

# **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 11/1/2024. For more recent information or other questions, please contact Pharmacy Services at **541-768-4550** or toll free **800-832-4580** (TTY 800-735-2900) or visit **samhealthplans.org**. Pharmacy Services is available Monday through Friday, from 8 a.m. to 5 p.m.

## **Abatacept (ORENCIA)**

### **Products Affected**

#### ORENCIA

#### • ORENCIA CLICKJECT

PA Criteria	Criteria Details
Required Medical Information	<ul> <li>All diagnoses:</li> <li>Initial testing for latent TB and treatment, if necessary, before starting treatment.</li> <li>No current active infection at initiation of therapy.</li> <li>Risks and benefits documented in cases of chronic or recurrent infection.</li> <li>Will NOT be used in combination with another biologic or Otezla</li> </ul>
	<ul> <li>Juvenile Idiopathic Arthritis (JIA):         <ul> <li>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</li> <li>The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of the following:</li></ul></li></ul>

PA Criteria	Criteria Details
	<ul> <li>Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine</li> <li>Trial and failure of both infliximab and adalimumab</li> </ul>
	Rheumatoid Arthritis (RA):
	<ul> <li>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)</li> <li>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</li> <li>Trial and failure of both infliximab and adalimumab</li> </ul>
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.
	<b>PsA:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
	<b>RA:</b> 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**

- 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**

- 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 <b>AND</b> 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**

- 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 & Biosimilars**

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

PA Criteria	Criteria Details
Required Medical Information	<ul> <li>All diagnoses</li> <li>Initial testing for latent TB and treatment, if necessary, before starting treatment.</li> <li>No current active infection at initiation of therapy.</li> <li>Risks and benefits documented in cases of chronic or recurrent infection.</li> <li>Will NOT be used in combination with another biologic or Otezla</li> <li>Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA):</li> <li>Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by:         <ul> <li>Back pain and stiffness for more than 3 months AND</li> <li>Signs of active inflammation on MRI OR radiological evidence of sacroillitis OR HLA-B27 positive AND</li> <li>BASDAI score of &gt;=4</li> </ul> </li> <li>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:         <ul> <li>At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated AND</li> <li>Physical therapy/exercise program</li> </ul> </li> <li>Crohn's Disease (CD):         <ul> <li>Documentation of moderate-to-severe Crohn's Disease</li> <li>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</li> </ul> </li> <li>Hidradenitis Suppurativa (HS):</li> </ul>

### 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 antiinflammatory 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 Plague 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

• At least 1 other second line systemic agent such as cyclosporine or

Methotrexate

acitretin

**Psoriatic Arthritis (PsA):** 

### PA Criteria **Criteria Details** 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) 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 antiinflammatory 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-
- Documented failure of all the following:
  - o Topical glucocorticoids for at least 1 month OR periocular steroid injection, AND
  - Oral corticosteroids, AND

PA Criteria	Criteria Details
	<ul> <li>At least one of the following: mycophenolate, tacrolimus, cyclosporine, azathioprine, or methotrexate</li> </ul>
Age Restrictions	
Prescriber Restrictions	Crohns 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	<b>AS/SpA:</b> Evidence of significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI.
	<b>CD:</b> Evidence of a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission.
	<b>HS:</b> Evidence of a reduction of 25% or more of the total abscess and inflammatory nodule count and no increase in abscesses and draining fistulas.
	<b>JIA:</b> Evidence of 20% or greater improvement in tender joint count and swollen joint count or has there been an improvement in functional ability.
	<b>PP:</b> 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.
	<b>PsA:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
	<b>RA:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
	<b>UC:</b> Evidence of a significant response such as a decrease in bloody stools per day or elimination of signs of toxicity.

PA Criteria	Criteria Details
	<b>Uveitis:</b> 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**

• Vjoice TAB

PA Criteria	Criteria Details
Required Medical Information	Confirmed diagnosis of PROS <b>AND</b> has at least one severe clinical manifestation of PROS <b>AND</b> has 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 <b>AND</b> 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 <b>OR</b> patient is currently on any therapy for the diagnosis of PAH. Documented failure or incomplete response to or 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.
	<b>Note:</b> 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	<ul> <li>All diagnoses:         <ul> <li>Initial testing for latent TB and treatment, if necessary, before starting treatment.</li> <li>No current active infection at initiation of therapy.</li> <li>Risks and benefits documented in cases of chronic or recurrent infection.</li> <li>Will NOT be used in combination with another biologic or Otezla</li> </ul> </li> <li>Rheumatoid Arthritis (RA):         <ul> <li>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)</li> <li>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</li> <li>Trial and failure of both infliximab and adalimumab</li> </ul> </li> </ul>
Age Restrictions	
Prescriber Restrictions	Rheumatoid Arthritis: Rheumatologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Renewal Criteria	<b>RA:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
Effective Date:	9/1/2023
P&T Approval Date	e: 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	<ul> <li>All diagnoses:</li> <li>Initial testing for latent TB and treatment, if necessary, before starting treatment.</li> <li>No current active infection at initiation of therapy.</li> <li>Risks and benefits documented in cases of chronic or recurrent infection.</li> <li>Will NOT be used in combination with another biologic or Otezla</li> </ul>
	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
	<ul> <li>Negative test result for RF</li> <li>Dactylitis (current of history)</li> <li>Radiological evidence of juxta-articular new bone formation</li> <li>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:         <ul> <li>NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND</li> <li>Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine</li> </ul> </li> <li>Trial and failure of both infliximab and adalimumab</li> </ul>
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	e:
P&T Revision Date	2:

# **Atovaquone-proguanil (MALARONE)**

- 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	<ul> <li>All diagnoses:</li> <li>Initial testing for latent TB and treatment, if necessary, before starting treatment.</li> <li>No current active infection at initiation of therapy.</li> <li>Risks and benefits documented in cases of chronic or recurrent infection.</li> <li>Will NOT be used in combination with another biologic or Otezla</li> </ul>
	<ul> <li>Rheumatoid Arthritis (RA):</li> <li>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)</li> <li>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</li> <li>Trial and failure of both infliximab and adalimumab</li> <li>Trial and failure of Actemra, Cimzia, Kineret, Orencia, and rituximab</li> </ul>
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

## **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	<ul> <li>Established clinical ASCVD:         <ul> <li>Documentation of very high risk ASCVD as evidenced by either:</li> <li>History of multiple major ASCVD events OR</li> <li>One major ASCVD event AND multiple high-risk conditions.</li> </ul> </li> <li>Documentation of a current LDL greater than or equal to 55 mg/dl.</li> <li>Documentation that:         <ul> <li>Patient is receiving maximally tolerated statin therapy (atorvastatin 40-80mg, rosuvastatin 20-40mg) or has a documented clinical intolerance to statins AND</li> <li>Is receiving ezetimibe or has a documented intolerance to ezetimibe.</li> </ul> </li> <li>Documentation of failure of PCSK9 inhibitor (Repatha or Praluent).</li> <li>Primary or familial hyperlipidemia:         <ul> <li>Documentation of an untreated (i.e., prior to lipid lowering therapy) LDL greater than 190 mg/dL.</li> <li>Documentation of current LDL greater than 100 mg/dL.</li> <li>Documentation that:             <ul> <li>Patient is receiving maximally tolerated statin therapy (atorvastatin 40-80mg, rosuvastatin 20-40mg) or has a documented clinical intolerance to statins AND</li> <li>Is receiving ezetimibe or has a documented intolerance to ezetimibe.</li> <li>Documentation of failure of PCSK9 inhibitor (Repatha or Praluent).</li> </ul> </li> </ul></li></ul>
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

## **Beumosudil (REZUROCK)**

### **Products Affected**

### Rezurock

PA Criteria	Criteria Details
Required Medical Information	Diagnosed with chronic graft-versus-host disease (cGVHD) <b>AND</b> who have tried and failed of at least two prior lines of systemic therapy for cGVHD <b>AND</b> 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	<ul> <li>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)</li> <li>One or more of the following:         <ul> <li>At least 10% of body surface area involved</li> <li>Hand, foot, face, or mucous membrane involvement</li> </ul> </li> <li>OR</li> <li>The patient on a current biologic product and experiencing intolerable side effects</li> <li>The patient tried and failed or have contraindications to ALL of the following?</li> <li>High-potency topical corticosteroids (augmented betamethasone, clobetasol, etc.)</li> <li>At least one other topical agent: calcipotriene, tazarotene, anthralin, tar, etc.</li> <li>PUVA or UVB Phototherapy</li> <li>Methotrexate</li> <li>At least 1 other second line systemic agent such as cyclosporine or acitretin</li> </ul>
	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
	<ul> <li>Improvement in symptoms (e.g. pruritus, inflammation) from baseline</li> <li>Evidence of functional improvement</li> </ul>

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)**

- Bosulif capsules Bosulif tablets

PA Criteria	Criteria Details
Required Medical Information	<ul> <li>Chronic Myelogenous/Myeloid Leukemia:         <ul> <li>Diagnosis of Philadelphia chromosome-positive chronic myelogenous/myeloid leukemia (Ph+ CML) AND</li> <li>One of the following:                  <ul></ul></li></ul></li></ul>
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	e:
P&T Revision Date	9:

### **Certolizumab Pegol SC (CIMZIA)**

### **Products Affected**

- CIMZIA
- CIMZIA PREFILLED

### • CIMZIA STARTER KIT

PA Criteria	Criteria Details
Required Medical Information	<ul> <li>All diagnoses:         <ul> <li>Initial testing for latent TB and treatment, if necessary, before starting treatment.</li> <li>No current active infection at initiation of therapy.</li> <li>Risks and benefits documented in cases of chronic or recurrent infection.</li> <li>Will NOT be used in combination with another biologic or Otezla</li> </ul> </li> <li>Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA):         <ul> <li>Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by:</li> </ul> </li> </ul>
	<ul> <li>Back pain and stiffness for more than 3 months AND</li> <li>Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive AND</li> <li>BASDAI score of &gt;=4</li> <li>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:         <ul> <li>At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND</li> <li>Physical therapy/exercise program</li> </ul> </li> <li>Trial and failure of both infliximab and adalimumab</li> </ul>
	<ul> <li>Crohn's Disease (CD):</li> <li>Documentation of moderate-to-severe Crohn's Disease</li> <li>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</li> <li>Trial and failure of both infliximab and adalimumab</li> </ul>
	<ul> <li>Plaque Psoriasis (PP):</li> <li>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</li> </ul>

### PA Criteria **Criteria Details** (or severe score on other validated tool) AND one or more of the 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) 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: NSAIDs for 3 months at maximum recommended or tolerated antiinflammatory 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

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	Crohns 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.
	<b>CD:</b> Evidence of a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission.
	<b>PP:</b> 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.
	<b>PsA:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
	<b>RA:</b> 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	e:
P&T Revision Date	2:

### **Cinacalcet Hydrochloride (SENSIPAR)**

### **Products Affected**

• CINACALCET HCL

P&T Revision Date:

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
Effective Date:	
P&T Approval Date	e:

### **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.
	<ul> <li>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:         <ul> <li>Patient has a contraindication to commercially available products</li> <li>Only one or no other therapeutic alternatives are commercially available</li> <li>Prepared strength(s) is/are not commercially available or currently in short supply</li> <li>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).</li> <li>Patient has an allergy or sensitivity to inactive ingredients (e.g. dyes, preservatives, sugars, etc.) that are found in commercially available products.</li> </ul> </li> </ul>
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

Clobazam zomg rabiets		
PA Criteria	Criteria Details	
Required Medical	Lennox-Gastaut Syndrome	
Information	Confirmed diagnosis.	
	Refractory Seizures	
	<ul> <li>Documentation showing appropriate trial of 2 or more tolerated anticonvulsant therapies.</li> </ul>	
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: 12 months.	
Renewal Criteria	Documentation of positive clinical response to therapy.	
Effective Date:	5/1/2024	
P&T Approval Date	e: 3/12/2024	
P&T Revision Date	: 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 <b>OR</b> child or adolescent under the age of 21 <b>OR</b> member is pregnant or plans to become pregnant within 6 months <b>OR</b> using short or intermediate acting insulin <b>AND</b> the criteria listed under "applies to all requests" has been met.
	Type 2 Diabetes Mellitus OR Gestational Diabetes:
	Using short or intermediate acting insulin <b>AND</b> the criteria listed under "applies to all requests" has been met.
	Applies to all requests
	<ul> <li>Must meet at least one of the following:         <ul> <li>Baseline HbA1c levels great than or equal to 8.0%</li> <li>Frequent or severe hypoglycemia</li> <li>Impaired awareness of hypoglycemia (including presence of these conditions prior to initiation of CGM</li> </ul> </li> </ul>
	<ul> <li>Diabetes related complications (e.g. peripheral neuropathy, end- organ damage, ect.)</li> </ul>
	Member has received or will receive diabetes education specific to the use of the CGM device.
	**If the request is for a <b>Dexcom</b> 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

### **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 <b>OR</b> non-transfusion-dependent thalassemia syndromes <b>AND</b> patient has a creatinine clearance of greater than or equal to 40 mL/minute <b>OR</b> serum creatinine less than or equal to 2 times the age-appropriate level <b>AND</b> 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) <b>AND</b> 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
<u> </u>	
Effective Date:	
P&T Approval Date	e:
P&T Revision Date	

## **Desmopressin (STIMATE)**

#### **Products Affected**

• Desmopressin Acetate Nasal Spray & Injections

PA Criteria	Criteria Details
Required Medical Information	<ul> <li>Being used for one of the following:</li> <li>Diabetes Insipidus</li> <li>Maintenance of hemostasis and control of bleeding in hemophilia A with factor VIII coagulant activity levels greater than 5%</li> <li>Mild-to-moderate classic von Willebrand's disease (type 1) with factor VIII coagulant activity greater than 5%.</li> </ul>
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.		
	<b>Tardive Dyskinesia:</b> Follow-up AIMS assessment showing improvement from Baseline <b>AND</b> documented improvement in functioning such as ability to perform ADLs, reduction in falls and increase in quality of life.		

Effective Date:	07/01/2023
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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 <b>OR</b> treatment of cluster headaches <b>AND</b> 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	e:	
P&T Revision Date	e:	

### **Dimethyl Fumarate (TECFIDERA)**

#### **Products Affected**

• DIMETHYL FUMARATE

#### • DIMETHYL FUMARATE STARTER PACK

PA Criteria	Criteria Details
Required Medical Information	<b>Multiple sclerosis:</b> 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

### **Direct-Acting Antivirals (use in Hepatitis C)**

#### **Products Affected**

- MAVYRET
- VOSEVI

#### • SOFOSBUVIR-VELPATASVIR

PA Criteria	Criteria Details				
Required Medical Information	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				
			for Adult		12 years of age and older
	Treatment History	Cirrhosis Status		Recommended Regi	men
	Treatment Naïve (Geno		1	SOF/VEL x 12 weeks	
	ттеаннени пагуе	Non-cirrhotic		G/P x 8 weeks	
Compensated			;	G/P x 8 weeks SOF/VEL x 12 weeks (baseline resistance testing recommended for GT3)	
	Decompensated cirrhosis  SOF/VEL + RBV x 12 weeks SOF/VEL x 24 weeks (if RBV ineligible)			weeks	
	Treatment Experienc Sofobuvir based regime including: sofosbuvir + Ledipasvir/Sofobuvir Ve	en treatment failures, ribavirin	Non-cirrho cirrhosis	otic or compensated	SOF/VEL/VOX x 12 weeks G/P x16 weeks (except GT3)

PA Criteria	Criteria Details					
	Elbasvir/grazoprevir treatment fa	Elbasvir/grazoprevir treatment failures		SOF/VEL/VOX x 12 weeks		
	Glecaprevir/pibrentasvir treatment	nt failures	Non-cirrhotic or compensated cirrhosis	G/P + SOF + RBV x 16 weeks SOF/VEL/VOX x 12 weeks (plus RBV if compensated cirrhosis) G/P + SOF + RBV x 16-24 weeks SOF/VEL/VOX x24 weeks		
	Multiple DAA Treatment Failures, Sofobuvir/velpatasvir/voxilaprev Glecaprevir/pibrentasvir + sofob	ir	Non-Cirrhotic or compensated cirrhosis			
	Table 2. Recommended Regim					
	Treatment History	Cirrhosis	Status	Recommended Regimen		
	Treatment Naïve (Genotype 1-6) Treatment Naïve		otic or compensated cirrhosis	SOF/VEL x 12 weeks G/P x 8 weeks		
		Decompe	nsated cirrhosis	SOF/VEL + RBV x 12 weeks		
cirrhosis. These patients should be handled on a case by case basis with the patient, presc CCO or FFS medical director  Ribavirin ineligible/intolerance may include: 1) neutrophils < 750 mm3, 2) hemoglobin < 10 platelets <50,000 cells/mm3, autoimmune hepatitis or other autoimmune condition, hyperso allergy to ribavirin				2) hemoglobin < 10 g/dl, 3)		
Age Restrictions						
Prescriber Restrictions						
Coverage Duration	8-24 weeks					
Renewal						

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			
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	
<u>.</u>		
Effective Date:		
P&T Approval Date	e:	
P&T Revision Date	2:	

## **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 (eg, 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	e:
P&T Revision Date	2:

### **Dupilumab (DUPIXENT)**

#### **Products Affected**

### • DUPIXENT

PA Criteria	Criteria Details
Required Medical Information	Moderate to severe Asthma with inadequate control of asthma symptoms with one of the following: inhaled corticosteroids and long acting beta2 agonist <b>OR</b> 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 other validated tool) AND one or more of the following: At least 10% of body surface area involvement OR hand, foot or mucous membrane involvement AND documented contraindication or failed trial to ALL of the following: Moderate-high potency corticosteroid (e.g., clobetasol, fluocinonide, fluticasone) AND Topical calcineurin inhibitor (e.g. tacrolimus) AND Oral immunomodulator therapy (e.g. cyclosporine, methotrexate, azathioprine, mycophenolate mofetil, oral corticosteroids).
	<b>Eosinophilic Esophagitis</b> : Confirmed diagnosis of EoE <b>AND</b> Weight ≥ 40 kg (88lbs) <b>AND</b> Two or more episodes of dysphagia per week <b>AND</b> inadequate response (8-week trial) or intolerance/contraindication to high-dose PPI therapy <b>AND</b> inadequate response (8- to 12- week trial), intolerance, or contraindication to swallowed inhaled respiratory corticosteroid therapy.
	CRSwNP: Diagnosis of CRSwNP, which includes objective evidence of the presence of bilateral nasal polyps AND not used in combination with other biologics for eosinophilic indications AND failure to adequately reduce symptoms after at least 2 months of saline nasal irrigations and INCS use at doses appropriate for nasal polyp treatment AND systemic corticosteroid treatment for NPs at least once within the last 2 years or prior NP removal surgery AND concomitant use of an INCS (unless not tolerated or contraindicated) while on biologic therapy  Prurigo Nodularis: Funded comorbid condition which would benefit from therapy AND diagnosis of PN verified by a dermatologist AND has had the diagnosis of PN for at least 3 months AND severe or very severe itch (WI-NRS score ≥7) reported within the past week AND at least 20 PN lesions in total on both legs and/or both arms and/or trunk.
Age Restrictions	Moderate to Severe Asthma: 6 years and older

PA Criteria	Criteria Details
	Atopic Dermatitis: 6 months and older Eosinophilic Esophagitis: 12 years and older CRSwNP & Prurigo Nodularis: 18 years and older
Prescriber Restrictions	Atopic dermatitis: Prescribed by a Dermatologist Eosinophilic Esophagitis: Prescribed by Gastroenterologist or Immunologist CRSwNP: Prescribed by ENT or Immunologist Prurigo Nodularis: Prescribed by Dermatologist
Coverage Duration	Initial: 6 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:	

## **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 <b>AND</b> trial and failure, contraindication, or intolerance to a 3-month trial of prescription strength NSAIDs <b>AND</b> trial and failure, contraindication, or intolerance to two 3-month trials of hormonal therapies (eg combined oral contraceptives, progestins, or levonorgestrel IUD, etc.). <b>Additional info required for 200 mg tablet twice daily:</b> 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 Renewals allowed 150MG dose: Initial: 6 months; Renewal: 18months
Renewal Criteria	<b>150MG ONLY:</b> Documentation of positive clinical response to therapy <b>AND</b> 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-ivacaft (TRIKAFTA)**

#### **Products Affected**

#### • TRIKAFTA

PA Criteria	Criteria Details
Required Medical Information	Clinical documentation of cystic fibrosis diagnosis with at least one F508del mutation (heterozygous or homozygous).
Age Restrictions	12 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:	

# **Elefibranor (IQIRVO)**

#### **Products Affected**

• Iqirvo tablets

PA Criteria	Criteria Details
Required Medical Information	<ul> <li>Primary biliary cholangitis:</li> <li>Diagnosis of primary biliary cholangitis (PBC) confirmed by two of the following:         <ul> <li>Biochemical evidence of cholestasis based on ALP elevation</li> <li>Presence of AMA or other PBC-specific autoantibodies</li> <li>Histology confirmation after biopsy</li> </ul> </li> <li>Trial and failure of 12 months of ursodiol.</li> <li>No current decompensated cirrhosis.</li> </ul>
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).
	<b>Preoperative for reduction of allogeneic blood transfusion:</b> 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 <b>AND</b> patient is at high risk of blood loss <b>AND</b> patient is unwilling or unable to donate autologous blood pre-operatively.
	<b>Anemia in Myelodysplastic Syndrome (MDS):</b> Diagnosis of MDS. Serum erythropoietin less than or equal to 500mU/mL <b>OR</b> 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:	

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 tabletes

PA Criteria	Criteria Details
Required Medical Information	<ul> <li>Ulcerative Colitis (UC):</li> <li>Documentation of moderate-to-severe ulcerative colitis</li> <li>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:         <ul> <li>Mesalamine, sulfasalazine OR</li> <li>Mercaptopurine, azathioprine, OR</li> <li>Corticosteroids (prednisone, methylprednisolone)</li> </ul> </li> <li>Trial and failure of both infliximab and adalimumab</li> </ul>
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	<ul> <li>All diagnoses:</li> <li>Initial testing for latent TB and treatment, if necessary, before starting treatment.</li> <li>No current active infection at initiation of therapy.</li> <li>Risks and benefits documented in cases of chronic or recurrent infection.</li> <li>Will NOT be used in combination with another biologic or Otezla</li> </ul>
	<ul> <li>Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA):</li> <li>Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by:         <ul> <li>Back pain and stiffness for more than 3 months AND</li> <li>Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive AND</li> <li>BASDAI score of &gt;=4</li> </ul> </li> <li>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:         <ul> <li>At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND</li> <li>Physical therapy/exercise program</li> <li>Trial and failure of both infliximab and adalimumab</li> </ul> </li> </ul>
	<ul> <li>Plaque Psoriasis (PP):</li> <li>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:         <ul> <li>At least 10% of body surface area involved</li> <li>Hand, foot, face, or mucous membrane involvement</li> </ul> </li> <li>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:</li> </ul>

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	<ul> <li>Vasomotor Symptoms (VMS):</li> <li>Diagnosis of moderate-to-severe VMS due to menopause</li> <li>Documented contraindication, intolerance, or inadequate response to at least 2 hormonal therapies AND</li> <li>Documented contraindication, intolerance, or inadequate response to two nonhormonal therapies (e.g., one SNRI and one SSRI).</li> </ul>
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 <sup>3</sup> ).
	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 <b>OR</b> 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 <sup>3</sup> .
	<b>Febrile Neutropenia (FN):</b> Patient receiving myelosuppressive chemotherapy associated with neutropenia (ANC less than or equal to 500 cells/mm <sup>3</sup> ) <b>AND</b> 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%
- FLUOROURACII SOL 2%

• FLUOROURACIL **SOL 5**%

FLUURUURAU	T
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
Effoctive Date:	

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	e:	
P&T Revision Date	o:	

# **General Oncology**

Products Affected			
<ul> <li>AKEEGA TAB</li> </ul>	<ul> <li>IBRANCE CAP</li> </ul>	<ul> <li>LYNPARZA TAB</li> </ul>	<ul> <li>TAFINLAR CAP</li> </ul>
<ul> <li>AUGTYRO CAP</li> </ul>	<ul> <li>IBRANCE TAB</li> </ul>	<ul> <li>LYNPARZA TAB</li> </ul>	<ul> <li>TASIGNA CAP</li> </ul>
<ul> <li>BRUKINSA CAP</li> </ul>	<ul> <li>IMBRUVICA CAP</li> </ul>	<ul> <li>LYTGOBI TAB</li> </ul>	<ul> <li>TEPMETKO TAB</li> </ul>
<ul> <li>CABOMETYX</li> </ul>	<ul> <li>IMBRUVICA TAB</li> </ul>	<ul> <li>MEKINIST TAB</li> </ul>	<ul> <li>THALOMID CAP</li> </ul>
TAB	<ul> <li>IMBRUVICA</li> </ul>	<ul> <li>NINLARO CAP</li> </ul>	<ul> <li>TIBSOVO TAB</li> </ul>
<ul> <li>CALQUENCE</li> </ul>	SUSP	<ul> <li>OGSIVEO TAB</li> </ul>	<ul> <li>TRUSELTIQ CAP</li> </ul>
TAB	<ul> <li>JAYPIRCA TAB</li> </ul>	<ul> <li>PEMAZYRE TAB</li> </ul>	<ul> <li>TRUQAP TAB</li> </ul>
<ul> <li>COTELLIC TAB</li> </ul>	<ul> <li>KISQALI TAB</li> </ul>	<ul> <li>RETEVMO TAB</li> </ul>	<ul> <li>TUKYSA TAB</li> </ul>
<ul> <li>EMCYT CAP</li> </ul>	<ul> <li>KRAZATI TAB</li> </ul>	<ul> <li>REZLIDHIA CAP</li> </ul>	<ul> <li>VANFLYTA TAB</li> </ul>
<ul> <li>ERLOTINIB TAB</li> </ul>	<ul> <li>LENALIDOMIDE</li> </ul>	<ul> <li>ROZLYTREK CAP</li> </ul>	<ul> <li>VERZENIO TAB</li> </ul>
<ul> <li>EVEROLIMUS</li> </ul>	CAP	<ul> <li>RYDAPT CAP</li> </ul>	<ul> <li>VONJO CAP</li> </ul>
<ul> <li>EXKIVITY CAP</li> </ul>	<ul> <li>LENVIMA CAP</li> </ul>	<ul> <li>SCEMBLIX TAB</li> </ul>	<ul> <li>VOTRIENT TAB</li> </ul>
<ul> <li>FOTIVDA CAP</li> </ul>	<ul> <li>LEUKERAN TAB</li> </ul>	<ul> <li>SORAFENIB TAB</li> </ul>	<ul> <li>XALKORI CAP</li> </ul>
<ul> <li>FRUZAQLA CAP</li> </ul>	<ul> <li>LONSURF TAB</li> </ul>	<ul> <li>SPRYCEL TAB</li> </ul>	<ul> <li>ZOLINZA TAB</li> </ul>
<ul> <li>GLEOSTINE CAP</li> </ul>	<ul> <li>LORBRENA TAB</li> </ul>	<ul> <li>SUNITINIB CAP</li> </ul>	
<ul> <li>HYCAMTIN CAP</li> </ul>	<ul> <li>LUMAKRAS TAB</li> </ul>	<ul> <li>TALZENNA CAP</li> </ul>	

PA Criteria	Criteria Details
Required Medical Information	Medication is being used for an FDA approved age <b>AND</b> Medication is being used for FDA approved indication <b>OR</b> Medication is being used according to National Comprehensive Cancer Network (NCCN) guidelines
Age Restrictions	
Prescriber Restrictions	Prescribed by oncologist
Coverage Duration	Initial: 3 months. Renewal: up to 6 months.
Renewal Criteria	Clinical documentation of provider follow-up indicating safety and efficacy with medication adherence over previous approval duration.

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

- TRULICITY
- VICTOZA

BYETTA 5 MCG PEN

PA Criteria	Criteria Details
Required Medical Information	<ul> <li>Type 2 diabetes:</li> <li>Documentation of clinically diagnosed Type 2 Diabetes.</li> <li>Documentation of adequate trial of maximally tolerated dose of metformin.</li> <li>Documentation of trial and failure of an SGLT-2 inhibitor or a DPP-4 inhibitor (or contraindication to both.</li> </ul>
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	<ul> <li>All diagnoses:</li> <li>Initial testing for latent TB and treatment, if necessary, before starting treatment.</li> <li>No current active infection at initiation of therapy.</li> <li>Risks and benefits documented in cases of chronic or recurrent infection.</li> <li>Will NOT be used in combination with another biologic or Otezla</li> </ul>
	<ul> <li>Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA):</li> <li>Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by:         <ul> <li>Back pain and stiffness for more than 3 months AND</li> <li>Signs of active inflammation on MRI OR radiological evidence of sacroilitis OR HLA-B27 positive AND</li> <li>BASDAI score of &gt;=4</li> </ul> </li> <li>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:         <ul> <li>At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND</li> <li>Physical therapy/exercise program</li> </ul> </li> <li>Trial and failure of both infliximab and adalimumab</li> </ul>
	<ul> <li>Psoriatic Arthritis (PsA):</li> <li>Documentation of psoriatic arthritis based on at least 3 out of 5 of the following:         <ul> <li>Psoriasis (1 point for personal or family history, 2 points for current)</li> <li>Psoriatic nail dystrophy</li> <li>Negative test result for RF</li> <li>Dactylitis (current of history)</li> <li>Radiological evidence of juxta-articular new bone formation</li> </ul> </li> <li>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:</li> </ul>

PA Criteria	Criteria Details
	<ul> <li>NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND</li> <li>Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine</li> <li>Trial and failure of both infliximab and adalimumab</li> </ul>
	<ul> <li>Rheumatoid Arthritis (RA):         <ul> <li>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)</li> <li>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</li> <li>Trial and failure of both infliximab and adalimumab</li> </ul> </li> <li>Ulcerative Colitis (UC):         <ul> <li>Documentation of moderate-to-severe ulcerative colitis</li> <li>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:</li></ul></li></ul>
Ana Doctrictions	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.
	<b>PsA:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.

PA Criteria	Criteria Details
	<b>RA:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
	<b>UC:</b> 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
	<ul> <li>Uterine Leiomyomata (Fibroids) - For the reduction of the size of fibroids         <ul> <li>For use prior to surgery to reduce the size of fibroids to facilitate a surgical procedure (e.g., myomectomy, hysterectomy)</li> </ul> </li> <li>Uterine Leiomyomata (Fibroids) - Anemia         <ul> <li>Anemia is caused by uterine leiomyomata (fibroids)</li> <li>Patient has tried and had an inadequate response to at least 1 month of monotherapy with iron</li> <li>Used in combination with iron therapy</li> <li>For use prior to surgery</li> </ul> </li> </ul>
	<ul> <li>Central Precocious Puberty (CPP)</li> <li>Diagnosis of central precocious puberty (idiopathic or neurogenic)</li> <li>Early onset of secondary sexual characteristics in one of the following:         <ul> <li>Females less than 8 years of age</li> <li>Males less than 9 years of age</li> </ul> </li> <li>Advanced bone age of at least one year compared with chronological age</li> <li>One of the following:         <ul> <li>Patient has undergone gonadotropin-releasing hormone agonist (GnRHa) testing and peak luteinizing hormone (LH) level above pre-pubertal range</li> <li>Patient has a random LH level in the pubertal range</li> <li>One of the following:</li> </ul> </li> </ul>

PA Criteria	Criteria Details
	<ul> <li>Patient had one of the following diagnostic evaluations to rule out tumors, when suspected:         <ul> <li>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</li> <li>Pelvic/testicular/adrenal ultrasound (if steroid levels suggest suspicion)</li> <li>Adrenal steroids to rule out congenital adrenal hyperplasia (when pubarche precedes thelarche or gonadarche)</li> <li>Patient has no suspected tumors</li> </ul> </li> </ul>
	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 prepubertal 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	<ul> <li>Established clinical ASCVD:         <ul> <li>Documentation of very high risk ASCVD as evidenced by either:</li> <li>History of multiple major ASCVD events OR</li> <li>One major ASCVD event AND multiple high-risk conditions.</li> </ul> </li> <li>Documentation of a current LDL greater than or equal to 55 mg/dl.</li> <li>Documentation that:         <ul> <li>Patient is receiving maximally tolerated statin therapy (atorvastatin 40-80mg, rosuvastatin 20-40mg) or has a documented clinical intolerance to statins AND</li> <li>Is receiving ezetimibe or has a documented intolerance to ezetimibe.</li> </ul> </li> <li>Documentation of failure of PCSK9 inhibitor (Repatha or Praluent).</li> <li>Primary or familial hyperlipidemia:         <ul> <li>Documentation of an untreated (i.e., prior to lipid lowering therapy) LDL greater than 190 mg/dL.</li> <li>Documentation of current LDL greater than 100 mg/dL.</li> <li>Documentation that:             <ul> <li>Patient is receiving maximally tolerated statin therapy (atorvastatin 40-80mg, rosuvastatin 20-40mg) or has a documented clinical intolerance to statins AND</li> <li>Is receiving ezetimibe or has a documented intolerance to ezetimibe.</li> </ul> </li> </ul> </li> <li>Documentation of failure of PCSK9 inhibitor (Repatha or Praluent).</li> </ul>
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

## **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 furmate  • 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 <b>AND</b> trial and failure, contraindication, or intolerance to all of the following: dimethyl furmate, 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 <b>AND</b> trial and failure, contraindication, or intolerance to all of the following: dimethyl furmate, 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	<ul> <li>Tinea Unguium:         <ul> <li>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.</li> </ul> </li> <li>All other conditions:         <ul> <li>Diagnosis is supported by compendia and is an above the line condition.</li> </ul> </li> </ul>
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, <b>Renewal</b> 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	<ul> <li>All diagnoses:</li> <li>Initial testing for latent TB and treatment, if necessary, before starting treatment.</li> <li>No current active infection at initiation of therapy.</li> <li>Risks and benefits documented in cases of chronic or recurrent infection.</li> <li>Will NOT be used in combination with another biologic or Otezla</li> </ul>
	<ul> <li>Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA):</li> <li>Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by:         <ul> <li>Back pain and stiffness for more than 3 months AND</li> <li>Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive AND</li> <li>BASDAI score of &gt;=4</li> </ul> </li> <li>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:         <ul> <li>At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND</li> <li>Physical therapy/exercise program</li> </ul> </li> <li>Trial and failure of both infliximab and adalimumab</li> </ul>
	<ul> <li>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:         <ul> <li>At least 10% of body surface area involved</li> <li>Hand, foot, face, or mucous membrane involvement</li> </ul> </li> <li>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:</li> </ul>

PA Criteria	Criteria Details
	<ul> <li>High-potency topical corticosteroids (augmented betamethasone, clobetasol, etc.)</li> <li>At least one other topical agent (calcipotriene, tazarotene, anthralin, tar, etc.)</li> <li>PUVA or UVB Phototherapy</li> <li>Methotrexate</li> <li>At least 1 other second line systemic agent such as cyclosporine or acitretin</li> <li>Trial and failure of both infliximab and adalimumab</li> </ul>
	<ul> <li>Psoriatic Arthritis (PsA):</li> <li>Documentation of psoriatic arthritis based on at least 3 out of 5 of the following:         <ul> <li>Psoriasis (1 point for personal or family history, 2 points for current)</li> <li>Psoriatic nail dystrophy</li> <li>Negative test result for RF</li> <li>Dactylitis (current of history)</li> <li>Radiological evidence of juxta-articular new bone formation</li> </ul> </li> <li>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:         <ul> <li>NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND</li> <li>Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine</li> </ul> </li> <li>Trial and failure of both infliximab and adalimumab</li> </ul>
Age Restrictions	That and failule of both illinximab and adaimidinab
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.
	<b>PP:</b> 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.
	<b>PsA:</b> 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,
 Lacosamide Solution 10MG/ML 200MG

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: 12 months.
Renewal Criteria	Documentation of positive clinical response to therapy.

Effective Date:	5/1/2024
P&T Approval Date:	3/12/2024
P&T Revision Date:	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 <b>AND</b> 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 <b>AND</b> documentation patient is on preventative therapy <b>AND</b> 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

### 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 <b>AND</b> will be used in combination with an optimized baseline regimen (OBR) <b>AND</b> 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	<ul> <li>Continues to be used in combination with an optimized background regimen (OBR)</li> <li>Provider states that patient continues to receive clinical benefit from the treatment</li> </ul>

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	

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

## **Lisdexamfetamine (VYVANSE)**

#### **Products Affected**

#### • LISDEXAMFETAMINE CAPS

PA Criteria	Criteria Details
Required Medical Information	ADHD: Clinical documentation of trial and failure (defined as at least 6 weeks of treatment) of generic Adderall XR, generic Concerta, and generic Focalin XR in the treatment of ADHD. In cases of concern of stimulant abuse, must provide clinical documentation of trial and failure of one long-acting formulary stimulant OR clinical justification as to why formulary long-acting stimulants are contraindicated for the patient.  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	<b>BED</b> : 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:	
P&T Approval Date	e:
P&T Revision Date:	

### **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	Cancer, end of life, or palliative care: No coverage restrictions.	
	<ul> <li>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.</li> <li>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].</li> <li>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].</li> <li>Restricted to 2 fills in a 60-day period for both naive and experienced.</li> </ul>	
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	i

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	e:
P&T Revision Date	e:

## **Memantine Hydrochloride (NAMENDA)**

#### **Products Affected**

• MEMANTINE HCL

PA Criteria	Criteria Details
Required Medical	Treatment of moderate-to-severe dementia of the Alzheimer's type.
	<b>Solution only:</b> Documentation that member can't use tablets/capsules and is under the age of 10
Age Restrictions	<b>Solution only:</b> 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**

P&T Revision Date:

Omvoh

PA Criteria	Criteria Details
Required Medical Information	<ul> <li>All diagnoses:         <ul> <li>Initial testing for latent TB and treatment, if necessary, before starting treatment.</li> <li>No current active infection at initiation of therapy.</li> <li>Risks and benefits documented in cases of chronic or recurrent infection.</li> <li>Will NOT be used in combination with another biologic or Otezla</li> </ul> </li> <li>Ulcerative Colitis (UC):         <ul> <li>Documentation of moderate-to-severe ulcerative colitis</li> <li>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:</li></ul></li></ul>
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	e: 05/14/2024

## 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 <b>AND</b> confirmation of current hemoglobin is ≤ 10mg/dL <b>AND</b> patient is not homozygous for the R479H mutation <b>AND</b> does not have two non-missense variants in the PKLR gene, without the presence of another missense variant <b>AND</b> patient has had at least 6 RBC transfusions within the previous year for hemolytic anemia due to PKD <b>AND</b> prescriber confirmed concomitant use of daily folic acid <b>AND</b> 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 <b>AND</b> inadequate treatment response, intolerance, or contraindication to fluticasone nasal spray, <b>AND</b> budesonide nasal spray <b>AND</b> 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

## Non-Formulary Criteria (standard criteria for nonformulary medication)

#### **Products Affected**

• All Non-formulary medications

PA Criteria	Criteria Details
Required Medical Information	<ul> <li>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.</li> <li>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.</li> <li>All appropriate formulary alternatives have been tried and failed or are contraindicated.</li> <li>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:         <ul> <li>For a child age 10 years old or younger, or the member has documented inability to swallow formulary tablets/capsules</li> <li>formulary equivalent (tablet/capsule) does not require PA OR member meets coverage criteria for formulary equivalent (tablet/capsule)</li> </ul> </li> </ul>
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	e:

P&T Revision Date:	

# Omalizumab (XOLAIR)

#### **Products Affected**

#### XOLAIR

PA Criteria	Criteria Details
Required Medical Information	<ul> <li>Severe Asthma:</li> <li>Confirmed diagnosis of moderate to severe persistent asthma.</li> <li>Positive skin test or RAST to a perennial aeroallergen.</li> <li>Baseline IgE serum level within FDA label.</li> <li>Documentation of steps taken to avoid, within reason, environmental allergens and other triggers environmental allergens and other triggers.</li> <li>Documented trial and failure, with claims history of adherence to: <ul> <li>High dose inhaled corticosteroid with a long-acting beta agonist (e.g., Advair),</li> <li>Long acting anti-muscarinic (e.g., Spiriva),</li> <li>Leukotriene Inhibitor (e.g., Singulair).</li> </ul> </li> <li>Documented trial and failure of, or contraindication to allergen immunotherapy.</li> </ul>
	<ul> <li>Chronic Rhinosinusitis with Nasal Polyps (CRSwNP):</li> <li>Confirmed diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP).</li> <li>Documentation of recurrent nasal polyps after prior sinus surgery.</li> <li>Documented risk of another sinus surgery, or a statement why sinus surgery is not medically appropriate.</li> <li>Documented trial and failure, with claims history of adherence to: <ul> <li>At least 2 intranasal corticosteroids (e.g., fluticasone, mometasone),</li> <li>Sinuva.</li> </ul> </li> <li>Documentation that Xolair is intended as adjunct therapy with nasal corticosteroids.</li> </ul>
	<ul> <li>Chronic Idiopathic Urticaria- refractory (CIU):         <ul> <li>Documentation of chronic spontaneous or idiopathic urticaria.</li> <li>Age under 21, or a comorbid condition which would make chronic urticaria coverable under the prioritized list.</li> </ul> </li> <li>Documented trial and failure of at least 6 weeks of maximally tolerated doses of all the following:         <ul> <li>1st generation antihistamine - (e.g., doxepin, hydroxyzine)</li> </ul> </li> </ul>

PA Criteria	Criteria Details
	<ul> <li>2<sup>nd</sup> generation antihistamine – (e.g., cetirizine, levocetirizine, fexofenadine, loratadine, desloratadine)</li> <li>Histamine Type-2 Receptor Antagonists (e.g., famotidine, cimetidine)</li> <li>Leukotriene inhibitor (e.g., montelukast, zafirlukast)</li> </ul>
	<ul> <li>Diagnosis of IgE Mediated Food Allergy as evidenced by one of the following: <ul> <li>Positive skin prick test (defined as greater than or equal to 4 mm wheal greater than saline control) to food,</li> <li>Positive food specific IgE (greater than or equal to 6 kUA/L),</li> <li>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.</li> </ul> </li> <li>Clinical history of IgE mediated food allergy.</li> <li>Used in conjunction with food allergen avoidance.</li> <li>Both of the following: <ul> <li>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,</li> <li>Dosing is according to serum total IgE levels and body weight.</li> </ul> </li> <li>Xolair will not be used concomitantly with Palforzia.</li> <li>Attestation that the member is co-prescribed epinephrine or has epinephrine at home.</li> </ul>
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:
	<ul> <li>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).</li> <li>Used in conjunction with food allergen avoidance.</li> <li>Dosing will continue to be based on body weight and pretreatment IgE serum levels.</li> </ul>
	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

## Pancrelipase (CREON) (PANCREAZE)

#### **Products Affected**

• Creon Capsules

#### • Pancreaze Capsules

PA Criteria	Criteria Details
Required Medical Information	Confirmed diagnosis of cystic fibrosis <b>OR</b> history of pancreatectomy <b>OR</b> diagnosis of exocrine pancreatic cancer <b>OR</b> diagnosis of chronic pancreatitis confirmed by imaging <b>OR</b> confirmed diagnosis of pancreatic insufficiency confirmed with one of the following methods:  • Steatorrhea with fecal fat determination <b>OR</b> • Measurement of fecal elastase <b>OR</b> • Secretin or CCK pancreatic function testing <b>OR</b> • 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	e:
P&T Revision Date	2:

#### **PCSK9** inhibitors

Prescriber

#### **Products Affected Praluent** Repatha **PA Criteria Criteria Details Required Medical** Established clinical atherosclerotic cardiovascular disease (ASCVD): Information 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 o 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 o Is receiving ezetimibe or has a documented intolerance to ezetimibe. Age Restrictions

Restrictions	specialist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Renewal Criteria	Documented positive clinical response to therapy (significant decrease in lipid levels).

Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid

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

P&T Revision Date:	01/11/2022, 09/10/2024
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## **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 <b>Initial</b> 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 <b>Initial</b> dose escalation happened between age 4 and 17.

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

## **Pramipexole Dihydrochloride (MIRAPEX)**

#### **Products Affected**

P&T Approval Date:

P&T Revision Date:

• 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:	

## **Potassium Binders**

#### **Products Affected**

• Lokelma Powder Pak: 5g, 10g

• Veltassa Packet: 8.4g, 16.8g, 25.2g

PA Criteria	Criteria Details
Required Medical Information	<ul> <li>Being used for the treatment of hyperkalemia based on current potassium labs</li> <li>Failed all of the following:         <ul> <li>Dietary changes (potassium restriction)</li> <li>Dose modification/discontinuation of ACE-inhibitor, ARB, or other hyperkalemia causing agents</li> <li>Diuretics titrated to maximum tolerated dose</li> </ul> </li> <li>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)</li> </ul>
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	<ul> <li>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.</li> <li>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.</li> <li>Documentation of failure of the requested medication within quantity limits, including failure of different strengths of the requested medication.</li> <li>All appropriate alternative treatments have been tried and failed.</li> </ul>
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	e:
P&T Revision Date	2:

## **Resmetirom (REZDIFFRA)**

#### **Products Affected**

Rezdiffra 60MG/80MG/100MG TAB

PA Criteria	Criteria Details
Required Medical Information	<ul> <li>Diagnosis of metabolic dysfunction-associated steatohepatitis (MASH), formulary known as nonalcoholic steatohepatitis (NASH)</li> <li>Patient does not have cirrhosis (e.g. decompensated cirrhosis)</li> <li>Submission of medical records (e.g. chart notes) showing diagnosis has been confirmed by one of the following:         <ul> <li>FibroScan-aspartate aminotransferase (FAST)</li> <li>MRI-aspartate aminotransferase (MAST)</li> <li>Liver biopsy</li> </ul> </li> <li>Submission of medical records (e.g. chart notes) showing disease is fibrosis stage F2 or F3 as confirmed by one of the following:         <ul> <li>FibroScan</li> <li>FibroScan</li> <li>Magnetic resonance Elastography (MRE)</li> </ul> </li> <li>Presence of greater than or equal to 3 metabolic risk factors (e.g., Type 2 diabetes, hypertension, obesity)</li> <li>Submission of medical records (e.g. chart notes) confirming drug is</li> </ul>
	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.
<b>Exclusion Criteria</b>	Prescribed by a county clinic with a state funded TB program (for these programs the drug is funded directly through the state).
Age Restrictions	
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:	5/1/2024
P&T Approval Date:	3/12/2024
P&T Revision Date:	

## Rifaximin (XIFAXAN)

#### **Products Affected**

#### XIFAXAN

PA Criteria	Criteria Details
Required Medical Information	<b>Diagnosis of Hepatic Encephalopathy:</b> must have one of the following: used as add-on therapy to lactulose <b>AND</b> unable to achieve an optimal clinical response with lactulose monotherapy <b>OR</b> 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	e:
P&T Revision Date	p:

## Risdiplam (EVRYSDI)

#### **Products Affected**

• Evrysdi SOL 0.75 MG/ML

PA Criteria	Criteria Details
Required Medical Information	<ul> <li>Spinal Muscular Atrophy (SMA):         <ul> <li>Confirmed (via genetic testing) diagnosis of 5q-autosomal recessive SMA (type 1, 2 or 3)</li> </ul> </li> <li>Patient is not dependent on invasive ventilation or tracheostomy OR use of non-invasive ventilation beyond uses for sleeping</li> <li>Is not receiving concomitant chronic SMN modifying therapy such as Spinraza</li> <li>Patient has not previously received gene replacement therapy for the treatment of SMA (e.g. Zolgensma)</li> </ul>
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	<ul> <li>Rheumatoid Arthritis</li> <li>Diagnosis of moderately to severely active rheumatoid arthritis</li> <li>One of the following         <ul> <li>The member is transitioning to the requested treatment from a different biologic product previously approved by the plan</li> <li>Trial and failure, contraindication or intolerance to one of the following: Methotrexate, Leflunomide, Sulfasalazine</li> </ul> </li> <li>Trial and failure to infliximab and adalimumab</li> </ul>
	<ul> <li>Non-Hodgkin's Lymphoma</li> <li>One of the following         <ul> <li>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</li> <li>Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma and used as a first-line treatment in combination with chemotherapy.</li> <li>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.</li> <li>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</li></ul></li></ul>

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

## Sacubitril/Valsartan (ENTRESTO)

#### **Products Affected**

P&T Revision Date:

#### • ENTRESTO

PA Criteria	Criteria Details
Required Medical Information	The patient has a diagnosis of New York Heart Association class II to IV heart failure <b>AND</b> the patient is receiving concomitant therapy with one of the following beta blockers: carvedilol, bisoprolol, sustained-released metoprolol, unless unable to tolerate or contraindicated <b>AND</b> 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 Dat	e:

### **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 Dat	e:
P&T Revision Date	e:

### **Secukinumab SC (COSENTYX)**

#### **Products Affected**

• COSENTYX (300 MG DOSE)

#### • COSENTYX SENSOREADY (300 MG)

PA Criteria	Criteria Details
Required Medical Information	<ul> <li>All diagnoses:</li> <li>Initial testing for latent TB and treatment, if necessary, before starting treatment.</li> <li>No current active infection at initiation of therapy.</li> <li>Risks and benefits documented in cases of chronic or recurrent infection.</li> <li>Will NOT be used in combination with another biologic or Otezla</li> </ul>
	<ul> <li>Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA):         <ul> <li>Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by:</li></ul></li></ul>
	<ul> <li>Juvenile Idiopathic Arthritis (JIA):         <ul> <li>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</li> <li>The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of the following:</li></ul></li></ul>

### 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 plague 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 o Negative test result for RF 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 antiinflammatory 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
	<ul> <li>Hidradenitis Suppurativa (HS):         <ul> <li>Documentation of one of the following:</li> <li>Moderate to severe hidradenitis suppurative (Hurley Stage II or Hurley Stage III)</li> <li>Patient is on a current biologic product and experiencing intolerable side effects.</li> </ul> </li> <li>The patient is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of the following:         <ul> <li>90-day trial of conventional therapy (e.g. oral antibiotics)</li> </ul> </li> <li>Trial and failure of both infliximab and adalimumab</li> </ul>
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

## Semaglutide (WEYGOVY)

### **Products Affected**

Weygovy

PA Criteria	Criteria Details
Required Medical Information	<ul> <li>Secondary Prevention of Major Adverse Events (MACE)</li> <li>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.</li> <li>Wegovy is being used as adjunct to lifestyle modification (e.g., dietary, or caloric restriction, exercise, behavioral support, community-based program).</li> <li>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 &lt;0.85, peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease)</li> <li>BMI greater than or equal to 27 kg/m2</li> <li>Obesity or Overweight – only applies to members under the age of 21</li> <li>BMI at or above the 95th percentile or 27kg/m2.</li> <li>Documentation of one of the following:         <ul> <li>Comorbidities (e.g., hypertension, dyslipidemia, fatty liver disease, depression, or sleep apnea).</li> <li>Trial and failure of at least 3 months of a diet/exercise plan administered by a health care provider in the last 6 months.</li> </ul> </li> <li>The patient is, or will be, engaged in a weight management lifestyle modification program in addition to pharmacotherapy.</li> </ul>
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	<ul> <li>Secondary Prevention of Major Adverse Events (MACE):         <ul> <li>Documentation of treatment success (BMI reduction of 5% or more).</li> <li>Documentation of continuation of lifestyle modification program with reduced calorie diet and regular physical activity alongside continuous Wegovy use (80% adherence).</li> </ul> </li> </ul>
	<ul> <li>Obesity or overweight:</li> <li>Patient is less than 21 years old.</li> <li>Documentation of at least a 1% decrease in BMI from baseline.</li> <li>Patient is continuing full weight loss plan (e.g., diet and exercise program, nutritional counseling).</li> </ul>

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	<ul> <li>Pulmonary Arterial Hypertension (PAH):</li> <li>Diagnosis of symptomatic PAH (WHO Group 1 PH) confirmed by right heart catheterization.</li> <li>WHO functional class II or III symptoms.</li> <li>On a stable dose of both         <ul> <li>Endothelin-1 receptor antagonists (ERA) and</li> <li>Phosphodiesterase type 5 inhibitors or guanylate cyclase stimulant</li> </ul> </li> <li>Current PAH background therapies (ERA, PDE5i, etc.) will be continued unless not tolerated.</li> <li>Baseline platelet count &gt;500,000</li> </ul>
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	<ul> <li>Primary immunoglobulin A nephropathy:         <ul> <li>Urine protein-to-creatine ratio (UPCR) ≥ 1.5 and eGFR ≥ 30 mL/min?1.73 m2</li> <li>Biopsy-verified primary IgA nephropathy</li> <li>No history of kidney transplant and not currently receiving dialysis</li> <li>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</li> </ul> </li> </ul>
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 <b>OR</b> 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	<b>T2DM:</b> Trial and failure of or contraindication to metformin <b>AND</b> 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 m² 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/1.73m².  HFpEF (Jardiance only): eGFR >30 mL/min/1.73²
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.)
	<ul> <li>For patients under the age of 18:         <ul> <li>Growth Hormone Deficiency (GHD)</li> <li>Prader-Willi Syndrome</li> <li>Patient does not have concurrent severe obesity nor history of upper airway obstruction nor sleep apnea nor severe</li> </ul> </li> </ul>
	respiratory impairment  Noonan Syndrome Turner Syndrome Idiopathic Short Stature
	<ul> <li>Growth Failure secondary to chronic kidney disease (CKD)</li> <li>Small for gestational age</li> <li>Short stature homeobox-containing (SHOX) gene deficiency</li> <li>HIV Associated Cachexia</li> </ul>
	For Adults aged 18 years and older  Growth hormone deficiency (GHD)  Prescribed by or in consultation with an endocrinologist;  AND  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  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
	<ul><li>HIV associated cachexia</li><li>Short Bowel Syndrome (SBS)</li></ul>
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	<ul> <li>Treatment with agent initiated in a patient prior to reaching adulthood (&lt;18 years of age) was to improve growth velocity or height; AND         <ul> <li>Growth velocity greater than 2.5 cm per year; OR</li> <li>Growth velocity less than 2.5 cm per year</li> <li>Documentation that benefits of therapy continue to outweigh risks</li> </ul> </li> <li>Documentation of improvement from baseline as assessed by the prescribing provider</li> </ul>

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

### **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 <b>OR</b> patient is having Bariatric surgery.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 1 treatment.
Renewal Criteria	
Effective Date:	
P&T Approval Date	e:
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	e:
P&T Revision Date	e:

### 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	e:
P&T Revision Date	2:

### **Tazarotene (AVAGE) (TAZORAC)**

### **Products Affected**

• Tazarotene 0.1% cream

PA Criteria	Criteria Details
Required Medical Information	<b>Psoriasis</b> : 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	e:
P&T Revision Date	2:

### **Terbinafine Hydrochloride (LAMISIL)**

### **Products Affected**

• TERBINAFINE CREAM 1%

PA Criteria	Criteria Details
Required Medical Information	Treatment of onychomycosis of the toenail or fingernail due to dermatophytes (tinea unguium) <b>AND</b> one of the following: Patient is experiencing pain which limits normal activity (i.e., unable to wear shoes, difficulty walking, etc.) <b>OR</b> patient has diabetes <b>OR</b> Patient has peripheral vascular disease <b>OR</b> patient is immunocompromised. Treatment of tinea corporis or tinea cruris in a patient who is immunocompromised or has extensive or complicated infection.
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	e:
P&T Revision Date	2:

### 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	e:
P&T Revision Date	9:

### **Testosterone**

#### **Products Affected**

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

Testosterone ethanate 200mg/mL

PA Criteria	Criteria Details
Required Medical Information	Diagnosis of: Gender dysphoria <b>OR</b> aids wasting syndrome <b>OR</b> post- menopausal breast cancer <b>OR</b> hypogonadism <b>AND</b> trial and failure or contraindication to injectable testosterone.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Gender dysphoria, aids wasting syndrome, post-menopausal breast cancer <b>Initial</b> : 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.
Ago Postrictions	FDA label
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

### **Tenapanor (XPHOZA)**

#### **Products Affected**

• Xphoza 20MG

• Xphoza 30MG

PA Criteria	Criteria Details
Required Medical Information	Add on therapy for hyperphosphatemia in chronic kidney disease, on chronic hemodialysis:  On chronic maintenance hemodialysis 3x per week for at least 3 months or chronic peritoneal dialysis for a minimum of 6 months  Other contributing factors for hyperphosphatemia have been addressed:  On a stable dose of calcimimetic or active vitamin D for at least 4 weeks  Serum parathyroid hormone is <1200 pg/mL  Dietary restrictions are in place to limit phosphate intake  Serum phosphate levels remain elevated despite use of at least 3 different phosphate binder agents (calcium acetate, sevelamer, lanthanum) used at therapeutic doses with adherence to therapy (at least 80% adherence based on fill history)  Medication will be used as add-on therapy with phosphate binder treatment
Age Restrictions	Must be at least 18 years of age
Prescriber Restrictions	Prescribed by or in collaboration with a Nephrologist
Coverage Duration	Initial: 6 months; Renewal: 12 months
Renewal Criteria	Clinical documentation of provider follow-up indicating safety and efficacy with medication adherence over previous approval duration

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

### **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:	

### **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:	

### **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: Cobombined Oral Contraceptive therapy Profestin therapy (oral or LM) or Levonogrestrel 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:	

### Vonoprazan (VONQUEZNA)

### **Products Affected**

Voquezna 10mg • Voquezna 20mg

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PA Criteria	Criteria Details
Required Medical Information	<ul> <li>Erosive esophagitis-</li> <li>Imaging confirmed LA Classification Grade C/D erosive esophagitis AND</li> <li>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.</li> </ul>
	<ul> <li>H.pylori eradication –</li> <li>Confirmed H. pylori positive infection AND</li> <li>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</li> <li>Documented contraindication, intolerance, or inadequate response to a quadruple bismuth regimen (e.g. standard twice daily dose PPI, bismuth subsalicylate, tetracycline, metronidazole) AND</li> <li>Co-prescribed in combination with antibiotics.</li> </ul>
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:	

### **Tocilizumab SC (ACTEMRA)**

### **Products Affected**

• Actemra INJ 162mg/0.9ml

Actemra INJ ACTPEN

PA Criteria	Criteria Details
PA Criteria Required Medical Information	<ul> <li>All diagnoses:         <ul> <li>Initial testing for latent TB and treatment, if necessary, before starting treatment.</li> <li>No current active infection at initiation of therapy.</li> <li>Risks and benefits documented in cases of chronic or recurrent infection.</li> <li>Will NOT be used in combination with another biologic or Otezla</li> </ul> </li> <li>Juvenile Idiopathic Arthritis (JIA):         <ul> <li>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</li> <li>The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of the following:</li></ul></li></ul>
	<ul> <li>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).</li> <li>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.</li> <li>Trial and failure of both infliximab and adalimumab.</li> </ul>

PA Criteria	Criteria Details
	Giant Cell Arteritis (GCA):  Diagnosis of giant cell arteritis.  Trial and failure of a glucocorticoid
	<ul> <li>Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD):</li> <li>Confirmed diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD).</li> <li>Trial and failure of mycophenolate mofetil.</li> </ul>
	Cytokine Release Syndrome (CRS) Risk due to CAR T-Cell Therapy (IV only):  • Member will receive or is receiving chimeric antigen receptor (CAR) T-
Age Restrictions	cell immunotherapy.
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	CRS: 2 months
Duration	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.
	<b>RA:</b> 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	<ul> <li>All diagnoses:         <ul> <li>Initial testing for latent TB and treatment, if necessary, before starting treatment.</li> <li>No current active infection at initiation of therapy.</li> <li>Risks and benefits documented in cases of chronic or recurrent infection.</li> <li>Will NOT be used in combination with another biologic or Otezla</li> </ul> </li> <li>Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA):         <ul> <li>Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by:                      <ul></ul></li></ul></li></ul>
	<ul> <li>Juvenile Idiopathic Arthritis (JIA):</li> <li>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</li> <li>The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of the following:         <ul> <li>NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND</li> <li>At least 6 months of 2 of Methotrexate, leflunomide, sulfasalazine, hydroxychloroquine, or systemic corticosteroids</li> </ul> </li> </ul>

### **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: o Psoriasis (1 point for personal or family history, 2 points for current) Psoriatic nail dystrophy Negative test result for RF 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: NSAIDs for 3 months at maximum recommended or tolerated antiinflammatory 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, Stelara, 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
	<ul> <li>Mesalamine, sulfasalazine OR</li> <li>Mercaptopurine, azathioprine, OR</li> <li>Corticosteroids (prednisone, methylprednisolone)</li> <li>Trial and failure of both infliximab and adalimumab</li> <li>Trial and failure of Entyvio and Stelara</li> </ul>
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.
	<b>JIA:</b> Evidence of 20% or greater improvement in tender joint count and swollen joint count or has there been an improvement in functional ability.
	<b>PsA:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
	<b>RA:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
	<b>UC:</b> 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	e: 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 <b>AND</b> 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) <b>AND</b> documented failure or incomplete response to sildenafil or tadalafil/ambrisentan combination <b>AND</b> 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:	
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## **Treprostinil sodium (REMODULIN)**

### **Products Affected**

• TREPROSTINIL

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PA Criteria	Criteria Details
Required Medical Information	Confirmed diagnosis of pulmonary arterial hypertension with right heart catheterization and WHO functional class II through IV <b>AND</b> 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) <b>AND</b> 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:	
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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 <b>AND</b> documentation patient is on preventative therapy <b>AND</b> 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	<ul> <li>All diagnoses:</li> <li>Initial testing for latent TB and treatment, if necessary, before starting treatment.</li> <li>No current active infection at initiation of therapy.</li> <li>Risks and benefits documented in cases of chronic or recurrent infection.</li> <li>Will NOT be used in combination with another biologic or Otezla</li> </ul>
	<ul> <li>Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA):</li> <li>Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by:         <ul> <li>Back pain and stiffness for more than 3 months AND</li> <li>Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive AND</li> <li>BASDAI score of &gt;=4</li> </ul> </li> <li>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:         <ul> <li>At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND</li> <li>Physical therapy/exercise program</li> </ul> </li> <li>Trial and failure of both infliximab and adalimumab</li> <li>Trial and failure of Cosentyx and Taltz or a reason they can't be used</li> </ul>
	<ul> <li>Atopic Dermatitis (AD):</li> <li>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:         <ul> <li>At least 10% of body surface area involved</li> <li>Hand, foot, face, or mucous membrane involvement</li> </ul> </li> <li>Documented contraindication or failed trial to ALL of the following:         <ul> <li>Moderate-high potency corticosteroid (e.g., clobetasol, fluocinonide, fluticasone)</li> </ul> </li> </ul>

## PA Criteria **Criteria Details** Topical calcineurin inhibitor (e.g. tacrolimus) o 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: 6mercaptopurine, azathioprine, corticosteroid, methotrexate Trial and failure of both infliximab and adalimumab Trial and failure of Cimzia, Entyvio, Stelara **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) Psoriatic nail dystrophy Negative test result for RF 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: NSAIDs for 3 months at maximum recommended or tolerated antiinflammatory 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, Stelara, 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
	<ul> <li>(dosed at least 20mg per week for at least 8 weeks), leflunomide or sulfasalazine</li> <li>Trial and failure of both infliximab and adalimumab</li> <li>Trial and failure of Actemra, Cimzia, Kineret, Orencia, and rituximab</li> </ul> Ulcerative Colitis (UC):
	<ul> <li>Documentation of moderate-to-severe ulcerative colitis</li> <li>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:         <ul> <li>Mesalamine, sulfasalazine OR</li> <li>Mercaptopurine, azathioprine, OR</li> <li>Corticosteroids (prednisone, methylprednisolone)</li> </ul> </li> <li>Trial and failure of both infliximab and adalimumab</li> <li>Trial and failure of Entyvio and Stelara</li> </ul>
Age Restrictions	
Prescriber Restrictions	Atopic Dermatitis: Dermatologist Crohns 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.
	<b>AD:</b> 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.
	<b>CD:</b> Evidence of a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission.
	<b>PsA:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.

PA Criteria	Criteria Details
	<b>RA:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
	<b>UC:</b> 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 SC (STELARA)**

### **Products Affected**

• STELARA 45MG/0.5ML, 90 MG/ML

PA Criteria	Criteria Details
Required Medical Information	<ul> <li>All diagnoses:</li> <li>Initial testing for latent TB and treatment, if necessary, before starting treatment.</li> <li>No current active infection at initiation of therapy.</li> <li>Risks and benefits documented in cases of chronic or recurrent infection.</li> <li>Will NOT be used in combination with another biologic or Otezla</li> </ul>
	<ul> <li>Crohn's Disease (CD):         <ul> <li>Documentation of moderate-to-severe Crohn's Disease</li> </ul> </li> <li>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</li> <li>Trial and failure of both infliximab and adalimumab</li> </ul> <li>Plaque Psoriasis (PP):         <ul> <li>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:</li></ul></li>
	<ul> <li>Methodrexate</li> <li>At least 1 other second line systemic agent such as cyclosporine or acitretin</li> </ul>

PA Criteria	Criteria Details
	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
Age Restrictions	<ul> <li>Trial and failure of both infliximab and adalimumab</li> <li>Ulcerative Colitis (UC):         <ul> <li>Documentation of moderate-to-severe ulcerative colitis</li> </ul> </li> <li>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:         <ul> <li>Mesalamine, sulfasalazine OR</li> <li>Mercaptopurine, azathioprine, OR</li> <li>Corticosteroids (prednisone, methylprednisolone)</li> </ul> </li> <li>Trial and failure of both infliximab and adalimumab</li> </ul>
Prescriber	Crobne Disease and Illegrative Colities Control to a logist
Restrictions	Crohns Disease and Ulcerative Colitis: Gastroenterologist.  Plaque Psoriasis: Dermatologist.  Psoriatic Arthritis: Dermatologist or Rheumatologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Renewal Criteria	<b>CD:</b> Evidence of a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission.

PA Criteria	Criteria Details
	<b>PP:</b> 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.
	<b>PsA:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
	<b>UC:</b> 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

# 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 <b>AND</b> 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:	

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