morphine sulfate therapy **AND** documented trial/failure of, or reason why fentanyl is not appropriate. **Other Chronic Pain:** Documented above the line diagnosis, FDA indicated, or guideline supported condition **AND** documented severe chronic pain (greater than 3mo) that is severe enough to require around the clock analgesic therapy **AND** documented trial and failure or contraindication to short-acting opioid therapy **AND** documented trial and failure of, or contraindication to long-acting morphine sulfate therapy **AND** documented trial and failure of, or reason why fentanyl is not appropriate.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial cancer/end of life:** 12 months. **Renewal**: 12 months. **Initial non-cancer/end of life:** 6 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Certolizumab Pegol SC (CIMZIA)

Products Affected

- **CIMZIA**
- **CIMZIA PREFILLED**
- **CIMZIA STARTER KIT**

PA Criteria	Criteria Details

Required Medical Information	**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:
	  o Back pain and stiffness for more than 3 months AND
	  o Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive AND
	  o 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:
	  o At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND
	  o Physical therapy/exercise program
	• Trial and failure of both infliximab and adalimumab
	
	Crohn's Disease (CD):
	• Documentation of moderate-to-severe Crohn's Disease
	• 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: 6-mercaptopurine, azathioprine, corticosteroid, methotrexate
	• Trial and failure of both infliximab and adalimumab
	
	Plaque Psoriasis (PP):
	• 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

PA Criteria	Criteria Details
	(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 • 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 o At least 1 other second line systemic agent such as cyclosporine or acitretin • Trial and failure of both infliximab and adalimumab **Psoriatic Arthritis (PsA):** • 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 • 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: o NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND o Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine • Trial and failure of both infliximab and adalimumab **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

PA Criteria	Criteria Details
	(dosed at least 20mg per week for at least 8 weeks), leflunomide or sulfasalazine • Trial and failure of both infliximab and adalimumab
Age Restrictions	
Prescriber Restrictions	**Crohn's Disease:** Gastroenterologist. **Plaque Psoriasis:** Dermatologist. **Psoriatic Arthritis:** Dermatologist or Rheumatologist. **Rheumatoid Arthritis, Juvenile Idiopathic Arthritis**: Rheumatologist. **Ankylosing Spondylitis**, Axial Spondyloarthritis: Rheumatologist.
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
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. **PP:** 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.

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

Chloroquine Phosphate (ARALEN)

Products Affected

- CHLOROQUINE PHOSPHATE

PA Criteria	Criteria Details
Required Medical Information	Treatment of Malaria or Extraintestinal amebiasis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 3 months.
Renewal Criteria	

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

Cinacalcet Hydrochloride (SENSIPAR)

Products Affected

- CINACALCET HCL

PA Criteria	Criteria Details
Required Medical Information	Treatment of secondary hyperparathyroidism in patients with chronic kidney disease (CKD) on dialysis. Treatment of hypercalcemia in patients with parathyroid carcinoma. Treatment of severe hypercalcemia in patients with primary hyperparathyroidism who are unable to undergo parathyroidectomy.
Age Restrictions	Patients 18 years of age and older.
Prescriber Restrictions	
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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:	

Conjugated Estrogens (Premarin Tablets)

Products Affected

- Premarin Tablets

PA Criteria	Criteria Details
Required Medical Information	**All FDA indicated or guideline supported diagnoses-** • Trial and failure of generic estradiol tablets and patches.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Lifetime**
Renewal Criteria	

Effective Date:	03/01/2024
P&T Approval Date:	01/09/2024
P&T Revision Date:	

Conjugated estrogens and medroxyprogesterone acetate (Prempro/Premphase)

Products Affected

- Prempro
- Premphase

PA Criteria	Criteria Details
Required Medical Information	**All FDA indicated or guideline supported diagnoses-** • Trial and failure of generic combination products OR estradiol tablets/patches used in combination with medroxyprogesterone capsules.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Lifetime**
Renewal Criteria	

Effective Date:	03/01/2024
P&T Approval Date:	01/09/2024
P&T Revision Date:	

Compounds (standard criteria for all compounded medications)

Products Affected

- All compounded medications

PA Criteria	Criteria Details
Required Medical Information	• The requested medication 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 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 two peer-reviewed literature 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 two FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless one of the following criteria are met: o Patient has a contraindication to commercially available products o Only one or no other therapeutic alternatives are commercially available o Prepared strength(s) is/are not commercially available or currently in short supply 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.
Age Restrictions	

PA Criteria	Criteria Details
Prescriber Restrictions	
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Clobazam (ONFI)

Products Affected

- Clobazam **10mg Tablets**
- Clobazam **20mg Tablets**
- Clobazam **2.5mg/mL suspension**

PA Criteria	Criteria Details
Required Medical Information	**Lennox-Gastaut Syndrome** • Confirmed diagnosis. **Refractory Seizures** • Documentation showing appropriate trial of 2 or more tolerated anticonvulsant therapies.
Age Restrictions	**Suspension:** ≥2 years of age and <10 years of age (or unable to use tablets)
Prescriber Restrictions	Neurologist
Coverage Duration	**Initial**: 12 months. **Renewal**: lifetime.
Renewal Criteria	Documentation of positive clinical response to therapy.

Effective Date:	7/1/2025
P&T Approval Date:	7/11/2023
P&T Revision Date:	3/11/2025, 3/12/2024, 7/11/2023

Continuous Glucose Monitors (CGM)

PA Criteria	Criteria Details
Required Medical Information	**Type 1 Diabetes Mellitus:** • Use of continuous insulin infusion via pump **OR** child or adolescent under the age of 21 **OR** member is pregnant or plans to become pregnant within 6 months **OR** using short or intermediate acting insulin **AND** the criteria listed under "applies to all requests" has been met. **Type 2 Diabetes Mellitus OR Gestational Diabetes:** • Using short or intermediate acting insulin **AND** the criteria listed under "applies to all requests" has been met. **Applies to all requests** • Must meet at least one of the following: o Baseline HbA1c levels great than or equal to 8.0% o Frequent or severe hypoglycemia o Impaired awareness of hypoglycemia (including presence of these conditions prior to initiation of CGM o 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** device the additional questions apply, must meet one of the following criteria: o Use of an insulin pump compatible with the requested Dexcom o Pediatric member under the age of 16 years old o Inability to use preferred Freestyle CGM device
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial:** 6 months. **Renewal:** 12 months.
Renewal Criteria	Use of CGM device for at least 50% of the time for a 90-day period by the time of their first follow-up visit (within 3-6 months) and provider visits

PA Criteria	Criteria Details
	within the last 6 months. **Note: two trials per yar of CGM are allowed to meet adherence for continuation of coverage.

Effective Date:	06/01/2022
P&T Approval Date:	05/08/2022
P&T Revision Date:	

Cyclosporine (GENGRAF) (NEORAL)

Products Affected

- CYCLOSPORINE
- CYCLOSPORINE MODIFIED
- **GENGRAF**
- **SANDIMMUNE**

PA Criteria	Criteria Details
Required Medical Information	Treatment of Solid Organ Transplant, Rheumatoid arthritis, or Psoriasis.
Age Restrictions	**Liquid only:** Member is under age 10 or unable to use tablets/capsules
Prescriber Restrictions	
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	**Renewal Criteria**: Documented positive clinical response to therapy

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

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 (EXJADE)

Products Affected

- DEFERASIROX

PA Criteria	Criteria Details
Required Medical Information	Patient has one of the following diagnoses: Chronic iron overload due to blood transfusion **OR** non-transfusion-dependent thalassemia syndromes **AND** patient has a creatinine clearance of greater than or equal to 40 mL/minute **OR** serum creatinine less than or equal to 2 times the age-appropriate level **AND** 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) **AND** patient has had a failure or contraindication to deferoxamine injection.
Age Restrictions	Patient is 2 years of age or older.
Prescriber Restrictions	
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Desmopressin (STIMATE)

Products Affected

- **Desmopressin Acetate Nasal Spray & Injections**

PA Criteria	Criteria Details
Required Medical Information	**Being used for one of the following:** • Diabetes Insipidus • Maintenance of hemostasis and control of bleeding in hemophilia A with factor VIII coagulant activity levels greater than 5% • Mild-to-moderate classic von Willebrand's disease (type 1) with factor VIII coagulant activity greater than 5%.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 12 months; **Renewal**: 12 months
Renewal Criteria	Documentation of positive clinical response to therapy.

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

Deutetrabenazine (AUSTEDO)

Products Affected

- Austedo 6mg TAB
- Austedo 9mg TAB
- Austedo 12mg TAB

PA Criteria	Criteria Details
Required Medical Information	**Chorea associated with Huntington's Disease:** Documentation of the degree of chorea present and the impact on functional ability and/or quality of life **AND** documentation of mental status, specifically depression and suicidality. **Tardive Dyskinesia:** Clinical documentation of tardive dyskinesia including 1) At least one month of past or current exposure to a dopamine receptor blocker, 2) Dyskinetic or dystonic involuntary movements, 3) Exclusion of other causes of abnormal movements **AND** clear documentation that tardive dyskinesia causes functional impairment **AND** documentation of the degree of tardive dyskinesia with the AIMS scale as a baseline. **AND** discontinuation of the medication precipitating TD **OR** 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 **OR** evidence the medications precipitating tardive dyskinesia are medically necessary **AND** trial and failure or contraindication to clonazepam and amantadine.
Age Restrictions	Age 18 and older
Prescriber Restrictions	**Huntington's Disease**: neurologist **Tardive Dyskinesia:** neurologist or psychiatrist
Coverage Duration	**Initial**: 3 months. **Renewal**: 12 months.
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.

Effective Date:	07/01/2023

P&T Approval Date:	05/09/2023
P&T Revision Date:	05/09/2023

Dihydroergotamine (MIGRANAL)

Products Affected

- DIHYDROERGOTAMINE MESYLATE INJ

PA Criteria	Criteria Details
Required Medical Information	Treatment of migraine headache with or without aura **OR** treatment of cluster headaches **AND** patient has tried and failed or has a contraindication to a formulary serotonin 5-HT1B, 1D receptor agonist.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Dimethyl Fumarate (TECFIDERA)

Products Affected

- DIMETHYL FUMARATE
- DIMETHYL FUMARATE STARTER PACK

PA Criteria	Criteria Details
Required Medical Information	**Multiple sclerosis:** Patient is diagnosed with relapsing forms of multiple sclerosis.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by a neurologist.
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Dipeptidyl Peptidase 4 (DPP-4) Inhibitor Step Therapy

Products Affected

- Janumet
- Janumet XR
- Januvia
- Kombiglyze XR
- Onglyza
- Tradjenta

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

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

Direct-Acting Antivirals (use in Hepatitis C)

Products Affected

- MAVYRET
- VOSEVI
- SOFOSBUVIR-VELPATASVIR

<table>
<tr><th>PA Criteria</th><th>Criteria Details</th></tr>
<tr><td>Required Medical Information</td><td>
PA is only required if the patient has previously been treated for hepatitis C.
Treatment of Hepatitis C infection:
• Appropriate pre-treatment testing
  ○ 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
• Has the patient been treated with a direct acting antiviral regimen previously
• Did patient achieve a sustained virological response (SVR) at week 12 or longer following the completion of their last DAA regimen
• Is this 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), OR
  ○ 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.
<u>Table 1. Recommended Regimens for Adults and adolescents 12 years of age and older</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="3">Treatment naïve</td><td>Non-cirrhotic</td><td>SOF/VEL x 12 weeks
G/P x 8 weeks</td></tr>
<tr><td>Compensated cirrhosis</td><td>G/P x 8 weeks
SOF/VEL x 12 weeks (baseline resistance testing recommended for GT3)</td></tr>
<tr><td>Decompensated cirrhosis</td><td>SOF/VEL + RBV x 12 weeks
SOF/VEL x 24 weeks (if RBV ineligible)</td></tr>
</table>
<table>
<tr><td colspan="3">Treatment Experienced (Genotype 1-6)</td></tr>
<tr><td><u>Sofosbuvir based regimen treatment failures, including</u>: sofosbuvir + ribavirin</td><td>Non-cirrhotic or compensated cirrhosis</td><td>SOF/VEL/VOX x 12 weeks G/P x16 weeks (except GT3)</td></tr>
</table>
</td></tr>
</table>

PA Criteria	Criteria Details

Ledipasvir/Sofosbuvir Velpatasvir/sofosbuvir		
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: Sofosbuvir/velpatasvir/voxilaprevir Glecaprevir/pibrentasvir + sofosbuvir	Non-Cirrhotic or compensated cirrhosis	G/P + SOF + RBV x 16-24 weeks SOF/VEL/VOX x24 weeks

Table 2. Recommended Regimens for children 3-12 years of age

Treatment History	Cirrhosis Status	Recommended Regimen
Treatment Naïve (Genotype 1-6)		
Treatment Naive	Non-cirrhotic or compensated cirrhosis	SOF/VEL x 12 weeks G/P x 8 weeks
	Decompensated cirrhosis	SOF/VEL + RBV x 12 weeks

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
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
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

Age Restrictions	
Prescriber Restrictions	
Coverage Duration	8-24 weeks
Renewal Criteria	

Effective Date:	12/01/2022
P&T Approval Date:	11/08/2022
P&T Revision Date:	

Disposable Insulin Pump (Omnipod)

Products Affected

- Omnipod 5
- Omnipod Dash

PA Criteria	Criteria Details

Required Medical Information	**Insulin dependent diabetes mellitus – pediatric (under age 18)**
	• 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).
	
	Insulin dependent diabetes mellitus – adult
	• All of the above pediatric requirements AND
	• Documentation of 1 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.

Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months
Renewal Criteria	Clinical documentation of positive clinical response to therapy and in-person visit with provider within the last 6 months.

Effective Date:	03/01/2024
P&T Approval Date:	01/09/2024
P&T Revision Date:	

Donepezil Hydrochloride (ARICEPT)

Products Affected

- DONEPEZIL HCL

PA Criteria	Criteria Details
Required Medical Information	Treatment of mild, moderate, or severe dementia of the Alzheimer's type. Alzheimer's disease, Prophylaxis - Impaired cognition (Mild). Multi-infarct dementia.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Dronabinol (MARINOL)

Products Affected

- DRONABINOL

PA Criteria	Criteria Details
Required Medical Information	**Nausea and Vomiting Associated with Cancer Chemotherapy (CINV):** Failure, contraindication, or intolerance to one 5HT-3 receptor antagonist (e.g., Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]) **AND** failure, contraindication, or intolerance to one of the following: Compazine (prochlorperazine), Decadron (dexamethasone), Haldol (haloperidol), Zyprexa (olanzapine). **AIDS anorexia:** Diagnosis of anorexia with weight loss in patients with AIDS **AND** patient is on antiretroviral therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	**Renewal Criteria**: Documented positive clinical response to therapy

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

Dupilumab (DUPIXENT)

Products Affected

- **DUPIXENT**

PA Criteria	Criteria Details

Required Medical Information	**Moderate to Severe Asthma:**
	• Documentation of inadequate control of asthma symptoms with one of the following:
	  ○ inhaled corticosteroids and long acting beta2 agonist **OR**
	  ○ inhaled corticosteroids and long-acting muscarinic antagonist.
	
	Atopic Dermatitis:
	• 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.
	
	Eosinophilic Esophagitis:
	• Confirmed diagnosis of EoE
	• 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.
	
	Chronic Rhinosinusitis with Nasal Polyps (CRSwNP):
	• Diagnosis of CRSwNP, including objective evidence of the presence of bilateral nasal polyps

PA Criteria	Criteria Details

	• 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).
	
	Prurigo Nodularis (PN):
	• 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).
	
	Chronic Obstructive Pulmonary Disease (COPD):
	• 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].

PA Criteria	Criteria Details
Age Restrictions	**Moderate to Severe Asthma:** 6 years and older **Atopic Dermatitis:** 6 months and older **Eosinophilic Esophagitis:** 1 year and older **CRSwNP:** 12 years and older **Prurigo Nodularis:** 18 years and older **COPD:** 18 years and older
Prescriber Restrictions	**Atopic dermatitis**: Dermatologist **Eosinophilic Esophagitis**: Gastroenterologist or Immunologist **CRSwNP**: ENT or Immunologist **Prurigo Nodularis**: Dermatologist **Asthma/COPD:** Pulmonologist
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

Effective Date:	03/01/2025
P&T Approval Date:	11/08/2022
P&T Revision Date:	1/14/2025

Elagolix (ORLISSA)

Products Affected

- **ORILISSA TAB 150MG**
- **ORILISSA TAB 200MG**

PA Criteria	Criteria Details
Required Medical Information	Diagnosis of moderate to severe pain associated with endometriosis **AND** trial and failure, contraindication, or intolerance to a 3-month trial of prescription strength NSAIDs **AND** trial and failure, contraindication, or intolerance to two 3-month trials of hormonal therapies (e.g. combined oral contraceptives, progestins, or levonorgestrel IUD, etc.). **Additional info required for 200 mg tablet twice daily:** documentation of coexisting dyspareunia
Age Restrictions	At least 18 years old but not yet through menopause
Prescriber Restrictions	Prescribed by obstetrician or gynecologist
Coverage Duration	**200MG dose**: **Initial**: 6 months; **Renewal**: No **Renewal**s allowed **150MG dose: Initial**: 6 months; **Renewal**: 18months
Renewal Criteria	**150MG ONLY:** Documentation of positive clinical response to therapy **AND** total therapy durations is less than 24 months.

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

Elexacaftor-tezacaftor-ivacaftor (TRIKAFTA)

Products Affected

- **TRIKAFTA**

PA Criteria	Criteria Details
Required Medical Information	**<u>Cystic Fibrosis</u>** • Documentation of cystic fibrosis diagnosis with at least one F508del mutation • Not used in combination with other CFTR modulator treatments
Age Restrictions	• 2 years of age and older
Prescriber Restrictions	Prescribed by pulmonologist
Coverage Duration	**Initial**: 6 months **Renewal**: 12 months
Renewal Criteria	Documented positive clinical response to therapy

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

Elefibranor (IQIRVO)

Products Affected

- **Iqirvo tablets**

PA Criteria	Criteria Details

Required Medical Information	**Primary biliary cholangitis:**
	• 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.

Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist or hepatologist.
Coverage Duration	**Initial**: 6 months **Renewal**: 12 months
Renewal Criteria	Documented positive clinical response to therapy

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

Epoetin Alpha (PROCRIT) (EPOGEN)

Products Affected

- **EPOGEN**
- **PROCRIT**

PA Criteria	Criteria Details
Required Medical Information	**Anemia due to Chronic Kidney Disease (CKD**): Anemia with hematocrit less than 30% or hemoglobin less than 10g/dL within 30 days of request **AND** patient is on dialysis **OR** 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. **Anemia in HIV Patients:** Anemia with hematocrit less than 36% or hemoglobin is less than 12 g/dL collected within 30 days of request, Serum erythropoietin less than or equal to 500mU/mL. Patient is receiving zidovudine therapy or diagnosed with HIV. **Anemia due to Chemotherapy:** Anemia with hematocrit less than 30% & hemoglobin less than 10 g/dL collected within the prior 2 weeks of request. All other causes of anemia have been ruled out, cancer is a non-myeloid malignancy **AND** patient is concurrently on chemo **OR** will receive concomitant chemo for a minimum of 2 months **OR** anemia is caused by cancer chemo (will not be approved if patient is not receiving cancer chemotherapy). **Preoperative for reduction of allogeneic blood transfusion:** Patient scheduled for an elective, non-cardiac, non-vascular surgery. Perioperative hemoglobin is greater than 10 to less than or equal to 13 g/dL **AND** patient is at high risk of blood loss **AND** patient is unwilling or unable to donate autologous blood pre-operatively. **Anemia in Myelodysplastic Syndrome (MDS):** Diagnosis of MDS. Serum erythropoietin less than or equal to 500mU/mL **OR** diagnosis of transfusion-dependent MDS.
Age Restrictions	
Prescriber Restrictions	

PA Criteria	Criteria Details
Coverage Duration	**Initial**: 3 months. Preop **Initial**: 1 month.
Renewal Criteria	Patient has a documented continued need for therapy demonstrated by an improvement in the hematocrit and hemoglobin levels or by a significant decrease in transfusion requirements.

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

Erenumab (AIMOVIG)

Products Affected

- **AIMOVIG 70 mg/mL**
- **AIMOVIG 140 mg/mL**

PA Criteria	Criteria Details
Required Medical Information	**Migraine prophylaxis:** Experiences at least 4 migraines per month **AND** trial and failure (defined as at least an 8-week trial) of 3 prophylactic medications from at least 2 different therapeutic classes including beta blockers, antidepressants, and anticonvulsants (e.g. propranolol, amitriptyline, topiramate). If the member has a diagnosis of chronic migraine (≥ 15 headache days & 8 migraine episodes per month) then trial and failure or intolerance to Botox.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	**Initial**: 3 months. **Renewal**: 6 months.
Renewal Criteria	Shows reduction in monthly headache days by at least 2 days from pre-CGRP treatment baseline. Clinical documented improvement in migraine-related disability.

Effective Date:	12/01/2022
P&T Approval Date:	11/08/2022
P&T Revision Date:	12/01/2022, 01/11/2022,

Erythromycin Gel & Solution

Products Affected

- Erythromycin 2% gel
- Erythromycin 2% solution

PA Criteria	Criteria Details
Required Medical Information	Documentation of trial and failure, intolerance, or contraindication to clindamycin 1% gel or solution
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Estradiol (ESTRING)

Products Affected

- Estring 2MG Vaginal Ring

PA Criteria	Criteria Details
Required Medical Information	Trial and failure of estradiol vaginal cream and estradiol vaginal tablet
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

Effective Date:	07/01/2023
P&T Approval Date:	05/09/2023
P&T Revision Date:	05/09/2023

Etrasimod arginine (Velsipity)

Products Affected

- Velsipity tablets

PA Criteria	Criteria Details

Required Medical Information	**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)
	• Trial and failure of both infliximab and adalimumab

Age Restrictions	Must be at least 18 years of age
Prescriber Restrictions	Prescribed by or in collaboration with a Gastroenterologist
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
Renewal Criteria	Evidence of a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission.

Effective Date:	03/01/2024
P&T Approval Date:	01/09/2024
P&T Revision Date:	

Etanercept (ENBREL)

Products Affected

- ENBREL **25/0.5ML, 50MG/ML**
- ENBREL SURECLICK **50MG/ML**

PA Criteria	Criteria Details

Required Medical Information	**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 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 both infliximab and adalimumab
	
	Plaque Psoriasis (PP):
	• 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:

PA Criteria	Criteria Details
	○ 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 both infliximab and adalimumab **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 • Trial and failure of both infliximab and adalimumab **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 both infliximab and adalimumab
Age Restrictions	

PA Criteria	Criteria Details
Prescriber Restrictions	**Plaque Psoriasis:** Dermatologist. **Psoriatic Arthritis:** Dermatologist or Rheumatologist. **Rheumatoid Arthritis**: Rheumatologist. **Ankylosing Spondylitis**, **Axial Spondyloarthritis**: Rheumatologist.
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
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. **PP:** 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.

Effective Date:	9/1/2023
P&T Approval Date:	7/11/2023
P&T Revision Date:	07/11/2023, 01/11/2022

Fezolinetant (VEOZAH)

Products Affected

- Veozah **TAB 45MG**

PA Criteria	Criteria Details
Required Medical Information	**Vasomotor Symptoms (VMS):** • Diagnosis of moderate-to-severe VMS due to menopause • Documented contraindication, intolerance, or inadequate response to at least 2 hormonal therapies AND • Documented contraindication, intolerance, or inadequate response to two nonhormonal therapies (e.g., one SNRI and one SSRI).
Age Restrictions	
Prescriber Restrictions	Gynecologist
Coverage Duration	**Initial**: 3 months. **Renewal**: 12 months.
Renewal Criteria	Documentation of at least 50% reduction in VMS from baseline.

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

Filgrastim (NEUPOGEN)

Products Affected

- **NEUPOGEN**

PA Criteria	Criteria Details
Required Medical Information	**Bone marrow/stem cell transplant (BMSCT):** Prescribed for non-myeloid malignancies & undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant **OR** for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis **OR** for peripheral stem cell transplant patients who have received myeloablative chemotherapy. **Acute myeloid leukemia (AML):** Patients diagnosed with AML following induction or consolidation chemotherapy. **Primary prophylaxis of chemotherapy-induced febrile neutropenia (CFN):** Patients receiving chemotherapy associated with greater than 20% incidence of febrile neutropenia **OR** selected chemotherapy regimen associated with 10-20% incidence of febrile neutropenia **AND** one or more risk factors associated with chemotherapy-induced infection, febrile neutropenia, or neutropenia. **Secondary prophylaxis of febrile neutropenia**: Patient has a history of febrile neutropenia with previous chemotherapy **AND** is receiving myelosuppressive chemotherapy associated with neutropenia (ANC less than 500 cells/mm^3). **Neutropenia associated with dose dense chemotherapy (NDDC):** Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer **OR** patient is receiving a dose-dense chemotherapy regimen and the incidence of febrile neutropenia is unknown. **Severe chronic neutropenia (SCN):** Diagnosed with congenital, cyclic, and idiopathic neutropenia with chronic ANC less than or equal to 500 cells/mm^3. **Febrile Neutropenia (FN):** Patient receiving myelosuppressive chemotherapy associated with neutropenia (ANC less than or equal to 500 cells/mm^3) **AND** is at high risk for infection-associated complications.

PA Criteria	Criteria Details
	Acute radiation syndrome (ARS): Patient is/was acutely exposed to myelosuppressive doses of radiation.
Age Restrictions	
Prescriber Restrictions	Prescribed by hematologist or oncologist.
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Fingolimod (GILENYA)

Products Affected

- **GILENYA**

PA Criteria	Criteria Details
Required Medical Information	Diagnosis of relapsing forms of multiple sclerosis
Age Restrictions	
Prescriber Restrictions	Neurologist
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Fluorouracil, topical (EFUDEX, FLUOROPLEX)

Products Affected

- FLUOROURACIL **CRE 5%**
- FLUOROURACIL **SOL 2%**
- FLUOROURACIL **SOL 5%**

PA Criteria	Criteria Details
Required Medical Information	Diagnosis of superficial basal cell carcinoma with multiple lesions and/or difficult to treat areas.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Galcanezumab-gnlm (EMGALITY)

Products Affected

- Emgality **120MG dose**
- Emgality **300MG dose**

PA Criteria	Criteria Details
Required Medical Information	**Diagnosis of cluster headache:** None 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, peripheral vascular disease **AND** tried and failed a 3-month trial of verapamil and topiramate. **Migraine prophylaxis:** Experiences at least 4 migraines per month **AND** trial and failure (defined as at least an 8-week trial) of 3 prophylactic medications from at least 2 different therapeutic classes including beta blockers, antidepressants, and anticonvulsants (e.g. propranolol, amitriptyline, topiramate). If the member has a diagnosis of chronic migraine (≥ 15 headache days & 8 migraine episodes per month) then trial and failure or intolerance to Botox.
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	**Initial**: 3 months **Renewal**: 6 months
Renewal Criteria	**Cluster Headache:** Documented positive clinical response to therapy **Migraine:** shows reduction in monthly headache days by at least 2 days from pre-CGRP treatment baseline. Clinical documented improvement in migraine-related disability.

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

General Oncology (Chemotherapy)

Products Affected

- Abemaciclib (Verzenio)
- Abiraterone
- Acalabrutinib (Calquence)
- Adagrasib (Krazati)
- Alectinib (Alecensa)
- Alpelisib (Piqray)
- Ascinimib (Scemblix)
- Asparaginase Erwinia (Rylaze)
- 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
- Elacestrant (Orserdu)
- Encorafenib (Braftovi)
- Entrectinib (Rozlytrek)
- Erlotinib
- Estramustine (Emcyt)
- Everolimus
- Fruquintinib (Fruzaqla)
- Futibatinib (Lytgobi)
- Gefitinib
- Ibrutinib (Imbruvica)
- Inavolisib (Itovebi)
- Infigratinib (Truseltiq)
- Ivosidenib (Tibsovo)
- Lazertinib (Lazcluze)
- Lenvatinib (Lenvima)
- Lomustine (Gleostine)
- Lorlatinib (Lobrena)
- Midostaurin (Rydapt)
- Mobocertinib (Exkivity)
- Nilotinib (Tasigna)
- Niraparib/Abiraterone (Akeega)
- Nirogacestat (Ogsiveo)
- Olaparib (Lynparza)
- Olutasidenib (Rezlidhia)
- Osimertinib (Tagrisso)
- Pacritinib (Vonjo)
- Palbociclib (Ibrance)
- Pazopanib
- Pemigatinib (Pemazyre)
- Pirtobrutinib (Jaypirca)
- Ponatinib (Iclusig)
- Quizartinib (Vanflyta)
- Repotrectinib (Augtyro)
- Ribociclib (Kisqali)
- Selpercatinib (Retevmo)
- Sorafenib
- Sotorasib (Lumakras)
- Sunitinib
- Talazoparib (Talzenna)
- Temozolomide
- Tepotinib (Tepmetko)
- Tivozanib (Fotivda)
- Topotecan (Hycamtin)
- Tovorafenib (Ojemda)
- Trametinib (Mekinist)
- Trifluridine/Tipiracil (Lonsurf)
- Tucatinib (Tukysa)
- Vimseltinib (Romvimza)
- Vorasidinib (Voranigo)
- Vorinostat (Zolinza)
- Zanubrutinib (Brukinsa)

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>**
	• 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:	7/1/2025
P&T Approval Date:	10/01/2022
P&T Revision Date:	3/11/2025, 5/14/2024, 03/01/2024, 01/09/2024, 11/1/2023, 09/01/2023, 7/11/2023, 05/09/2023, 03/14/2023, 01/10/2023, 10/01/2022

Glatiramer (GLATOPA)

Products Affected

- **GLATIRAMER INJ 20MG/ML**
- **GLATIRAMER INJ 40MG/ML**

PA Criteria	Criteria Details
Required Medical Information	Diagnosis of relapsing forms of multiple sclerosis
Age Restrictions	
Prescriber Restrictions	Prescribed by Neurologist
Coverage Duration	**Initial**: 12 months. **Renewal**: up to 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Glucagon-Like Peptide-1 (GLP-s) Receptor Agonist

Products Affected

- BYDUREON BCISE
- BYETTA **10 MCG PEN**
- BYETTA **5 MCG PEN**
- TRULICITY
- VICTOZA

PA Criteria	Criteria Details
Required Medical Information	**Type 2 diabetes:** • Documentation of clinically diagnosed Type 2 Diabetes. • Documentation of adequate trial of maximally tolerated dose of metformin. • Documentation of trial and failure of an SGLT-2 inhibitor or a DPP-4 inhibitor (or contraindication to both.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 12 months, **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Golimumab (SIMPONI)

Products Affected

- SIMPONI **50/0.5ML, 100MG/ML**

PA Criteria	Criteria Details

Required Medical Information	**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 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 both infliximab and adalimumab
	
	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:

PA Criteria	Criteria Details
	○ 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 both infliximab and adalimumab **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 both infliximab and adalimumab **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) ○ Trial and failure of both infliximab and adalimumab
Age Restrictions	
Prescriber Restrictions	**Ulcerative Colitis:** Gastroenterologist. **Psoriatic Arthritis:** Dermatologist or Rheumatologist. **Rheumatoid Arthritis**: Rheumatologist. **Ankylosing Spondylitis, Axial Spondyloarthritis:** Rheumatologist.
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
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. **PsA:** Evidence of a 20% or greater improvement in tender joint count and swollen joint count.

PA Criteria	Criteria Details
	RA: Evidence of a 20% or greater improvement in tender joint count and swollen joint count. **UC:** Evidence of a significant response such as a decrease in bloody stools per day or elimination of signs of toxicity.

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

Gonadotropin-Releasing Hormone Agonists

Products Affected

- **Lupron**

PA Criteria	Criteria Details

Required Medical Information	**Endometriosis**
	• 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
	
	Uterine Leiomyomata (Fibroids) – For the reduction of the size of fibroids
	• For use prior to surgery to reduce the size of fibroids to facilitate a surgical procedure (e.g., myomectomy, hysterectomy)
	
	Uterine Leiomyomata (Fibroids) – Anemia
	• 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
	
	Central Precocious Puberty (CPP)
	• 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:

PA Criteria	Criteria Details
	○ 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 **Prostate Cancer** • Diagnosis of advanced or metastatic prostate cancer **Gender Dysphoria/Gender Incongruence** • Using gonadotropin for suppression of puberty • Diagnosis of gender dysphoria/gender incongruence
Age Restrictions	
Prescriber Restrictions	**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.
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.

Effective Date:	07/01/2024
P&T Approval Date:	05/14/2024
P&T Revision Date:	05/14/2024, 01/10/2023

Grass Pollen Allergen Extract -Timothy Grass (GRASTEK)

Products Affected

- GRASTEK

PA Criteria	Criteria Details
Required Medical Information	Patient has a diagnosis of grass pollen-induced allergic rhinitis.
Age Restrictions	
Prescriber Restrictions	Prescribed by an Allergy or Immunology specialist.
Coverage Duration	**Initial**: 3 months. **Renewal**: 3 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Inclisiran (LEQVIO)

Products Affected

- Leqvio solution

PA Criteria	Criteria Details

Required Medical Information	**Established clinical ASCVD:**
	• 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 that:
	  ○ Patient is receiving maximally tolerated statin therapy (atorvastatin 40-80mg, rosuvastatin 20-40mg) or has a documented clinical intolerance to statins **AND**
	  ○ Is receiving ezetimibe or has a documented intolerance to ezetimibe.
	• Documentation of failure of PCSK9 inhibitor (Repatha or Praluent).
	
	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 that:
	  ○ Patient is receiving maximally tolerated statin therapy (atorvastatin 40-80mg, rosuvastatin 20-40mg) or has a documented clinical intolerance to statins **AND**
	  ○ Is receiving ezetimibe or has a documented intolerance to ezetimibe.
	• Documentation of failure of PCSK9 inhibitor (Repatha or Praluent).

Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist.
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy (significant decrease in lipid levels).

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

Insulin Degludec (TRESIBA)

Products Affected

- TRESIBA **FLEXTOUCH**

PA Criteria	Criteria Details
Required Medical Information	**(both U-100 & U-200)** Must have tried and failed insulin glargine or have documented intolerance or contraindication to insulin glargine **AND** have significant barriers to standardized administration requiring flexibility in dose timing. **(U-200)** Patient must require greater than 160 units of insulin per dose **AND** have difficulty with multiple daily injections.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Insulin U-500

Products Affected

- Humulin R U-500 pens and vials

PA Criteria	Criteria Details
Required Medical Information	Attestation that the use of U-500 insulin is medically safe and appropriate.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: Lifetime
Renewal Criteria	

Effective Date:	03/01/2025
P&T Approval Date:	01/14/2025
P&T Revision Date:	01/14/2025

Interferon beta-1a (AVONEX)

Products Affected

- **AVONEX PEN**
- **AVONEX PREFILLED**

PA Criteria	Criteria Details
Required Medical Information	Diagnosis of a relapsing form of Multiple Sclerosis **AND** Trial and failure, contraindication, or intolerance to all of the following: • dimethyl fumarate • fingolimod • glatiramer acetate/glatopa
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Interferon beta-1a (REBIF)

Products Affected

- REBIF **INJ 22/0.5ML**
- REBIF **INJ 44/0.5ML**
- REBIF REBIDO **INJ 22/0.5**
- REBIF REBIDO **INJ 44/0.5**

PA Criteria	Criteria Details
Required Medical Information	Diagnosis of relapsing forms of multiple sclerosis **AND** trial and failure, contraindication, or intolerance to all of the following: dimethyl fumarate, fingolimod, glatiramer acetate/glatopa, avonex.
Age Restrictions	
Prescriber Restrictions	Neurologist
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Interferon beta-1b (EXTAVIA)

Products Affected

- EXTAVIA **INJ 0.3MG**

PA Criteria	Criteria Details
Required Medical Information	Diagnosis of relapsing forms of multiple sclerosis **AND** trial and failure, contraindication, or intolerance to all of the following: dimethyl fumarate, fingolimod, glatiramer acetate/glatopa.
Age Restrictions	
Prescriber Restrictions	Neurologist
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Itraconazole (SPORANOX)

Products Affected

- ITRACONAZOLE **ORAL SOLUTION**

PA Criteria	Criteria Details
Required Medical Information	**Tinea Unguium:** • Patient is experiencing pain which limits normal activity (i.e., unable to wear shoes, difficulty walking, etc.), **OR** Patient has diabetes, **OR** patient has peripheral vascular disease, **OR** patient is immunocompromised. **All other conditions:** • Diagnosis is supported by compendia and is an above the line condition.
Age Restrictions	Member is under age 10 or unable to use tablets
Prescriber Restrictions	
Coverage Duration	**Initial**: 3 months. **Renewal**: 3 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Iron sulfate (Ferrous Sulfate)

Products Affected

- **Ferrous Sulfate 300mg/5mL**

PA Criteria	Criteria Details
Required Medical Information	Documentation of inability to use ferrous sulfate tabs or 200mg/5mL liquid
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Lifetime approval
Renewal Criteria	

Effective Date:	01/01/2024
P&T Approval Date:	11/14/2023
P&T Revision Date:	

Ivacaftor (KALYDECO)

Products Affected

- KALYDECO

PA Criteria	Criteria Details
Required Medical Information	Diagnosis of Cystic Fibrosis with documentation showing at least one CFTR gene mutation that has shown to be responsive to Kalydeco.
Age Restrictions	6 months of age and older
Prescriber Restrictions	Prescribed by pulmonologist
Coverage Duration	**Initial**: 3 months **Renewal**: 6 months
Renewal Criteria	Documentation of improved or stable lung function, shown by FEV1 improvement or a reduction in pulmonary exacerbations

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

Ivermectin (STROMECTOL)

Products Affected

- IVERMECTIN

PA Criteria	Criteria Details
Required Medical Information	Treatment of FDA approved diagnosis including Strongyloidiasis, Onchocerciasis, Infestation by Phthirus pubis, Scabies, Enterobiasis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months, **Renewal**s: reinfection 6 months
Renewal Criteria	Documented positive clinical response to therapy

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

Ixekizumab (TALTZ)

Products Affected

- TALTZ **80MG/ML (auto-injector and prefilled syringe)**

PA Criteria	Criteria Details
Required Medical Information	**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: o Back pain and stiffness for more than 3 months AND o Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive AND o 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: o At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND o Physical therapy/exercise program • Trial and failure of both infliximab and adalimumab **Plaque Psoriasis (PP):** • 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 • 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:

PA Criteria	Criteria Details
	○ 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 both infliximab and adalimumab **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 • Trial and failure of both infliximab and adalimumab
Age Restrictions	
Prescriber Restrictions	**Plaque Psoriasis:** Dermatologist. **Psoriatic Arthritis:** Dermatologist or Rheumatologist. **Ankylosing Spondylitis**, Axial Spondyloarthritis: Rheumatologist.
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
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. **PP:** Evidence of positive clinical response to therapy as evidenced by ONE of the following: reduction of body surface area (BSA) involvement from

PA Criteria	Criteria Details
	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.

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

Lacosamide (VIMPAT)

Products Affected

- Lacosamide **TAB 50MG, 100MG, 150MG, 200MG**
- Lacosamide **Solution 10MG/ML**

PA Criteria	Criteria Details
Required Medical Information	**Focal seizures OR Primary generalized tonic-clonic seizures**: • Documented epilepsy or seizure disorder
Age Restrictions	**Solution only:** Member is under age 10 or unable to use tablets
Neurology	Neurologist
Coverage Duration	**Initial**: 12 months. **Renewal**: lifetime.
Renewal Criteria	Documentation of positive clinical response to therapy.

Effective Date:	7/1/2025
P&T Approval Date:	7/11/2023
P&T Revision Date:	3/11/2025, 3/12/2024, 7/11/2023

Lanthanum Carbonate (FOSRENOL)

Products Affected

- Lanthanum carbonate **500MG**
- Lanthanum carbonate **750MG**
- Lanthanum carbonate **1000MG**

PA Criteria	Criteria Details
Required Medical Information	Diagnosis of hyperphosphatemia in chronic kidney disease **AND** trial and failure, contraindication, or intolerance (at least 6 weeks) to both maximally tolerated calcium acetate and sevelamer carbonate
Age Restrictions	6 years or older
Prescriber Restrictions	Nephrologist
Coverage Duration	**Lifetime**
Renewal Criteria	Documentation of positive clinical response to therapy.

Effective Date:	07/01/2023
P&T Approval Date:	05/09/2023
P&T Revision Date:	05/09/2023

Lasmiditan (REYVOW)

Products Affected

- Reyvow **50MG TAB**
- Reyvow **100MG TAB**

PA Criteria	Criteria Details
Required Medical Information	Diagnosis of migraine **AND** documentation patient is on preventative therapy **AND** trial and failure (defined as trial period of 6 weeks per agent) or contraindication to at least 3 generic oral formulary triptans use at up to the maximally indicated dosing and in combination with NSAID therapy (naproxen)
Age Restrictions	Patient is 18 years of age or older
Prescriber Restrictions	Prescribed by neurologist or headache specialist
Coverage Duration	**Initial**: 3 months **Renewal**: 6 months
Renewal Criteria	Documented positive clinical response to therapy

Effective Date:	07/01/2023
P&T Approval Date:	05/09/2023
P&T Revision Date:	05/09/2023

Lebrikizumab (EBGLYSS)

Products Affected

- Ebglyss autoinjector
- Ebglyss prefilled syringe

PA Criteria	Criteria Details

Required Medical Information	**Atopic dermatitis:**
	• 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.

Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist.
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy.

Effective Date:	01/01/2025
P&T Approval Date:	11/12/2024
P&T Revision Date:	11/12/2024

Lenacapavir (SUNLENCA)

Products Affected

- SULENCA THERAPY PACK
- SULENCA SUBCUTANEOUS 463.5MG/1.5mL ***(must be billed to medical benefit)***

PA Criteria	Criteria Details
Required Medical Information	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 **AND** will be used in combination with an optimized baseline regimen (OBR) **AND** current ARV regimen has been stable for at least 2 months and HIV-1 RNA is ≥400 copies/mL
Age Restrictions	≥ 18 years
Prescriber Restrictions	HIV Specialist
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
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

Effective Date:	4/1/2023
P&T Approval Date:	03/14/2023
P&T Revision Date:	03/14/2023

Lidocaine Topical Anesthetic (LIDODERM)

Products Affected

- LIDOCAINE EXTERNAL PATCH

PA Criteria	Criteria Details
Required Medical Information	Diagnosis of post-herpetic neuralgia.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 3 months. **Renewal**: 3 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Lisdexamfetamine (VYVANSE)

Products Affected

- **LISDEXAMFETAMINE CAPS**

PA Criteria	Criteria Details
Required Medical Information	**ADHD:** Prior trial (30-day trial) of an extended-release amphetamine product (amphetamine salts ER, dextroamphetamine ER, etc.) and an extended-release methylphenidate product (dexmethylphenidate ER, methylphenidate ER). **BED:** Clinical documentation confirming binge eating disorder diagnosis per DSM-5 criteria. Trial and failure of at least two therapeutic alternatives including SSRIs, topiramate, and/or methylphenidate.
Age Restrictions	**BED**: 18 years of age or older
Prescriber Restrictions	
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

Effective Date:	03/01/2025
P&T Approval Date:	01/14/2025
P&T Revision Date:	01/14/2025

Long Acting Opiates and Dolophine

Products Affected

- FENTANYL PATCH 72 HOUR **100 MCG/HR; 12 MCG/HR; 25 MCG/HR; 37.5 MCG/HR; 50 MCG/HR; 62.5 MCG/HR; 75 MCG/HR; 87.5 MCG/HR TRANSDERMAL**
- HYDROCODONE BITARTRATE ER CAPSULE EXTENDED RELEASE 12 HOUR **10 MG**; **15 MG; 20 MG; 30 MG; 40 MG; 50 MG ORAL**
- HYDROCODONE BITARTRATE ER ORAL TABLET ER 24 HOUR ABUSE-DETERRENT
- HYDROMORPHONE HCL ER
- METHADONE HCL ORAL TABLET
- MORPHINE SULFATE ER BEADS CAPSULE EXTENDED RELEASE 24 HOUR **120 MG; 30 MG; 45 MG; 60 MG; 75 MG; 90 MG**
- MORPHINE SULFATE ER ORAL CAPSULE EXTENDED RELEASE 24 HOUR
- MORPHINE SULFATE ER ORAL TABLET EXTENDED RELEASE
- NUCYNTA ER
- OXYCODONE HCL ER
- OXYCONTIN
- OXYMORPHONE HCL ER
- XTAMPZA ER

PA Criteria	Criteria Details
Required Medical Information	**Cancer, end of life, or palliative care:** No coverage restrictions. **Non-cancer/end of life care:** Documented use of current and/or recent usage of short-acting opioids for at least 15 days prior to long-acting opioids. • For opioid naive (14 or fewer days filled in previous 120 days): 7-day maximum quantity limit; equal to or less than 50 MED [morphine equivalents per day]. • For opioid experienced (greater than or equal to 15 days filled in previous 120 days): equal to or less than 90 MED [morphine equivalents per day]. • Restricted to 2 fills in a 60-day period for both naive and experienced.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Lotilaner (Xdemvy)

Products Affected

- Xdemvy 0.25% Ophthalmic solution

PA Criteria	Criteria Details
Required Medical Information	**Diagnosis:** Demodex Blepharitis • 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
Age Restrictions	18 years of age and older
Prescriber Restrictions	Optometrist or Ophthalmologist
Coverage Duration	**Initial**: 6 weeks. **Renewal**: No renewals allowed
Renewal Criteria	N/A

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

Lumacaftor/ivacaftor (ORKAMBI)

Products Affected

- **ORKAMBI GRA 100-125**
- **ORKAMBI GRA 150-188**
- **ORKAMBI TAB 100-125**
- **ORKAMBI TAB 200-125**

PA Criteria	Criteria Details
Required Medical Information	Clinical documentation of cystic fibrosis diagnosis with homozygous F508del mutation.
Age Restrictions	2 years of age and older
Prescriber Restrictions	Prescribed by pulmonologist
Coverage Duration	**Initial**: 3 months **Renewal**: 6 months
Renewal Criteria	Documented positive clinical response to therapy

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

Mefloquine (LARIAM)

Products Affected

- MEFLOQUINE HCL

PA Criteria	Criteria Details
Required Medical Information	Malaria treatment.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 1 month.
Renewal Criteria	Documented positive clinical response to therapy

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

Memantine Hydrochloride (NAMENDA)

Products Affected

- MEMANTINE HCL

PA Criteria	Criteria Details
Required Medical Information	Treatment of moderate-to-severe dementia of the Alzheimer's type. **Solution only:** Documentation that member can't use tablets/capsules and is under the age of 10
Age Restrictions	**Solution only:** Documentation that member can't use tablets/capsules and is under the age of 10
Prescriber Restrictions	
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Mirikizumab-mrkz (OMVOH)

Products Affected

- Omvoh

PA Criteria	Criteria Details
Required Medical Information	**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 **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) • Trial and failure of both infliximab and adalimumab
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultations with a Gastroenterologist.
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
Renewal Criteria	Evidence of a significant response such as a decrease in bloody stools per day or elimination of signs of toxicity.

Effective Date:	07/01/2024
P&T Approval Date:	05/14/2024
P&T Revision Date:	

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
Prescriber Restriction	• N/A

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

- Pyrukynd

PA Criteria	Criteria Details
Required Medical Information	Diagnosis of PKD with at least two mutations within the PKLR gene, including a missense mutation **AND** confirmation of current hemoglobin is ≤ 10mg/dL **AND** patient is not homozygous for the R479H mutation **AND** does not have two non-missense variants in the PKLR gene, without the presence of another missense variant **AND** patient has had at least 6 RBC transfusions within the previous year for hemolytic anemia due to PKD **AND** prescriber confirmed concomitant use of daily folic acid **AND** confirmation that the patient does not have moderate or severe hepatic dysfunction.
Age Restrictions	At least 18 years of age
Prescriber Restrictions	Prescribed by or in consultations with a hematologist
Coverage Duration	**Initial**: 3 months. **Renewal**: 6 months.
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.

Effective Date:	08/01/2022
P&T Approval Date:	07/12/2022
P&T Revision Date:	

Mometasone (NASONEX)

Products Affected

- MOMETASONE FUROATE NASAL

PA Criteria	Criteria Details
Required Medical Information	Diagnosis of asthma or an above the line comorbid condition that may worsen if not treated **AND** inadequate treatment response, intolerance, or contraindication to fluticasone nasal spray, **AND** budesonide nasal spray **AND** triamcinolone nasal spray.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

Effective Date:	12/01/2022
P&T Approval Date:	11/08/2022
P&T Revision Date:	

Naltrexone (VIVITROL)

Products Affected

- **Vivitrol Inj.**

PA Criteria	Criteria Details
Required Medical Information	The drug will be dispensed directly to the provider and not the member.
Coverage Duration	**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

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:	

Non-Formulary Criteria (standard criteria for non-formulary medication)

Products Affected

- **All Non-formulary medications**

PA Criteria	Criteria Details

Required Medical Information	• The requested medication 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 under the age of 21.
	• The requested 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.
	• All appropriate formulary alternatives have been tried and failed or are contraindicated.
	• **If the request for a non-formulary medication to allow for an alternative dosage form of a formulary agent with *ALL* the following criteria being met:**
	  ○ **For a child age 10 years old or younger, or the member has documented inability to swallow formulary tablets/capsules**
	  ○ **formulary equivalent (tablet/capsule) does not require PA *OR* member meets coverage criteria for formulary equivalent (tablet/capsule)**

Age Restrictions	FDA indicated age limits (vary by drug)
Prescriber Restrictions	Appropriate Specialist (vary by drug)
Coverage Duration	**Initial**: 6 months **Renewal**: 12 months
Renewal Criteria	Clinical documentation of follow-up indicating safety, efficacy and medication adherence over previous approval duration.

Effective Date:	
P&T Approval Date:	

P&T Revision Date:	

Omalizumab (XOLAIR)

Products Affected

- **XOLAIR**

PA Criteria	Criteria Details
Required Medical Information	**Severe Asthma:** • 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**:** o High dose inhaled corticosteroid with a long-acting beta agonist (e.g., Advair), o Long acting anti-muscarinic (e.g., Spiriva)**,** o 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**:** o At least 2 intranasal corticosteroids (e.g., fluticasone, mometasone), o Sinuva. • Documentation that Xolair is intended as adjunct therapy with nasal corticosteroids. **Chronic Idiopathic Urticaria- refractory (CIU):** • 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)

PA Criteria	Criteria Details
	○ 2nd generation antihistamine – (e.g., cetirizine, levocetirizine, fexofenadine, loratadine, desloratadine) ○ Histamine Type-2 Receptor Antagonists (e.g., famotidine, cimetidine) ○ Leukotriene inhibitor (e.g., montelukast, zafirlukast) **IgE-Mediated Food Allergy:** • Diagnosis of IgE Mediated Food Allergy as evidenced by one of the following: ○ Positive skin prick test (defined as greater than or equal to 4 mm wheal greater than saline control) to food, ○ Positive food specific IgE (greater than or equal to 6 kUA/L), ○ 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: ○ 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, ○ 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.
Age Restrictions	**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 Restrictions	**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 - Initial:** 6 months. **Renewal**: 12 months. **CRSwNP - Initial:** 6 months. **Renewal**: 12 months. **CIU - Initial**: 4 months. **Renewal**: 6 months. **IgE Mediated Food Allergy - Initial:** 6 months. **Renewal**: 12 months.

PA Criteria	Criteria Details
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.

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

Oral Nutrition Supplements

Products Affected

PA Criteria	Criteria Details

Required Medical Information	• 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.

Exclusions	• 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
Prescriber Restrictions	
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
Renewal Criteria	Documentation of continued positive response for the requested enteral nutrition/formula with a continued need for requested supplement.

Effective Date:	01/01/2025
P&T Approval Date:	11/12/2024
P&T Revision Date:	11/12/2024

Pancrelipase (CREON) (PANCREAZE)

Products Affected

- **Creon Capsules**
- **Pancreaze Capsules**

PA Criteria	Criteria Details
Required Medical Information	Confirmed diagnosis of cystic fibrosis **OR** history of pancreatectomy **OR** diagnosis of exocrine pancreatic cancer **OR** diagnosis of chronic pancreatitis confirmed by imaging **OR** confirmed diagnosis of pancreatic insufficiency confirmed with one of the following methods: • Steatorrhea with fecal fat determination **OR** • Measurement of fecal elastase **OR** • Secretin or CCK pancreatic function testing **OR** • 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)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months
Renewal Criteria	Documented positive clinical response to therapy

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

PCSK9 inhibitors

Products Affected

- **Praluent**
- **Repatha**

PA Criteria	Criteria Details

Required Medical Information	**Established clinical atherosclerotic cardiovascular disease (ASCVD):**
	• Confirmed diagnosis of atherosclerotic cardiovascular disease (ASCVD).
	• Documentation of a current LDL greater than or equal to 55 mg/dl.
	• Documentation that:
	  ○ Patient is receiving maximally tolerated statin therapy (atorvastatin 40-80mg, rosuvastatin 20-40mg) or has a documented clinical intolerance to statins **AND**
	  ○ Is receiving ezetimibe or has a documented intolerance to ezetimibe.
	
	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 that:
	  ○ Patient is receiving maximally tolerated statin therapy (atorvastatin 40-80mg, rosuvastatin 20-40mg) or has a documented clinical intolerance to statins **AND**
	  ○ Is receiving ezetimibe or has a documented intolerance to ezetimibe.

Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist.
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy (significant decrease in lipid levels).

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

P&T Revision Date:	01/11/2022, 09/10/2024

PEANUT POWDER (PALFORZIA)

Products Affected

- **PALFORZIA (12 MG DAILY DOSE)**
- **PALFORZIA (120 MG DAILY DOSE)**
- **PALFORZIA (160 MG DAILY DOSE)**
- **PALFORZIA (20 MG DAILY DOSE)**
- **PALFORZIA (200 MG DAILY DOSE)**
- **PALFORZIA (240 MG DAILY DOSE)**
- **PALFORZIA (3 MG DAILY DOSE)**
- **PALFORZIA (300 MG MAINTENANCE)**
- **PALFORZIA (300 MG TITRATION)**
- **PALFORZIA (40 MG DAILY DOSE)**
- **PALFORZIA (6 MG DAILY DOSE)**
- **PALFORZIA (80 MG DAILY DOSE)**
- **PALFORZIA INITIAL ESCALATION**

PA Criteria	Criteria Details
Required Medical Information	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.
Age Restrictions	Patient must be between 4 and 17 at therapy initiation
Prescriber Restrictions	Prescribed by allergist or immunologist enrolled in Palforzia REMS program
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Reauthorization: Currently receiving medication byway 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 less than 18 years old, 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.

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

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:	

Pramipexole Dihydrochloride (MIRAPEX)

Products Affected

- PRAMIPEXOLE DIHYDROCHLORIDE

PA Criteria	Criteria Details
Required Medical Information	For the treatment of Parkinson's Disease.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Pretomanid

Products Affected

- Pretomanid tablets

PA Criteria	Criteria Details
Required Medical Information	**<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.
Exclusion Criteria	Use outside of recognized treatment guidelines. Medication is being received through a county clinic with a state funded TB program.
Age Restrictions	Age of 14 or greater
Prescriber Restrictions	Infectious Disease
Coverage Duration	**Pulmonary tuberculosis:** 24 weeks
Renewal Criteria	N/A

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

Pitolisant (WAKIX)

Products Affected

- WAKIX 4.45MG TAB
- WAKIX 17.8MG TAB

PA Criteria	Criteria Details

Required Medical Information	• Confirmation of diagnosis of narcolepsy based on polysomnography AND 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.
	• For Excessive Daytime Sleepiness (EDS) the following is required:
	  ○ 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
	• For Cataplexy the following is required:
	  ○ 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.

Exclusions	• Severe renal or hepatic impairment • Pregnant or actively trying to conceive
Prescriber Restrictions	Prescribed by Sleep Specialist or Neurologist
Coverage Duration	**Initial**: 3 months. **Renewal**: 6 months.
Renewal Criteria	Documented positive clinical response to therapy

Effective Date:	03/01/2025
P&T Approval Date:	01/14/2025

P&T Revision Date:	01/14/2025

Potassium Binders

Products Affected

- Lokelma Powder Pak: 5g, 10g
- Veltassa Packet: 8.4g, 16.8g, 25.2g

PA Criteria	Criteria Details

Required Medical Information	**Hyperkalemia**
	• Being used for the treatment of hyperkalemia based on current potassium labs
	• Failed all of 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 Lokelma or does the member have a trial and failure or contraindication to Lokelma therapy (Lokelma is not recommended in those with heart failure or are on sodium restriction)

Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 6 months; **Renewal**: 12 months
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

Effective Date:	07/01/2024
P&T Approval Date:	05/14/2024
P&T Revision Date:	09/13/2022

Quantity Limit Exception Criteria (standard criteria for quantity exception

Products Affected

- All drugs with quantity limits

PA Criteria	Criteria Details
Required Medical Information	• The requested medication 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 under the age of 21. • The requested 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. • Documentation of failure of the requested medication within quantity limits, including failure of different strengths of the requested medication. • All appropriate alternative treatments have been tried and failed.
Age Restrictions	FDA indicated age limits (vary by drug)
Prescriber Restrictions	Appropriate Specialist (vary by drug)
Coverage Duration	Will vary by drug and situation.
Renewal Criteria	Documented positive clinical response to therapy

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

Resmetirom (REZDIFFRA)

Products Affected

- Rezdiffra 60MG/80MG/100MG TAB

PA Criteria	Criteria Details

Required Medical Information	• 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)

Age Restrictions	For patients ≥18 years old
Prescriber Restrictions	Gastroenterologist; Hepatologist
Coverage Duration	Initial: 6 months; Renewal: 12 months
Renewal Criteria	Patient demonstrates positive response to therapy (e.g., MASH resolution, fibrosis stage improvement, etc.) AND 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)

Effective Date:	07/01/2024
P&T Approval Date:	5/14/2024
P&T Revision Date:	

Rifapentine (Priftin)

Products Affected

- Priftin 150mg tablets

PA Criteria	Criteria Details
Required Medical Information	**Latent tuberculosis:** • Used in combination with isoniazid (INH). **Active tuberculosis:** • Used as part of a multi-drug regimen.
Exclusion Criteria	Prescribed by a county clinic with a state funded TB program (for these programs the drug is funded directly through the state).
Age Restrictions	• Age ≥ 2 years old with latent TB • Age ≥ 12 years old with active TB
Prescriber Restrictions	**Active tuberculosis:** Infectious disease specialist required for multidrug resistant cases only
Coverage Duration	**Latent TB**: 3 months **Active TB**: 6 months
Renewal Criteria	N/A

Effective Date:	7/1/2025
P&T Approval Date:	3/12/2024
P&T Revision Date:	3/11/2025, 3/12/2024

Rifaximin (XIFAXAN)

Products Affected

- **XIFAXAN**

PA Criteria	Criteria Details
Required Medical Information	**Diagnosis of Hepatic Encephalopathy:** must have one of the following: used as add-on therapy to lactulose **AND** unable to achieve an optimal clinical response with lactulose monotherapy **OR** a history of contraindication or intolerance to lactulose.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Risdiplam (EVRYSDI)

Products Affected

- Evrysdi **SOL 0.75 MG/ML**

PA Criteria	Criteria Details
Required Medical Information	**Spinal Muscular Atrophy (SMA):** • 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 • 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)
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a neurologist with expertise in the treatment of SMA
Coverage Duration	**Initial**: 12 months. **Renewal**: up to 12 months.
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)

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

Rituximab (RITUXIMAB)

Products Affected

- RUXIENCE INJ **(100/10ML & 500/50ML)**
- RIABNI SOL **(100/10ML & 500/50ML)**
- TRUXIMA INJ **(100/10ML & 500/50ML)**
- RITUXAN INJ **(100MG & 500MG)**

PA Criteria	Criteria Details

Required Medical Information	**Rheumatoid Arthritis**
	• Diagnosis of moderately to severely active rheumatoid arthritis
	• One of the following
	  ○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan
	  ○ Trial and failure, contraindication or intolerance to one of the following: Methotrexate, Leflunomide, Sulfasalazine
	• Trial and failure to infliximab and adalimumab
	
	Non-Hodgkin's Lymphoma
	• One of the following
	  ○ Diagnosis of diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma and used as a first-line treatment in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens
	  ○ Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma and used as a first-line treatment in combination with chemotherapy.
	  ○ Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma and patient achieved a complete or partial response to a rituximab product in combination with chemotherapy and followed by rituximab used as monotherapy for maintenance therapy.
	  ○ Diagnosis of low-grade, CD20-positive, B-cell non Hodgkin's lymphoma and patient has stable disease following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy and patient achieved a partial or complete response following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy
	  ○ Diagnosis of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin's lymphoma

PA Criteria	Criteria Details
	○ Diagnosis of one of the following previously untreated, advanced stage indications: ▪ CD-20-positive diffuse large B-cell lymphoma (DLBCL) ▪ Burkitt lymphoma (BL) ▪ Burkitt-like lymphoma (BLL) ▪ Mature B-cell acute leukemia (B-AL) • Used in combination with chemotherapy **Chronic Lymphocytic Leukemia** • Diagnosis of chronic lymphocytic leukemia • Used in combination with fludarabine and cyclophosphamide **Immune or Idiopathic Thrombocytopenic Purpura (Off-Label)** • Diagnosis of immune or idiopathic thrombocytopenic purpura (off-label) • Trial and failure, contraindication, or intolerance to at least ONE of the following: ○ Glucocorticoids (e.g., prednisone, methylprednisolone) ○ Immunoglobulins (e.g., IVIg) ○ Splenectomy • Documented platelet count of less than 50 x 10^9 / L **Pemphigus Vulgaris** • Diagnosis of moderate to severe Pemphigus Vulgaris **Waldenstrom's macroglobulinemia** • Diagnosis of relapsed/refractory Waldenstrom's macroglobulinemia **Wegener's Granulomatosis and Microscopic Polyangiitis** • One of the following ○ Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) ○ Microscopic Polyangiitis • Used in combination with glucocorticoids (e.g., prednisone)
Age Restrictions	**Non-Hodgkin's Lymphoma:** 6 months of age or older
Prescriber Restrictions	**Rheumatoid Arthritis:** Prescribed by or in consultation with rheumatologist

PA Criteria	Criteria Details
Coverage Duration	**Rheumatoid Arthritis: Initial**: 6 months. **Renewal**: up to 12 months. **Non-Hodgkin's Lymphoma: Initial**: 12 months. **Chronic Lymphocytic Leukemia: Initial**: 12 months. **Immune or Idiopathic Thrombocytopenic Purpura: Initial**: 12 months. **Pemphigus Vulgaris: Initial**: 12 months. **Renewal**: 12 months. **Waldenstrom's macroglobulinemia: Initial**: 12 months. **Wegener's Granulomatosis and Microscopic Polyangiitis: Initial:** 3 months
Renewal Criteria	**Pemphigus Vulgaris:** Documentation of positive clinical response to Rituxan therapy

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

Roflumilast (DALIRESP)

Products Affected

- **DALIRESP**

PA Criteria	Criteria Details
Required Medical Information	Diagnosis of moderate to severe COPD and patient has chronic bronchitis and patient has tried and failed or has an intolerance or contraindication to two previous COPD therapies.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	COPD **Initial**: 12 months. COPD **Renewal**: 12 months.
Renewal Criteria	Documentation of positive clinical response to Daliresp therapy.

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

Ropinirole Hydrochloride (REQUIP)

Products Affected

- ROPINIROLE HCL

PA Criteria	Criteria Details
Required Medical Information	For the treatment of Parkinson's Disease.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Sacubitril/Valsartan (ENTRESTO)

Products Affected

- **ENTRESTO**

PA Criteria	Criteria Details
Required Medical Information	The patient has a diagnosis of New York Heart Association class II to IV heart failure **AND** the patient is receiving concomitant therapy with one of the following beta blockers: carvedilol, bisoprolol, sustained-released metoprolol, unless unable to tolerate or contraindicated **AND** the patient will discontinue use of any concomitant ACE inhibitor or ARB before initiating therapy. ACE inhibitors must be discontinued at least 36 hours prior to ENTRESTO.
Age Restrictions	
Prescriber Restrictions	Cardiologist or in consultation with a cardiologist
Coverage Duration	**Initial**: 12 months **Renewal**: 12 months
Renewal Criteria	Documented positive clinical response to therapy

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

Sargramostim (LEUKINE)

Products Affected

- **LEUKINE INJ 250MCG**

PA Criteria	Criteria Details
Required Medical Information	**Acute myelogenous leukemia (AML):** To shorten time to neutrophil recovery and to reduce the incidence of severe and life-threatening infections and infections resulting in death following induction chemotherapy in older adults (greater than or equal to 55 years of age). **Bone marrow transplant (allogeneic or autologous):** For graft failure or engraftment delay. **Myeloid reconstitution after allogeneic bone marrow transplantation:** To accelerate myeloid recovery following transplantation in non-Hodgkin lymphoma (NHL), acute lymphoblastic leukemia (ALL), Hodgkin lymphoma. Febrile neutropenia Primary prophylaxis of neutropenia in patients receiving chemotherapy (outside transplant and AML) or who are at high risk for neutropenic fever. **Peripheral stem cell transplantation:** Mobilization of hematopoietic progenitor cells for leukapheresis and myeloid reconstitution following autologous peripheral stem cell transplantation. **Acute Radiation Syndrome:** Treatment of radiation induced myelosuppression of the bone marrow.
Age Restrictions	
Prescriber Restrictions	Requested by a specialist.
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Secukinumab SC (COSENTYX)

Products Affected

- **COSENTYX (300 MG DOSE)**
- **COSENTYX SENSOREADY (300 MG)**

PA Criteria	Criteria Details

Required Medical Information	**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 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 both infliximab and adalimumab
	
	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:
	  ○ 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

PA Criteria	Criteria Details

	• Documented intolerance or contraindication to DMARDs OR DMARD will be continued
	• Trial and failure of both infliximab and adalimumab
	
	Plaque Psoriasis (PP):
	• 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
	• Trial and failure of both infliximab and adalimumab
	
	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
	• Trial and failure of both infliximab and adalimumab

PA Criteria	Criteria Details

	Hidradenitis Suppurativa (HS):
	• 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:
	  o 90-day trial of conventional therapy (e.g. oral antibiotics)
	• Trial and failure of both infliximab and adalimumab

Age Restrictions	
Prescriber Restrictions	**Plaque Psoriasis:** Dermatologist. **Psoriatic Arthritis:** Dermatologist or Rheumatologist. **Juvenile Idiopathic Arthritis**: Rheumatologist. **Ankylosing Spondylitis**, Axial Spondyloarthritis: Rheumatologist.
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
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. **JIA:** Evidence of 20% or greater improvement in tender joint count and swollen joint count or has there been an improvement in functional ability. **PP:** 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.

Effective Date:	7/1/2024
P&T Approval Date:	5/14/2024
P&T Revision Date:	9/1/2023, 07/11/2023, 01/11/2022

Seladelpar (LIVDELZI)

Products Affected

- Livdelzi Capsules

PA Criteria	Criteria Details

Required Medical Information	**Primary biliary cholangitis:**
	• 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

Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a hepatologist or gastroenterologist
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
Renewal Criteria	Documented adherence to medication regimen and clinical benefit

Effective Date:	01/01/2025
P&T Approval Date:	11/12/2024
P&T Revision Date:	11/12/2024

Semaglutide (WEGOVY)

Products Affected

- Wegovy

PA Criteria	Criteria Details

Required Medical Information	**Secondary Prevention of Major Adverse Events (MACE)**
	• 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 MI, 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
	
	Obesity or Overweight – only applies to members under the age of 21
	• 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.

Age Restrictions	**Secondary Prevention of Major Adverse Events (MACE):** 12 years or older **Obesity or overweight:** Age 12 to under 21 years of age
Prescriber Restrictions	**Secondary Prevention of Major Adverse Events (MACE):** Prescribed by or in consultation with a cardiologist.
Coverage Duration	**Secondary Prevention of Major Adverse Events (MACE):** • **Initial**: 6 months. **Renewal**: 12 months. **Obesity or overweight:** • **Initial**: 6 months. **Renewal**: 12 months or until age 21, whichever is less.

PA Criteria	Criteria Details
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. • 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).

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

Sildenafil Citrate (REVATIO)

Products Affected

- SILDENAFIL CITRATE 20MG TAB

PA Criteria	Criteria Details
Required Medical Information	Clinical diagnosis of pulmonary arterial hypertension (PAH).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist.
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Sotatercept (WINREVAIR)

Products Affected

- Winrevair injection

PA Criteria	Criteria Details

Required Medical Information	**Pulmonary Arterial Hypertension (PAH):**
	• 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

Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Sirolimus (RAPAMUNE)

Products Affected

- SIROLIMUS ORAL SOLUTION

PA Criteria	Criteria Details
Required Medical Information	Lymphangioleiomyomatosis, Renal transplant rejection prophylaxis.
Age Restrictions	Member is under age 10 or unable to use tablets
Prescriber Restrictions	
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Sparsentan (FILSPARI)

Products Affected

- Filspari **TAB 200MG , 400MG**

PA Criteria	Criteria Details
Required Medical Information	**Primary immunoglobulin A nephropathy:** • 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
Age Restrictions	18 or older
Prescriber Restrictions	Nephrologist
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
Renewal Criteria	Improved or stable kidney function compared to baseline **OR** reduction in proteinuria

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

Sodium-Glucose Co-Transporter 2 (Sglt2) Inhibitors

Products Affected

- FARXIGA **TABLET 5MG; 10 MG ORAL**
- INVOKANA **TABLET 100 MG; 300 MG ORAL**
- JARDIANCE **TABLET 10 MG, 25 MG ORAL**

PA Criteria	Criteria Details
Required Medical Information	**T2DM:** Trial and failure of or contraindication to metformin **AND** trial and failure or reason why it is inappropriate to use a sulfonylurea or pioglitazone. **CKD (Farxiga)**: Concurrent therapy with an ACEi or ARB at maximum tolerated doses, or documented contraindication to both **AND** eGFR of 25 to 75 mL/min/1.73 m^2 or stage 2, 3, or 4 CKD **AND** no previous use of dialysis **AND** no history of polycystic kidney disease, type 1 diabetes, lupus nephritis, or antineutrophil cytoplasmic antibody-associate vasculitis. **HFrEF:** Patient must be stabilized and titrated to maximally tolerated or target dose of ACEi, ARB, or ARNI **AND** patient must be stabilized and titrated to maximally tolerated or target dose of either carvedilol, metoprolol succinate, or bisoprolol **OR** have a contraindication to beta blocker use **AND** NYHA class II-IV (EF≤40%) **AND** eGFR >30 mL/min/1.73$m^{2.}$ **HFpEF (Jardiance only)**: eGFR >30 mL/min/1.73^2
Age Restrictions	
Prescriber Restrictions	HFrEF & HFpEF: Cardiologist
Coverage Duration	**Initial**: Lifetime Approval. **Renewal**: Lifetime Approval
Renewal Criteria	

Effective Date:	04/01/2022
P&T Approval Date:	03/08/2022
P&T Revision Date:	03/08/2022

Somatropin, E-Coli Derived (HUMATROPE)

Products Affected

- **HUMATROPE**

PA Criteria	Criteria Details

Required Medical Information	Documentation of goals of therapy and objective baseline assessment (e.g., quality of life, exercise capacity, height, body composition improvements, etc.)
	
	For patients under the age of 18:
	• Growth Hormone Deficiency (GHD)
	• Prader-Willi Syndrome
	  o Patient does not have concurrent severe obesity nor history of upper airway obstruction nor sleep apnea nor severe respiratory impairment
	• 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
	
	For Adults aged 18 years and older
	• Growth hormone deficiency (GHD)
	  o Prescribed by or in consultation with an endocrinologist; **AND**
	  o Either
	  ▪ 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); **OR**
	  ▪ Patient has had the pituitary removed or destroyed or has had panhypopituitarism since birth; **AND**
	  o The prescriber certifies that the growth hormone is not being prescribed for anti-aging therapy or to enhance athletic ability or body building

PA Criteria	Criteria Details
	• HIV associated cachexia • Short Bowel Syndrome (SBS)
Age Restrictions	
Prescriber Restrictions	An endocrinologist for adults or a pediatric endocrinologist or pediatric nephrologist for children/adolescents
Coverage Duration	**Initial**: up to 12 months. **Renewal**: up to 12 months.

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**
	  ○ Growth velocity greater than 2.5 cm per year; **OR**
	  ○ 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

Effective Date:	04/01/2023
P&T Approval Date:	03/14/2023
P&T Revision Date:	03/14/2023

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:	

SUPREP Bowel Prep

Products Affected

- **na sulfate-k sulfate-mg sulf solution**

PA Criteria	Criteria Details
Required Medical Information	Bowel cleansing prior to GI examination. Prior use of formulary agent, golytely solution, must be tried and failed **OR** patient is having Bariatric surgery.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 1 treatment.
Renewal Criteria	

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

- Chou, Roger et al. Management of Postoperative Pain: A Clinical Practice Guideline From the American Pain Society, the American Society of Regional Anesthesia and Pain Medicine, and the American Society of Anesthesiologists' Committee on Regional Anesthesia, Executive Committee, and Administrative Council. The Journal of Pain, Volume 17, Issue 2, 131 - 157

- 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
- Hegmann, Kurt T. MD, MPH; Weiss, Michael S. MD, MPH; Bowden, Kirk PhD; Branco, Fernando MD; DuBrueler, Kimberly PharmD, RPh; Els, Charl MBChB, FCPsych, MMed Psych; Mandel, Steven MD; McKinney, David W. MD, MPH; Miguel, Rafael MD; Mueller, Kathryn L. MD, MPH; Nadig, Robert J. MD, MPH; Schaffer, Michael I. PhD, MS, DABFT, NRCC-TC; Studt, Larry MD; Talmage, James B. MD; Travis, Russell L. MD; Winters, Thomas MD; Thiese, Matthew S. PhD, MSPH; Harris, Jeffrey S. MD, MPH. ACOEM Practice Guidelines: Opioids for Treatment of Acute, Subacute, Chronic, and Postoperative Pain. Journal of Occupational and Environmental Medicine 56(12):p e143-e159, December 2014. | DOI: 10.1097/JOM.0000000000000352.
- 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.
- Hsu, Joseph R. MD*; Mir, Hassan MD†; Wally, Meghan K. MSPH*; Seymour, Rachel B. PhD*; the Orthopaedic Trauma Association Musculoskeletal Pain Task Force. Clinical Practice Guidelines for Pain Management in Acute Musculoskeletal Injury. Journal of Orthopaedic Trauma 33(5):p e158-e182, May 2019. | DOI: 10.1097/BOT.0000000000001430
- 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 (PROTOPIC)

Products Affected

- TACROLIMUS OINT

PA Criteria	Criteria Details
Required Medical Information	**Atopic Dermatitis:** Clinically diagnosed moderate-to-severe atopic dermatitis: (10 percent BSA, hand, foot or mucous membrane involvement, or functional impairment). Trial and failure of topical steroids, UVB phototherapy, or reason why they would not be medically appropriate. **Psoriasis:** diagnosis of moderate to severe Psoriasis (10 percent BSA, hand, foot or mucous membrane involvement, or functional impairment). Trial and failure or contraindication to a high potency topical corticosteroid and/or UVB phototherapy.
Age Restrictions	
Prescriber Restrictions	Psoriasis: prescribed by or in consultation with a dermatologist.
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months
Renewal Criteria	Documented positive clinical response to therapy

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

Tadalafil (CIALIS)

Products Affected

- TADALAFIL (PAH) 20MG TAB

PA Criteria	Criteria Details
Required Medical Information	Clinical diagnosis of pulmonary arterial hypertension (PAH).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist.
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Tazarotene (AVAGE) (TAZORAC)

Products Affected

- Tazarotene 0.1% cream

PA Criteria	Criteria Details
Required Medical Information	**Psoriasis**: diagnosis of moderate to severe Psoriasis (10% BSA, hand, foot or mucous membrane involvement and functional impairment (IHN). Trial and failure of high potency topical corticosteroids or medical reason why they would be inappropriate **Other FDA approved indications that are above the line** (i.e., severe acne): trial and failure/contraindication to two formulary alternatives used to treat the approved indication.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Tiagabine (GABITRIL)

Products Affected

- TIAGABINE HCL TABLET 12 MG ORAL
- TIAGABINE HCL TABLET 16 MG ORAL

PA Criteria	Criteria Details
Required Medical Information	For the treatment of Partial seizures as adjunct therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Testosterone

Products Affected

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

Testosterone enanthate 200mg/mL

PA Criteria	Criteria Details
Required Medical Information	Diagnosis of: Gender dysphoria **OR** aids wasting syndrome **OR** post-menopausal breast cancer **OR** hypogonadism **AND** trial and failure or contraindication to injectable testosterone.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Gender dysphoria, aids wasting syndrome, post-menopausal breast cancer **Initial**: Indefinite Hypogonadism: **Initial**: 12 months; **Renewal**: 12 months
Renewal Criteria	Documented positive clinical response to therapy

Effective Date:	07/01/2024
P&T Approval Date:	05/14/2024
P&T Revision Date:	09/13/2022

Tenofovir Alafenamide-Emtricitabine (DESCOVY)

Products Affected

- Descovy

PA Criteria	Criteria Details
Required Medical Information	**Treatment of HIV infection:** Clinical contraindication to generic Truvada and documentation that the drug will be used in combination with other HIV drugs as part of a complete treatment regimen. **Pre-exposure prophylaxis of HIV infection (PrEP):** Clinical contraindication to generic Truvada.
Age Restrictions	FDA label
Prescriber Restrictions	
Coverage Duration	Lifetime
Renewal Criteria	N/A

Effective Date:	07/01/2024
P&T Approval Date:	07/11/2024
P&T Revision Date:	07/11/2024

Tezacaftor/ivacaftor and ivacaftor (SYMDEKO)

Products Affected

- **SYMDEKO**

PA Criteria	Criteria Details
Required Medical Information	Clinical documentation of cystic fibrosis diagnosis with homozygous F508del mutation.
Age Restrictions	6 years of age and older
Prescriber Restrictions	Prescribed by a pulmonologist
Coverage Duration	**Initial**: 3 months **Renewal**: 6 months
Renewal Criteria	Documented positive clinical response to therapy

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

Thickener (THICK-IT)

Products Affected

- Thick-it
- Thick-it #2

PA Criteria	Criteria Details
Required Medical Information	• Documented swallowing study/evaluation for the treatment of swallowing disorder due to one of the following medical conditions: o Diagnosis of dysphagia which negatively impacts the ability to swallow; OR o Chronic diseases such as, but not limited to, Parkinson's, dementia, reflux disease, stroke, neuromuscular disease/disorder, and spinal cord injury; OR o Treatment of head, neck, or throat cancer; OR o Documented aspiration of food or liquid associated with chronic illness or disease
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
Renewal Criteria	Documentation of appointment in the last 12 months confirming effectiveness of the requested thickener and continued need.

Effective Date:	01/01/2025
P&T Approval Date:	11/12/2024
P&T Revision Date:	11/12/2024

Ticagrelor (BRILINTA)

Products Affected

- Brilinta **TAB 60MG, 90MG**

PA Criteria	Criteria Details

Required Medical Information	**Acute Coronary Syndrome**
	• Patient has acute coronary syndrome (ACS)
	  ○ Either NSTE-ACS or STEMI and has had a coronary stent implanted OR
	  ○ Patient has NSTE-ACS and is treated with medical therapy alone (i.e., has not had revascularization)?

Age Restrictions	18 or older
Prescriber Restrictions	Gynecologist
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documentation of positive clinical response to therapy.

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

Tolterodine Step Therapy

Products Affected

- Tolterodine ER capsule
- Tolterodine tablet

Step Therapy Criteria	• Trial and failure of ○ Oxybutynin

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

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 650MG TAB

PA Criteria	Criteria Details

Required Medical Information	**Hemophilia Diagnosis**
	• Intending to use for hemorrhage prophylaxis for tooth extraction(s)
	
	Abnormal Uterine Bleeding
	• Currently using or documented trial and failure or contradiction to ALL the following treatments:
	  ○ Combined Oral Contraceptive therapy
	  ○ Progestin therapy (oral or LM) or Levonorgestrel IUD
	  ○ NSAID therapy

Age Restrictions	
Prescriber Restrictions	Hematologist, Hemophilia specialist, Dentist, Gynecologist
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documentation of positive clinical response to therapy.

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

Trospium Step Therapy

Products Affected

- Trospium IR tablets
- Trospium ER caps

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

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

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:	

Vonoprazan (VOQUEZNA)

Products Affected

- **Voquezna 10mg**
- **Voquezna 20mg**

PA Criteria	Criteria Details
Required Medical Information	**Erosive esophagitis-** • 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. **H. Pylori eradication –** • Confirmed H. pylori positive infection AND • Documented contraindication, intolerance, or inadequate response to standard first-line therapies for H. Pylori infection (e.g. PPI (standard or double dose), clarithromycin, amoxicillin (or metronidazole)) AND • Documented contraindication, intolerance, or inadequate response to a quadruple bismuth regimen (e.g. standard twice daily dose PPI, bismuth subsalicylate, tetracycline, metronidazole) AND • Co-prescribed in combination with antibiotics.
Age Restrictions	Must be at least 18 years of age
Prescriber Restrictions	Prescribed by or in collaboration with a Gastroenterologist or Infectious Disease specialist
Coverage Duration	**Initial healing of erosive esophagitis**: 2 months **Maintenance of healing of erosive esophagitis:** 6 months **H. Pylori eradication:** 14 days
Renewal Criteria	Renewals past the above timelines are not allowed

Effective Date:	03/01/2024
P&T Approval Date:	01/09/2024
P&T Revision Date:	

Tobramycin Solution

Products Affected

- Tobramycin nebulization solution

PA Criteria	Criteria Details
Required Medical Information	Use must be for cystic fibrosis or any FDA-approved or compendia supported indication.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist, pulmonologist, or cystic fibrosis specialist
Coverage Duration	**Cystic Fibrosis:** Lifetime **Other diagnoses: Initial**: 3 months. **Renewal**: 12 months.
Renewal Criteria	Confirmed diagnosis with clinical evidence supporting chronic use

Effective Date:	01/01/2025
P&T Approval Date:	11/12/2024
P&T Revision Date:	11/12/2024

Tocilizumab SC (ACTEMRA, TYENNE)

Products Affected

- Actemra INJ 162mg/0.9ml
- Tyenne INJ 162mg/0.9mL
- Actemra INJ ACTPEN
- Tyenne AUTO-INJ

PA Criteria	Criteria Details

Required Medical Information	**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
	
	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:
	  ○ 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
	• Trial and failure of both infliximab and adalimumab
	
	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).
	• Documentation of a minimum duration of 3-month trial and failure of maximally tolerated dose of nonbiologic DMARD therapy: methotrexate, leflunomide or sulfasalazine; OR documentation that the member is transitioning to the requested treatment from a different biologic product previously approved by IHN.
	• Trial and failure of both infliximab and adalimumab.

PA Criteria	Criteria Details
	Giant Cell Arteritis (GCA): • Diagnosis of giant cell arteritis. • Trial and failure of a glucocorticoid **Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD):** • Confirmed diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD). • Trial and failure of mycophenolate mofetil. **Cytokine Release Syndrome (CRS) Risk due to CAR T-Cell Therapy (IV only):** • Member will receive or is receiving chimeric antigen receptor (CAR) T-cell immunotherapy.
Age Restrictions	
Prescriber Restrictions	**Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Giant Cell Arteritis**: Rheumatologist. **Systemic Sclerosis-Associated Interstitial Lung Disease:** Rheumatologist or Pulmonologist. **Cytokine Release Syndrome (CRS) Risk due to CAR T-Cell Therapy (IV only):** Oncologist or hematologist
Coverage Duration	**CRS:** 2 months **All other diagnosis - Initial**: 6 months. **Renewal**: 12 months.
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. **RA:** Evidence of a 20% or greater improvement in tender joint count and swollen joint count. **GCA:** Demonstrated positive clinical response to therapy. **SSc-ILD:** Demonstrated positive clinical response to therapy.

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

Tofacitinib (XELJANZ)

Products Affected

- **Xeljanz**
- **Xeljanz XR**

PA Criteria	Criteria Details

Required Medical Information	**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 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 both infliximab and adalimumab
	• Trial and failure of Cosentyx and Taltz or a reason they can't be used
	
	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:
	  ○ 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

PA Criteria	Criteria Details

	• Documented intolerance or contraindication to DMARDs OR DMARD will be continued
	• Trial and failure of both infliximab and adalimumab
	• Trial and failure of Actemra and Orencia
	
	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
	• Trial and failure of both infliximab and adalimumab
	• Trial and failure of Cosentyx, Otezla, ustekinumab, Orencia, and Taltz
	
	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 both infliximab and adalimumab
	• Trial and failure of Actemra, Cimzia, Kineret, Orencia, and rituximab
	
	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:

PA Criteria	Criteria Details
	○ Mesalamine, sulfasalazine OR ○ Mercaptopurine, azathioprine, OR ○ Corticosteroids (prednisone, methylprednisolone) ○ Trial and failure of both infliximab and adalimumab ○ Trial and failure of Entyvio and ustekinumab
Age Restrictions	
Prescriber Restrictions	**Ulcerative Colitis:** Gastroenterologist. **Psoriatic Arthritis:** Dermatologist or Rheumatologist. **Rheumatoid Arthritis, Juvenile Idiopathic Arthritis**: Rheumatologist. **Ankylosing Spondylitis**, Axial Spondyloarthritis: Rheumatologist.
Coverage Duration	**Initial**: 6 months. **Renewal**: up to 12 months.
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. **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. **UC:** Evidence of a significant response such as a decrease in bloody stools per day or elimination of signs of toxicity.

Effective Date:	9/1/2023
P&T Approval Date:	7/11/2023
P&T Revision Date:	07/11/2023, 01/11/2022

Topical Antifungal Agents

Products Affected

Ciclopirox 8% solution
Econazole 1% cream
Selenium Sulfide 2.5% Lotion
Ketoconazole 2% Cream & Shampoo

PA Criteria	Criteria Details
Required Medical Information	The following alternatives have been tried and failed or are not appropriate for use: clotrimazole 1% cream, miconazole 2% (cream, aerosol, or powder), terbinafine 1%, cream, terbinafine tablets, nystatin 100,000 units/gram (ointment, cream, or powder).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 3 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

Effective Date:	9/1/2023
P&T Approval Date:	7/11/2023
P&T Revision Date:	07/11/2023, 01/11/2022

Treprostinil diolamine (ORENITRAM)

Products Affected

- ORENITRAM

PA Criteria	Criteria Details
Required Medical Information	Confirmed diagnosis of pulmonary arterial hypertension with right heart catheterization and WHO functional class II through IV **AND** evidence of either an unfavorable acute response to vasodilators or evidence of being refractory to or unable to tolerate calcium channel blockers (e.g., extended release nifedipine or extended-release diltiazem) **AND** documented failure or incomplete response to sildenafil or tadalafil/ambrisentan combination **AND** trial and failure of Remodulin or clinical justification for the need of an alternative route of administration.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist.
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Treprostinil sodium (REMODULIN)

Products Affected

- TREPROSTINIL

PA Criteria	Criteria Details
Required Medical Information	Confirmed diagnosis of pulmonary arterial hypertension with right heart catheterization and WHO functional class II through IV **AND** evidence of either an unfavorable acute response to vasodilators or evidence of being refractory to or unable to tolerate calcium channel blockers (e.g., extended release nifedipine or extended-release diltiazem) **AND** documented failure or incomplete response to sildenafil or tadalafil/ambrisentan combination.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist.
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Treprostinil (TYVASO)

Products Affected

- **TYVASO**
- **TYVASO REFILL**
- **TYVASO STARTER**

PA Criteria	Criteria Details
Required Medical Information	Confirmed diagnosis of pulmonary hypertension associated with interstitial lung disease (WHO Group 3). Any other indication would be required to try and fail formulary alternatives.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by pulmonologist or cardiologist.
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Ubrogepant (UBRELVY)

Products Affected

- **Ubrelvy**

PA Criteria	Criteria Details
Required Medical Information	Diagnosis of migraine **AND** documentation patient is on preventative therapy **AND** trial and failure (defined as trial period of 6 weeks per agent) or contraindication to at least 3 generic oral formulary triptans used at up to maximally indicated dosing combined with NSAIDs
Age Restrictions	18 years of age and older
Prescriber Restrictions	
Coverage Duration	**Initial**: 3 months **Renewal**: 6 months
Renewal Criteria	Documented positive clinical response to therapy

Effective Date:	07/01/2023
P&T Approval Date:	05/09/2023
P&T Revision Date:	05/09/2023

Upadacitinib (RINVOQ)

Products Affected

- Rinvoq **TAB 15MG ER, 30MG ER, 45MG ER**
- Rinvoq **LQ solution 1mg/mL**

PA Criteria	Criteria Details
Required Medical Information	**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: o Back pain and stiffness for more than 3 months AND o Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive AND o 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: o At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND o Physical therapy/exercise program • Trial and failure of both infliximab and adalimumab Trial and failure of Cosentyx and Taltz or a reason they can't be used **Atopic Dermatitis (AD):** • Documentation of 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 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 • Documented contraindication or failed trial to ALL of the following: o Moderate-high potency corticosteroid (e.g., clobetasol, fluocinonide, fluticasone)

PA Criteria	Criteria Details
	○ Topical calcineurin inhibitor (e.g. tacrolimus) ○ Oral immunomodulator therapy (e.g. cyclosporine, methotrexate, azathioprine, mycophenolate mofetil). • Failure of Dupixent **Crohn's Disease (CD):** • Documentation of moderate-to-severe Crohn's Disease • 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: 6-mercaptopurine, azathioprine, corticosteroid, methotrexate • Trial and failure of both infliximab and adalimumab • Trial and failure of Cimzia, Entyvio, ustekinumab **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 • Trial and failure of both infliximab and adalimumab • Trial and failure of Cosentyx, Otezla, ustekinumab, Orencia, and Taltz **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

PA Criteria	Criteria Details
	(dosed at least 20mg per week for at least 8 weeks), leflunomide or sulfasalazine • Trial and failure of both infliximab and adalimumab • Trial and failure of Actemra, Cimzia, Kineret, Orencia, and rituximab **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: o Mesalamine, sulfasalazine OR o Mercaptopurine, azathioprine, OR o Corticosteroids (prednisone, methylprednisolone) • Trial and failure of both infliximab and adalimumab • Trial and failure of Entyvio and ustekinumab
Age Restrictions	
Prescriber Restrictions	**Atopic Dermatitis:** Dermatologist **Crohn's Disease and Ulcerative Colitis:** Gastroenterologist. **Psoriatic Arthritis:** Dermatologist or Rheumatologist. **Rheumatoid Arthritis**: Rheumatologist. **Ankylosing Spondylitis**, **Axial Spondyloarthritis:** Rheumatologist.
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
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. **AD:** 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. **CD:** Evidence of a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission. **PsA:** Evidence of a 20% or greater improvement in tender joint count and swollen joint count.

PA Criteria	Criteria Details
	RA: Evidence of a 20% or greater improvement in tender joint count and swollen joint count. **UC:** Evidence of a significant response such as a decrease in bloody stools per day or elimination of signs of toxicity.

Effective Date:	9/1/2023
P&T Approval Date:	7/11/2023
P&T Revision Date:	07/11/2023, 01/11/2022

Ustekinumab

Products Affected

- Selarsdi
- Yesintek
- Steqeyma

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
	• 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: 6-mercaptopurine, azathioprine, corticosteroid, methotrexate
	• Trial and failure of both infliximab and 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
	• 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 • Trial and failure of both infliximab and adalimumab **<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 both infliximab and adalimumab **<u>Ulcerative Colitis (UC)</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 both infliximab and adalimumab
Renewal Criteria	• **CD:** Evidence of a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission. • **PP:** 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. • **UC:** 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:** Dermatologist. • **Psoriatic Arthritis:** Dermatologist or Rheumatologist.
Coverage Duration	• **All diagnoses:** o Initial: 6 months o Renewal: 12 months

Effective Date:	7/1/2025
P&T Approval Date:	7/11/2023
P&T Revision Date:	3/11/2025, 7/11/2023, 1/11/2022

References

- Selarsdi [package insert]. Parsippany, NJ: Teva Pharmaceuticals; 2025.
- Yesintek [package insert]. Cambridge, MA: Biocon Biologics; 2024.
- Steqeyma [package insert]. Jersey City, NJ: Celltrion USA Inc.; 2024.

Vanzacaftor-texacaftor-deutivacaftor (ALYFTEK)

Products Affected

- Alyftrek Tablets

PA Criteria	Criteria Details
Required Medical Information	**<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): o F508del mutation o 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
Age Restrictions	Age 6 and older
Prescriber Restrictions	Pulmonologist or Specialist affiliated with a CF care center
Coverage Duration	**Initial**: 6 months. **Renewal**: 12 months.
Renewal Criteria	Demonstrated positive clinical response to therapy

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

Voriconazole (VFEND)

Products Affected

- VORICONAZOLE

PA Criteria	Criteria Details
Required Medical Information	Approved for treatment of invasive aspergillosis and treatment of serious fungal infections in patients intolerant of, or refractory to other therapy.
Age Restrictions	**Suspension only:** Member is under age 10 or unable to use tablets
Prescriber Restrictions	
Coverage Duration	**Initial**: 3 months. **Renewal**: 3 months.
Renewal Criteria	Documented positive clinical response to therapy

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

Zafirlukast (ACCOLATE)

Products Affected

- ZAFIRLUKAST

PA Criteria	Criteria Details
Required Medical Information	Patient has a diagnosis of asthma **AND** Patient has experienced suboptimal control with combined use of an inhaled steroid and beta agonist.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	**Initial**: 12 months. **Renewal**: 12 months.
Renewal Criteria	Documented positive clinical response to therapy

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