

## **Prior Authorization Criteria**

Samaritan Choice

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

Updated on 03/01/2025. 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

Criteria Details		
Required Medical Information	Adult Rheumatoid Arthritis (RA) Diagnosis of moderately to severely active rheumatoid arthritis AND trial and failure, contraindication, or intolerance to ONE nonbiologic disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate [Rheumatrex/Trexall], Arava [leflunomide], Azulfidine [sulfasalazine]) AND trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate Cimzia (certolizumab pegol) adalimumab Rinvoq (upadacitinib) Simponi (golimumab) Xeljanz/XR (tofacitinib/ER).	
	<b>Polyarticular Juvenile Idiopathic Arthritis (PJIA)</b> Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis <b>AND</b> trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, <b>AND</b> trial and failure, contraindication, or intolerance to two of the following, or attestation demonstrating a trial may be inappropriate : Enbrel (etanercept), adalimumab, Xeljanz (tofacitinib).	
	<b>Psoriatic Arthritis (PsA)</b> Diagnosis of active psoriatic arthritis with one of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, active skin and/or nail involvement <b>AND</b> trial and failure, contraindication, or intolerance to <b>TWO</b> of the following: Cimzia (certolizumab pegol), adalimumab, Simponi (golimumab) Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib/ER).	
	<b>Prophylaxis for Acute Graft versus Host Disease (aGVHD)</b> Used for prophylaxis of acute graft versus host disease (aGVHD) <b>AND</b> patient will receive hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor <b>AND</b> recommended antiviral	

	Criteria Details
	prophylactic treatment for Epstein-Barr Virus (EBV) reactivation (e.g., acyclovir) will be administered prior to Orencia <b>AND</b> continued for six months after HSCT <b>AND</b> Used in combination with both of the following: calcineurin inhibitor (e.g., cyclosporine, tacrolimus) methotrexate.
Age Restrictions	aGVHD: 2 years of age or older
Prescriber Restrictions	<b>RA, PJIA:</b> Prescribed by or in consultation with a rheumatologist <b>PsA:</b> Prescribed by or in consultation with a dermatologist or rheumatologist
Coverage Duration	RA, PJIA, PsA: Initial: 6 months. Renewal: 12 months aGVHD: Initial: 2 months. Renewal: N/A
Renewal Criteria	<ul> <li>Documented positive clinical response to therapy</li> <li>RA, PJIA: Documentation of a positive clinical response to therapy as evidenced by one of the following: reduction in the total active (swollen and tender) joint count from baseline, or improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline.</li> <li>PsA: Documentation of a positive clinical response to therapy as evidenced by one of the following: reduction in the total active (swollen active devidenced by one of the following: reduction in the total active (swollen active devidenced by one of the following: reduction in the total active (swollen active devidenced by one of the following: reduction in the total active (swollen active devidenced by one of the following: reduction in the total active (swollen active devidenced by one of the following: reduction in the total active (swollen active devidenced by one of the following: reduction in the total active (swollen active devidenced by one of the following: reduction in the total active (swollen active devidenced by one of the following: reduction in the total active (swollen active devidenced by one of the following: reduction in the total active (swollen active devidenced by one of the following: reduction in the total active (swollen active devidenced by one of the following: reduction in the total active (swollen active devidenced by one devidenced</li></ul>
	and tender) joint count from baseline, improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline, or reduction in the body surface area (BSA) involvement from baseline.
Effective Date	
P&T Approval Date	
P&T Revision Date	

### Abemaciclib (VERZENIO)

#### **Products Affected**

- VERZENIO TAB 50MG
- VERZENIO TAB 100MG

- VERZENIO TAB 150MG
- VERZENIO TAB 200MG

	Criteria Details
Required Medical Information	<ul> <li>Breast Cancer- Early: Hormone receptor (HR) positive AND HER2 negative breast cancer AND Node-positive disease at high risk or recurrence AND Patient is using in combination with anastrozole, exemestane, or letrozole OR Patient is using in combination with tamoxifen.</li> <li>Breast Cancer – Recurrent or Metastatic: HR positive AND HER2</li> </ul>
	negative breast cancer <b>AND</b> Recurrent or metastatic breast cancer diagnosis <b>AND</b> Patient has tried chemotherapy for metastatic breast cancer <b>AND</b> Medication will be used in combination with anastrozole, exemestane, or letrozole OR medication will be used in combination with fulvestrant OR medication will be used as monotherapy.
Age Restrictions	Must be at least 18 years of age
Prescriber Restrictions	Prescribed by or in collaboration with an oncologist
<b>Coverage Duration</b>	Initial: 3 months; Renewal: 3 months
Renewal Criteria	Clinical documentation of provider follow-up indicating safety <b>AND</b> efficacy with medication adherence over previous approval duration
Effective Date	
P&T Approval Date	
P&T Revision Date	

### **Adalimumab Biosimilars**

#### **Products Affected**

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

	Criteria Details
	<ul> <li>Rheumatoid arthritis (RA): Diagnosis of moderately to severely active RA</li> <li>AND trial and failure, contraindication, or intolerance to one non-biologic disease-modifying antirheumatic drug (DMARD) [e.g., methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)].</li> <li>Polyarticular Juvenile idiopathic arthritis (PJIA): Diagnosis of moderate</li> </ul>
Required Medical Information	to severely active polyarticular JIA <b>AND</b> trial and failure, contraindication, or intolerance to one of the following non-biologic disease-modifying antirheumatic drugs (DMARDs): Arava (leflunomide), methotrexate (Rheumatrex/Trexall).
	<b>Psoriatic arthritis (PsA):</b> Diagnosis of active PsA with one of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, active skin and/or nail involvement.
	<b>Ankylosing spondylitis (AS):</b> Diagnosis of active ankylosing spondylitis <b>AND</b> trial and failure, contraindication, or intolerance to two NSAIDs (e.g., diclofenac, ibuprofen, indomethacin, meloxicam, naproxen)
	<b>Crohn's disease (CD):</b> Diagnosis of moderately to severely active Crohn's disease with one of the following: 1) frequent diarrhea and abdominal pain, 2) at least 10% weight loss, 3) complications such as obstruction, fever, abdominal mass, 4) abnormal lab values (e.g. C-reactive protein), CD Activity Index greater than 220. <b>AND</b> trial and failure,

	Criteria Details	
	contraindication, or intolerance to one of the following conventional	
	therapies: 6-mercaptopurine, azathioprine, corticosteroids (e.g.,	
	prednisone, methylprednisolone), methotrexate	
	<b>Ulcerative Colitis (UC):</b> Diagnosis of moderately to severely active ulcerative colitis with one of the following: 1) Greater than 6 stools per day, 2) frequent blood in the stools, 3) frequent urgency, 4) presence of ulcers, 5) abnormal lab values (e.g. hemoglobin, ESR, CRP), 6) dependent on, or refractory to, corticosteroids <b>AND</b> trial and failure, contraindication, or intolerance to one of the following conventional therapies: 6-mercaptopurine, aminosalicylate [e.g., mesalamine sulfasalazine, azathioprine, Corticosteroids (e.g., prednisone, methylprednisolone).	
	<b>Plaque Psoriasis (PP):</b> Diagnosis of moderate to severe chronic plaque psoriasis with one of the following: 1) greater than or equal to 3% body surface area involvement, 2) severe scalp psoriasis, 3) palmoplantar, facial, or genital involvement. <b>AND</b> a minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids, vitamin D analogs, tazarotene, calcineurin inhibitors, anthralin, coal tar.	
	Hidradenitis Suppurativa (HS): Diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley Stage II or III)	
	<b>Uveitis (UV):</b> Diagnosis of non-infectious uveitis <b>AND</b> uveitis is classified as one of the following: intermediate, posterior or panuveitis.	
Age Restrictions		
Prescriber Restrictions	<ul> <li>RA, PJIA, AS: Prescribed by or in consultation with a rheumatologist</li> <li>PsA: Prescribed by or in consultation with one of the following:</li> <li>Dermatologist or Rheumatologist.</li> <li>CD, UC: Prescribed by or in consultation with a gastroenterologist</li> <li>PsO, HS: Prescribed by or in consultation with a dermatologist</li> <li>UV: Prescribed by or in consultation with one of the following:</li> <li>ophthalmologist or rheumatologist</li> </ul>	
Coverage Duration	RA, PJIA, PsA, PsO, AS, CD, HS, UV Initial: 6 months; Renewal: 12	
	months	
	UC: Initial: 12 weeks; Renewal: 12 months	
Renewal Criteria	<b>RA, PJIA:</b> Documentation of a positive clinical response to therapy as	
	evidenced by one of the following: reduction in the total active (swollen	

#### **Criteria Details**

and tender) joint count from baseline, or improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline.

	<b>PsA:</b> Documentation of a positive clinical response to therapy as evidenced by one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline, or reduction in the body surface area (BSA) involvement from baseline.
	<b>AS:</b> Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following: disease activity (e.g., pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (e.g., lumbar spine motion, chest expansion), or total active (swollen and tender) joint count.
	<b>CD:</b> Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, or reversal of high fecal output state.
	<b>UC:</b> One of the following: For patients who initiated adalimumab therapy within the past 12 weeks: Documentation of clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy OR For patients who have been maintained on adalimumab therapy for longer than 12 weeks: Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, or reversal of high fecal output state.
	<b>PsO:</b> Documentation of a positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, or improvement in symptoms (e.g., pruritus, inflammation) from baseline.
Effective Date	<b>HS, UV:</b> Documentation of positive clinical response to therapy.
P&T Approval Date	
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Criteria Details	
P&T Revision Date	

### Alpelisib (VIJOICE)

#### **Products Affected**

• Vijoice TAB

	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
<b>Coverage Duration</b>	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	
P&T Approval Date	
P&T Revision Date	

### Ambrisentan (LETAIRIS)

#### **Products Affected**

#### • AMBRISENTAN

	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 <b>AND</b> 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.
	Documentation of positive clinical response to therapy.
Renewal Criteria	Note: Letairis (ambrisentan) has a black box warning for embryo-fetal toxicity. Because of the risks of birth defects, Letairis is available for females only through a special restricted distribution program under a Risk Evaluation and Mitigation Strategy (REMS).
Effective Date	
P&T Approval Date	
P&T Revision Date	

### Apremilast (OTEZLA)

#### **Products Affected**

#### • OTEZLA

	Criteria Details
Required Medical Information	<ul> <li>Plaque Psoriasis (PsO): Diagnosis of plaque psoriasis with one of the following: 1) greater than or equal to 3% body surface area involvement, 2) severe scalp psoriasis, 3) palmoplantar, facial, or genital involvement AND a minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids, vitamin D analogs, tazarotene, calcineurin inhibitors, anthralin, coal tar.</li> <li>Psoriatic Arthritis (PsA): Diagnosis of active psoriatic arthritis with one of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, active skin and/or nail involvement.</li> </ul>
	<b>Oral Ulcers Associated with Behçet's Disease:</b> Diagnosis of Behçet's Disease AND Patient has active oral ulcers.
Age Restrictions	
Prescriber Restrictions	<b>Plaque psoriasis:</b> Prescribed by or in consultation with a dermatologist. <b>Psoriatic arthritis</b> : Prescribed by or in consultation with a dermatologist or rheumatologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Renewal Criteria	<ul> <li>Ps0: Documentation of positive clinical response to therapy as evidenced by ONE of the following: Reduction the body surface area (BSA) involvement from baseline OR improvement in symptoms (e.g., pruritus, inflammation) from baseline.</li> <li>PsA: Documentation of positive clinical response to therapy as evidenced by one of the following: Reduction in BSA from baseline,</li> </ul>
	reduction in total active joint count, improvement in symptoms <b>Behçet's Disease</b> : Documentation of positive clinical response to therapy (e.g., reduction in pain from oral ulcers or reduction in number of oral ulcers).

Criteria Details	
Effective Date	
P&T Approval Date	
P&T Revision Date	

### Asciminib (SCEMBLIX)

#### **Products Affected**

• SCEMBLIX

	Criteria Details
Required Medical Information	Philadelphia positive CML that has been treated with at least two other TKIs OR Philadelphia positive CML with the T3151 mutation <b>AND</b> ECOG performance status of 0 or 1
Age Restrictions	Patient must be 18 years of age or older
Prescriber Restrictions	Prescribed by a hematologist or oncologist
Coverage Duration	Initial: 3 months Renewal: 6 months
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

### Belzutifan (WELIREG)

#### **Products Affected**

• WELIREG

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

### Bempedoic acid (NEXLETOL)

#### Products Affected

• NEXLETOL TABLETS

• NEXLIZET TABLETS

Criteria Details	
Required Medical Information	<ul> <li>Established clinical ASCVD:</li> <li>Documentation of very high risk ASCVD as evidenced by either: <ul> <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> </ul>
	<ul> <li>Primary or familial hyperlipidemia:</li> <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> <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.

Criteria Details	
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 (REXUROCK)

#### **Products Affected**

• REZUROCK

	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	12 years of age or older	
Prescriber Restrictions	Prescribed by oncologist or transplant specialist	
Coverage Duration	Initial: 3 months. Renewal: 6 months.	
Renewal Criteria	Documentation of positive clinical response to therapy.	
Effective Date		
P&T Approval Date		
P&T Revision Date		

### Bimekizumab-bkzx (BIMEZELX)

#### **Products Affected**

• Bimzelx

Criteria Details	
Required Medical Information	<ul> <li>Plaque Psoriasis</li> <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>Both of the following:</li> <li>At least 10% of body surface area involved</li> <li>Hand, foot, face, or mucous membrane involvement</li> <li>The patient on a current biologic product and experiencing intolerable side effects</li> </ul> </li> <li>The patient tried and failed or have contraindications to ALL of the following? <ul> <li>High-potency topical corticosteroids (augmented betamethasone, clobetasol, etc.)</li> <li>At least 1 other second line systemic agent such as cyclosporine or acitretin</li> <li>The patient tried and failed BOTH first line agents (infliximab or biosimilar AND Humira or biosimilar)</li> </ul> </li> </ul>
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 6 months. Renewal: 12 months.

Criteria Details	
Renewal Criteria	<ul> <li>Documentation of positive clinical response to therapy as evidenced by ONE of the following: <ul> <li>Reduction of body surface area (BSA) involvement from baseline</li> <li>Improvement in symptoms (e.g. pruritus, inflammation) from baseline</li> </ul> </li> <li>Evidence of functional improvement</li> </ul>
Effective Date	7/1/2024
P&T Approval Date	5/14/2024
P&T Revision Date	

### **Binimetinib (MEKTOVI)**

#### **Products Affected**

• Mektovi

	Criteria Details
Required Medical Information	<ul> <li>Diagnosis of unresectable or metastatic melanoma or Non-Small Cell Lung Cancer (NSCLC :</li> <li>Cancer is BRAF V600E or V600K mutant type as detected by an FDA- approved test (THxID-BRAF Kit) or performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)</li> <li>Used in combination with encorafenib</li> <li>Trial and failure, contraindication or intolerance to one of the following:         <ul> <li>Cotellic</li> <li>Mekinist</li> </ul> </li> </ul>
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 12 months. Renewal: 12 months.
Renewal Criteria	Patient does not show evidence of progressive disease while on therapy
Effective Date	03/01/2024
P&T Approval Date	
P&T Revision Date	

### **Bosentan (TRACLEER)**

#### **Products Affected**

• BOSENTAN

Criteria Details	
Required Medical Information	<b>Pulmonary arterial hypertension (PAH):</b> Diagnosed with PAH WHO Group 1 confirmed by right heart catheterization. Documentation of NYHA Functional Classification II, III, or IV symptoms <b>AND</b> 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	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

### **Bosutinib (BOSULIF)**

#### **Products Affected**

• Bosutinib capsules

• Bosutinib tablets

Criteria Details	
Required Medical Information	<ul> <li>Chronic Myelogenous/Myeloid Leukemia:</li> <li>Diagnosis of Philadelphia chromosome-positive chronic myelogenous/myeloid leukemia (Ph+ CML) AND</li> <li>One of the following: <ul> <li>Disease is in the accelerated or blast phase OR</li> <li>Disease is in the chronic phase and patient is 1 year of age or older</li> </ul> </li> <li>One of the following: <ul> <li>Trial and failure or intolerance to generic imatinib</li> <li>Continuation of prior therapy</li> </ul> </li> </ul>
Age Restrictions	
Prescriber Restrictions	Oncologist or hematologist
<b>Coverage Duration</b>	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	3/12/2024

### Brexipiprazole (REXULTI)

#### **Products Affected**

REXULTI

Required Medical	Criteria Details Major Depressive Disorder (MDD): A diagnosis of MDD AND prior treatment failure (at least 3 weeks) of or contraindication to 3 prior antidepressants AND one antipsychotic FDA approved as adjunct
Information	treatment for MDD <b>AND</b> to be used concurrently with an antidepressant. <b>Schizophrenia:</b> A diagnosis of schizophrenia <b>AND</b> prior treatment failure with a minimum of 2 antipsychotics <b>AND</b> Vraylar.
	Schizophrenia: Aged 13 or older
Age Restrictions	Major Depressive Disorder (MDD): Aged 18 or older
Prescriber Restrictions	
Coverage Duration	Initial: 3 months. Renewal: 12 months.
Renewal Criteria	Documentation of treatment success <b>AND</b> continued need for Rexulti.
Effective Date	
P&T Approval Date	
P&T Revision Date	

### **Brigantinib (ALUNBRIG)**

#### **Products Affected**

• ALUNBRIG

Criteria Details	
Required Medical Information	Treatment supported for the diagnosis in NCCN guidelines. Treatment being used according to FDA indication
Age Restrictions	
Prescriber Restrictions	Prescribed by oncologist or hematologist
Coverage Duration	<b>Initial:</b> 3 months unless otherwise specified in drug specific criteria <b>Renewal</b> : Up to 12 months
Renewal Criteria	Clinical documentation showing continued adherence <b>AND</b> toleration with lack of disease progression
Effective Date	
P&T Approval Date	
P&T Revision Date	

### **BUTRANS, BUPRENORPHINE PATCH, BELBUCA**

#### **Products Affected**

• BELBUCA

• BUPRENORPHINE PATCH

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

### Cabozantinib (CABOMETYX)

#### **Products Affected**

• CABOMETYX TAB 20MG

• CABOMETYX TAB 60MG

• CABOMETYX TAB 40MG

	Criteria Details
Required Medical Information	Treatment is supported for the diagnosis in NCCN guidelines. <b>For HCC</b> : trial and failure or a contraindication to either Stivarga or Cyramza. Cabometyx is first line for RCC and DTC
Age Restrictions	Aged 12 years and older
Prescriber Restrictions	Treatment being prescribed or supervised by a hematologist, or oncologist as appropriate for the type of cancer.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Renewal Criteria	Clinical documentation showing continued adherence and toleration of Cabometyx with lack of disease progression.
Effective Date	
P&T Approval Date	
P&T Revision Date	

### Ceritinib (ZYKADIA)

#### **Products Affected**

• Zykadia

	Criteria Details
Required Medical Information	Treatment supported for the diagnosis in NCCN guidelines. Treatment being used according to FDA indication
Age Restrictions	
Prescriber Restrictions	Prescribed by oncologist or hematologist
Coverage Duration	<b>Initial:</b> 3 months unless otherwise specified in drug specific criteria <b>Renewal:</b> Up to 12 months
Renewal Criteria	Clinical documentation showing continued adherence <b>AND</b> toleration with lack of disease progression.
Effective Date	
P&T Approval Date	
P&T Revision Date	

### Certolizumab Pegol (CMIZIA)

#### **Products Affected**

• Cimzia

Criteria Details	
	<b>Crohn's Disease (CD):</b> Diagnosis of moderately to severely active Crohn's disease with one of the following: 1) frequent diarrhea and abdominal pain, 2) at least 10% weight loss, 3) complications such as obstruction, fever, abdominal mass, 4) abnormal lab values (e.g. C- reactive protein), CD Activity Index greater than 220. <b>AND</b> trial and failure, contraindication, or intolerance to ONE of the following conventional therapies: 6-mercaptopurine, Azathioprine, Corticosteroids (e.g., prednisone, methylprednisolone), Methotrexate.
	<b>Rheumatoid Arthritis (RA):</b> Diagnosis of moderately to severely active RA <b>AND</b> trial and failure, contraindication or intolerance to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine.
Required Medical Information	<b>Psoriatic Arthritis (PsA):</b> Diagnosis of active psoriatic arthritis with one of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, active skin and/or nail involvement.
	<b>Ankylosing Spondylitis (AS):</b> Diagnosis of active ankylosing spondylitis <b>AND</b> minimum duration of one month trial and failure, contraindication, or intolerance to two different nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses.
	<b>Plaque Psoriasis (PsO):</b> Diagnosis of moderate to severe plaque psoriasis with one of the following: 1) greater than or equal to 3% body surface area involvement, 2) severe scalp psoriasis, 3) palmoplantar, facial, or genital involvement <b>AND</b> a minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids, vitamin D analogs, tazarotene, calcineurin inhibitors, anthralin, coal tar.

	Criteria Details	
	<b>Non-radiographic Axial Spondyloarthritis (nr-axSpA):</b> Diagnosis of active non-radiographic axial spondyloarthritis <b>AND</b> patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) <b>AND</b> minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses	
Age Restrictions		
Prescriber Restrictions	<ul> <li>CD: Prescribed by or in consultation with a gastroenterologist</li> <li>RA, AS, nr-axSpA: Prescribed by or in consultation with a rheumatologist</li> <li>PsA: Prescribed by or in consultation with one of the following:</li> <li>Dermatologist or Rheumatologist</li> <li>Ps0: Prescribed by or in consultation with a dermatologist</li> </ul>	
Coverage Duration	<b>CD: Initial:</b> 16 weeks; <b>Renewal:</b> 12months <b>RA, PsA, AS, PsO, nr-axSpA: Initial:</b> 6 months; <b>Renewal</b> : 12 months	
Renewal Criteria	<b>CD:</b> Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, or reversal of high fecal output state.	
	<b>RA:</b> Documentation of a positive clinical response to therapy as evidenced by one of the following: reduction in the total active (swollen and tender) joint count from baseline, or improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline.	
	<b>PsA:</b> Documentation of a positive clinical response to therapy as evidenced by one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline, or reduction in the body surface area (BSA) involvement from baseline.	
	<b>AS, nr-axSpA:</b> Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following: disease activity (e.g., pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial	

	Criteria Details
	status (e.g., lumbar spine motion, chest expansion), or total active (swollen and tender) joint count.
	<b>PsO:</b> Documentation of a positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, or improvement in symptoms (e.g., pruritus, inflammation) from baseline.
Effective Date	
P&T Approval Date	
P&T Revision Date	

### Clobazam (ONFI)

#### **Products Affected**

• Clobazam 10mg Tablets

• Clobazam 2.5mg/mL suspension

• Clobazam 20mg Tablets

	Criteria Details
Required Medical Information	<ul> <li>Lennox-Gastaut Syndrome         <ul> <li>Confirmed diagnosis.</li> </ul> </li> <li>Refractory Seizures         <ul> <li>Documentation showing appropriate trial of 2 or more tolerated anticonvulsant therapies.</li> </ul> </li> </ul>
Age Restrictions	<ul> <li>Solution only</li> <li>One of the following:</li> <li>Pediatric member age 10 or under</li> <li>Documentation inability of the member to use the preferred tablet formulation</li> </ul>
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	3/12/2024
P&T Revision Date	3/12/2024

# Compounds (standard criteria for all compounded medications)

#### **Products Affected**

• All compounded medications

	Critoria Notails
Required Medical Information	<ul> <li>Criteria Details</li> <li>Each active ingredient in the compounded drug is FDA-approved or national compendia* supported for the condition being treated.</li> <li>The requested amounts are supported by national compendia* or two peer-reviewed literature for the condition being treated in the requested route of delivery.</li> <li>If any prescription ingredients require prior authorization and/or step therapy, all drug-specific criteria must be also met.</li> <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 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	

Criteria Details	
Prescriber Restrictions	
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

### **Continuous Glucose Monitor (CGM)**

#### **Products Affected**

• DEXCOM G6 & G7 SYSTEMS

FREESTYLE LIBRE SYSTEMS

	Criteria Details
Required Medical Information	<ul> <li>Patient has documented diagnosis of type 1 or type 2 diabetes mellitus.</li> <li>Patient must have ALL of the following: <ul> <li>Intensive insulin regimen (3 or more insulin injections per day, or use of continuous subcutaneous insulin infusion pump).</li> <li>Patient consistently monitors blood glucose 3 or more times per day.</li> <li>Patient is motivated and knowledgeable about use of continuous glucose monitoring, is adherent to diabetic treatment plan, and participates in ongoing education and support.</li> <li>Patient must have 1 OR more of the following: <ul> <li>Dawn phenomenon, known or suspected, Hypoglycemic unawareness (i.e., patient does not have symptoms with hypoglycemia).</li> <li>Nocturnal hypoglycemia, known or suspected.</li> <li>Significant change to diabetes treatment regimen (e.g., initiation of insulin, change from multiple-dose insulin to insulin pump therapy).</li> </ul> </li> </ul></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	01/01/2024
P&T Approval Date	11/14/2023

	Criteria Details
P&T Revision Date	

### **Colony-Stimulating Factors**

#### **Products Affected**

- NIVESTYM
- ZARIXIO

- NUESASTA/NEULASTA ONPRO
- UDENYCA/UDENYCA ONPRO

Criteria Details	
	<ul> <li>Bone Marrow/Stem Cell Transplant:         <ul> <li>One of the following:</li> <li>Patient has non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT) OR</li> <li>Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis OR</li> <li>Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy.</li> </ul> </li> </ul>
	<ul> <li>Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy:</li> <li>Diagnosis of acute myeloid leukemia (AML).</li> <li>Patient has completed induction or consolidation chemotherapy.</li> </ul>
Required Medical Information	<ul> <li>Febrile Neutropenia Prophylaxis:</li> <li>Patient will be receiving prophylaxis for febrile neutropenia (FN) due to one of the following: <ul> <li>Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer.</li> <li>Patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown.</li> <li>Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN.</li> <li>Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN AND has one or more risk factors associated with chemotherapy induced infection, FN, or neutropenia.</li> <li>Patient is receiving myelosuppressive anticancer drugs associated with neutropenia AND has a history of FN or dose-</li> </ul> </li> </ul>

	Critoria Dotaila
	Criteria Details limiting event during a previous course of chemotherapy (secondary prophylaxis).
	<ul> <li>Treatment of High-Risk Febrile Neutropenia:</li> <li>Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia.</li> <li>Diagnosis of febrile neutropenia (FN).</li> <li>Patient is at high risk for infection-associated complications.</li> </ul>
	<ul> <li>Severe Chronic Neutropenia (SCN):</li> <li>For patients with severe chronic neutropenia (SCN) (i.e., congenital, cyclic, and idiopathic neutropenias with chronic absolute neutrophil count [ANC] less than or equal to 500 cells/mm^3)</li> </ul>
	<ul> <li>Acute Radiation Syndrome (ARS):</li> <li>Patient was/will be acutely exposed to myelosuppressive doses of radiation cells/mm<sup>3</sup>).</li> </ul>
	<ul> <li>Human Immunodeficiency Virus (HIV) Related Neutropenia:</li> <li>Patient is infected with HIV virus.</li> <li>ANC less than or equal to 1,000 (cells/mm3).</li> </ul>
Age Restrictions	
Prescriber Restrictions	HIV Related Neutropenia – Hematologist, Oncologist, or Infectious Disease Specialist All Other Diagnosis - Hematologist or Oncologist
Coverage Duration	Bone Marrow/Stem Cell Transplant: 3 months or duration of therapy. AML Induction/Consolidation Therapy: 3 months or duration of therapy. Febrile Neutropenia (FN) Prophylaxis: 3 months or duration of therapy. Treatment of High-Risk FN: 3 months or duration of therapy. Severe Chronic Neutropenia (SCN): 12 months. Acute Radiation Syndrome (ARS): 1 month
Renewal Criteria	
Effective Date	09/01/2024
P&T Approval Date	07/09/2024

# Crizotinib (XALKORI)

### **Products Affected**

XALKORI

	Criteria Details
Required Medical Information	<b>NSCLC:</b> Confirmed diagnosis of ALK-positive NSCLC or NSCLC with ROS1 rearrangement. ALCL: Confirmed diagnosis of ALK positive ALCL <b>AND</b> Trial <b>AND</b> failure of at least one prior systemic therapy
Age Restrictions	NSCLC: 18 years of age or older. ALCL: 1 year and older.
Prescriber Restrictions	Prescribed by oncologist
Coverage Duration	Initial: 3 months. Renewal: 3 months
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

# **Cyclosporine ophthalmic emulsion (RESTASIS)**

#### **Products Affected**

• RESTASIS

• RESTASIS MULTIDOSE

	Critorio Dotoilo
Required Medical Information	<b>Criteria Details</b> The patient has a diagnosis of lack of tear production due to ocular inflammation associated with keratoconjunctivitis sicca <b>AND ONE</b> of the following: The patient is not currently using a topical ophthalmic anti- inflammatory drug or punctal plug <b>OR</b> the patients current use of topical ophthalmic anti-inflammatory drug or punctal plug will be discontinued before starting the requested agent <b>AND</b> the patient has previously tried or is currently using aqueous enhancements (e.g. artificial tears, gels, ointments) <b>OR</b> the patient has a documented intolerance, contraindication, or hypersensitivity to aqueous enhancements <b>AND</b> the patient is not currently using Xiidra OR the patients current use of Xiidra will be discontinued before starting Restasis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 12 months. Renewal: 12 months
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

# **Deutetrabenazine (AUSTEDO)**

#### **Products Affected**

- Austedo 6mg TAB

• Austedo 12mg TAB

• Austedo 9mg TAB

	Criteria Details
Required Medical Information	<ul> <li>Chorea associated with Huntington's Disease: Documentation of the degree of chorea present and the impact on functional ability and/or quality of life as a baseline AND documentation of mental status, specifically depression and suicidality.</li> <li>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 one of the following: 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.</li> </ul>
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.

Criteria Details	
	<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	
P&T Approval Date	
P&T Revision Date	

# **Dimethyl Fumarate (TECFIDERA)**

#### **Products Affected**

• DIMETHYL FUMARATE

• DIMETHYL FUMARATE STARTER PACK

	Criteria Details
Required Medical Information	<b>Multiple sclerosis:</b> Patient is diagnosed with relapsing forms of multiple sclerosis.
Age Restrictions	
Prescriber Restrictions	Prescribed by a neurologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

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

### **Products Affected**

• LEDIPASVIR-SOFOSBUVIR

SOFOSBUVIR-VELPATASVIR

MAVYRET

Criteria Details		
	Treatment of Hepatitis C:	
Required Medical Information	<ul> <li>Expected survival from non-HCV-associated morbidities more than 1 year.</li> <li>Must have all pretreatment testing completed: including genotype, HBV, HIV, and cirrhosis status.</li> <li>Care must be provided by or in consultation with a specialist (hepatologist, gastroenterologist, or infectious disease specialist).</li> <li>Attestation that the patient and provider will comply with case management to promote the best possible outcome for the patient and adhere to monitoring requirements required by the Oregon Health Authority, including measuring and reporting of a posttreatment viral load OR attestation from the patient and provider that they have opted out of OHA case management. Case management includes assessment of treatment barriers and offer of patient support to mitigate potential barriers to regimen adherence as well as facilitation of SVR12 evaluation to assess treatment success.</li> <li>Documentation if the patient had a baseline NS5a resistance test that documents a resistant variant to Elbasvir/grazoprevir or Daclatasvir + sofosbuvir. Note: Baseline NS5A resistance testing is required.</li> <li>Documentation of the prescribed regimen includes a NS3/4a protease inhibitor (glecaprevir, simeprevir, paritaprevir, voxilaprevir).</li> <li>Documentation if the patient has moderate-severe hepatic impairment (Child-Pugh B or Child-Pugh C).</li> </ul>	

Criteria Details	
	drug regimen is a recommended regimen based on the patient's genotype, age, treatment status (retreatment or treatment naive) and cirrhosis status.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
Coverage Duration	Initial: 2-4 months.
Renewal Criteria	
Effective Date	
P&T Approval Date	
P&T Revision Date	

# **Disposable Insulin Pump (OMNIPOD)**

#### **Products Affected**

• OMNIPOD 5

• OMNIPOD DASH

	Criteria Details
Required Medical Information	<ul> <li>Insulin dependent diabetes mellitus - pediatric (under age 18)</li> <li>Documentation of Type 1 Diabetes Mellitus or Diabetes with C-reactive protein levels indicating insulin dependence.</li> <li>On intensive insulin therapy (&gt;3 daily insulin injections) requiring frequent self-adjustments for at least 6 months prior to initiation of the insulin pump.</li> <li>Documentation self-testing of blood glucose at least 4 times per day during the previous 2 months</li> <li>Evidence of completion of a comprehensive diabetes education program in the last 12 months (member or caregiver/parent).</li> <li>Insulin dependent diabetes mellitus - adult</li> <li>All of the above pediatric requirements AND</li> <li>Documentation of 1 of the following: <ul> <li>HbA1c &gt;7%</li> <li>History of recurring hypoglycemia</li> <li>Wide fluctuations in blood glucose before mealtime</li> <li>Dawn phenomenon with fasting blood sugars frequently exceeding 200mg/dL</li> <li>History of severe glycemic excursions</li> <li>Inability to use a traditional (non-disposable) insulin pump.</li> </ul> </li> </ul>
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 6 months Renewal: 12 months
Renewal Criteria	Documentation of positive clinical response to therapy and in-person visit with provider within the last 6 months.

Criteria Details	
Effective Date	03/01/2024
P&T Approval Date	01/09/024
P&T Revision Date	

# Dupilumab (DUPIXENT)

### **Products Affected**

#### DUPIXENT

Criteria Details		
Required Medical Information	<ul> <li>Moderate to Severe Asthma:</li> <li>Documentation of inadequate control of asthma symptoms with one of the following: <ul> <li>inhaled corticosteroids and long acting beta2 agonist OR</li> <li>inhaled corticosteroids and long-acting muscarinic antagonist.</li> </ul> </li> <li>Atopic Dermatitis: <ul> <li>Diagnosed with severe atopic dermatitis defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's Dermatology Life Quality Index (CDLQI) ≥ 13 (or severe score on another validated tool)</li> <li>One or more of the following: <ul> <li>At least 10% of body surface area involvement</li> <li>Hand, foot, 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> <li>Topical calcineurin inhibitor (e.g. tacrolimus)</li> <li>Oral immunomodulator therapy (e.g. cyclosporine, methotrexate, azathioprine, mycophenolate mofetil) OR the member is oral corticosteroid dependent.</li> </ul> </li> </ul></li></ul>	
	<ul> <li>Confirmed diagnosis of EoE</li> <li>Weight ≥ 15 kg</li> </ul>	
	<ul> <li>Two or more episodes of dysphagia per week</li> <li>Inadequate response to an 8-week trial, intolerance, or contraindication to high-dose PPI therapy</li> <li>Inadequate response to and 8-to-12-week trial, intolerance, or contraindication to swallowed inhaled respiratory corticosteroid therapy.</li> </ul>	

#### **Criteria Details**

#### Chronic Rhinosinusitis with Nasal Polyps (CRSwNP):

- Diagnosis of CRSwNP, including objective evidence of the presence of bilateral nasal polyps
- Will not be used in combination with other biologics for eosinophilic indications.
- Trial and failure to adequately reduce symptoms with:
  - At least 2 months of saline nasal irrigations and inhaled nasal corticosteroids used at doses appropriate for nasal polyp treatment.
  - Systemic corticosteroid treatment for nasal polyps at least once within the last 2 years or prior nasal polyp removal surgery.
- Inhaled nasal corticosteroids will be used concomitantly with dupilumab (unless not tolerated or contraindicated).

#### Prurigo Nodularis (PN):

- Diagnosis of PN verified by a dermatologist and the patient has had the diagnosis for at least 3 months.
- Severe or very severe itch (WI-NRS score ≥7) reported within the past week.
- At least 20 PN lesions in total on both legs and/or both arms and/or trunk.
- Trial and failure (inadequate efficacy after 4 week trial, intolerable side effects) or contraindication to recommended first line agents for the treatment of PN including:
  - High potency topical steroids
  - Phototherapy
  - At least one systemic agent (immunosuppressant, gabapentinoid, or antidepressant).

#### Chronic Obstructive Pulmonary Disease (COPD):

- Diagnosis of COPD confirmed by post-bronchodilator FEV1/FVC < 0.7 on spirometry.
- Blood eosinophil count (BEC)  $\geq$  300 cells/µL within the past 3 months.
- Chronic bronchitis, defined as a chronic productive cough for ≥ 3 months in the past year, in the absence of other known causes of chronic cough.
- ≥ 2 moderate COPD exacerbation (defined as requiring treatment with either systemic corticosteroids and/or antibiotics) or ≥ 1 severe COPD exacerbation (defined as requiring hospitalization or observation for over 24 hours in emergency department of urgent

	Criteria Details
	care) within the past year despite the adherent use of inhaled LABA + LAMA+ ICS triple therapy [or LABA + LAMA dual therapy if ICS are contraindicated].
	Moderate to Severe Asthma: 6 years and older
	Atopic Dermatitis: 6 months and older
	Eosinophilic Esophagitis: 1 year and older
Age Restrictions	CRSwNP: 12 years and older
	Prurigo Nodularis: 18 years and older
	COPD: 18 years and older
	Atopic dermatitis: Prescribed by a Dermatologist
	Eosinophilic Esophagitis: Prescribed by Gastroenterologist or
Prescriber	Immunologist
Restrictions	CRSwNP: Prescribed by ENT or Immunologist
	Prurigo Nodularis: Prescribed by Dermatologist
	Asthma/COPD: Pulmonologist
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	03/01/2025
P&T Approval Date	11/08/2022
P&T Revision Date	01/14/2025

# Elagolix (ORLISSA)

### Products Affected

• ORILISSA TAB 150MG

ORILISSA TAB 200MG

	Critorio Dotoilo
	Criteria Details 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
Required Medical Information	intolerance to two 3-month trials of hormonal therapies (eg combined oral contraceptives, progestins, or levonorgestrel IUD, etc.).
	Additional info required for 200 mg tablet twice daily: documentation of coexisting dyspareunia
Age Restrictions	At least 18 years old but not yet through menopause
Prescriber Restrictions	Prescribed by obstetrician or gynecologist
Coverage Duration	200MG dose: Initial: 6 months; Renewal: No 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	
P&T Approval Date	
P&T Revision Date	

# Elefibranor (IQIRVO)

#### **Products Affected**

• IQIRVO TABLETS

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

# Elexacaftor-tezacaftor-ivacaft (TRIKAFTA)

### **Products Affected**

• TRIKAFTA

	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	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

# Encorafenib (BRAFTOVI)

### **Products Affected**

• Braftovi

	Criteria Details
Required Medical Information	<ul> <li>Criteria Details</li> <li>BRAF V600E or V600K unresectable or metastatic melanoma: <ul> <li>Cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA</li> <li>Used in combination with Mektovi (binimetinib)</li> <li>Trial and failure, contraindication or intolerance to one of the following: <ul> <li>Zelboraf</li> <li>Tafinlar</li> </ul> </li> <li>Colorectal Cancer (CRC):</li> <li>One of the following <ul> <li>Unresectable or advanced disease</li> <li>Metastatic disease</li> </ul> </li> <li>Patient has received prior therapy</li> <li>Cancer is BRAFV600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)</li> </ul> </li> <li>Non-Small Cell Lung Cancer (NSCLC): <ul> <li>Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)</li> <li>Used in combination with Erbitux (cetuximab)</li> </ul> </li> </ul>
	Used in combination with Mektovi (binimetinib)
Age Restrictions	
Prescriber Restrictions	

Criteria Details	
Coverage Duration	Initial: 12 months. Renewal: 12 months.
Renewal Criteria	Patient does not show evidence of progressive disease while on therapy
Effective Date	03/01/2024
P&T Approval Date	
P&T Revision Date	

# Entrectinib (ROZLYTREK)

### **Products Affected**

ROZLYTREK

	Criteria Details
Required Medical Information	<ul> <li>Non-Small Cell Lung Cancer (NSCLC):</li> <li>Patient has ROS1 rearrangement positive tumor(s)</li> <li>Solid Tumors:</li> <li>Disease has neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, TPR-NTRK1, etc.) as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)</li> <li>Disease is without a known acquired resistance mutation (e.g., TRKA G595R, TRKA G667C or TRKC G623R substitutions)</li> <li>Disease is one of the following: <ul> <li>Metastatic</li> <li>Unresectable (including cases where surgical resection is likely to result in severe morbidity)</li> </ul> </li> <li>One of the following: <ul> <li>Disease has progressed following previous treatment (e.g., surgery, radiation therapy, or systemic therapy) [3]</li> <li>Disease has no satisfactory alternative treatments</li> </ul> </li> </ul>
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 12 months Renewal: 12 months
Renewal Criteria	Patient does not show evidence of progressive disease while on therapy
Effective Date	03/01/2024

	Criteria Details
P&T Approval Date	
P&T Revision Date	

## **Erythropoietic Agents**

### **Products Affected**

PROCRIT

ARANESP

RETACRIT

	Oritorio Dotoilo
	Criteria Details
	<ul> <li>Anemia due to Chronic Kidney Disease (CKD):</li> <li>Diagnosis of chronic kidney disease.</li> <li>Verification of adequate iron stores.</li> <li>Verification of anemia with hematocrit less than 30% or hemoglobin less than 10g/dL within 30 days of request AND <ul> <li>Patient is on dialysis. OR</li> <li>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.</li> </ul> </li> </ul>
Required Medical Information	<ul> <li>Anemia in HIV Patients:</li> <li>Verification of adequate iron stores.</li> <li>Verification of anemia with hematocrit less than 36% or hemoglobin less than 12g/dL within 30 days of request.</li> <li>Serum erythropoietin less than or equal to 500mU/mL.</li> <li>Patient is receiving zidovudine therapy or diagnosed with HIV.</li> </ul>
	<ul> <li>Anemia due to Chemotherapy:</li> <li>Verification that other causes of anemia have been ruled out.</li> <li>Verification of adequate iron stores.</li> <li>Verification of anemia with hematocrit less than 30% or hemoglobin less than 10g/dL within 2 weeks of request.</li> <li>Verification that the cancer is a non-myeloid malignancy.</li> <li>Patient is receiving chemotherapy.</li> </ul>
	<ul> <li>Preoperative for reduction of allogeneic blood transfusion:</li> <li>Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery.</li> <li>Hemoglobin is greater than 10 to less than or equal to 13.</li> </ul>

Criteria Details	
	<ul> <li>Patient is at high risk for perioperative transfusions.</li> <li>Patient is unwilling or unable to donate autologous blood pre- operatively.</li> <li>Verification of adequate iron stores.</li> </ul>
	<ul> <li>Anemia in Myelodysplastic Syndrome (MDS):</li> <li>Diagnosis of MDS.</li> <li>Serum erythropoietin less than or equal to 500mU/mL OR diagnosis of transfusion dependent MDS.</li> <li>Verification of adequate iron stores.</li> </ul>
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	<ul> <li>Anemia in HIV or CKD</li> <li>Initial: 6 months. Renewal: 12 months.</li> <li>Anemia due to chemotherapy</li> <li>Initial: 3 months. Renewal: 3 months.</li> <li>Anemia in MDS</li> <li>Initial: 3 months. Renewal: 12 months.</li> <li>Preop Initial: 1 month.</li> </ul>
Renewal Criteria	<ul> <li>Anemia due to CKD:</li> <li>One of the following: <ul> <li>Patient is on dialysis and most recent or average Hct over 3 months is 33% or less (Hgb 11g/dL or less)</li> <li>Patient is not on dialysis and most recent or average Hct over 3 months is 30% or less (Hgb 10g/dL or less)</li> <li>Request is for a pediatric member and most recent or average Hct over 3 months is 36% or less (Hgb 12g/dL or less)</li> <li>Decrease in the need for blood transfusion OR Hemoglobin increased greater than or equal to 1d/dL from pre-treatment level</li> <li>Verification of adequate iron stores</li> </ul> </li> <li>Anemia in HIV Patients: <ul> <li>Most recent or average Hct over 3 months is 36% or less (Hgb 12g/dL or less).</li> </ul> </li> <li>Decrease in the need for blood transfusion OR Hemoglobin increased greater than or equal to 1d/dL from pre-treatment level</li> <li>Verification of adequate iron stores</li> </ul>

	Criteria Details
	<ul> <li>Anemia due to chemotherapy:</li> <li>Most recent or average Hct over 3 months is 30% or less (Hgb 10g/dL or less).</li> <li>Decrease in the need for blood transfusion OR Hemoglobin increased greater than or equal to 1d/dL from pre-treatment level.</li> <li>Patient is receiving chemotherapy.</li> </ul>
	<ul> <li>Anemia in MDS Patients:</li> <li>Most recent or average Hct over 3 months is 36% or less (Hgb 12g/dL or less).</li> <li>Decrease in the need for blood transfusion OR Hemoglobin increased greater than or equal to 1.5d/dL from pre-treatment level.</li> </ul>
Effective Date	9/1/2024
P&T Approval Date	7/9/2024
P&T Revision Date	7/9/2024

# Erenumbab (AIMOVIG)

#### **Products Affected**

• AIMOVIG 70MG/ML

• AIMOVIG 140MG/ML

	Criteria Details
	Diagnosis of episodic migraines: Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month OR Diagnosis of chronic migraines: Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months AND medication overuse headache has been considered and potentially offending medication(s) have been discontinued AND
Required Medical Information	<b>Two of the following:</b> History of failure or contraindication (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine) <b>OR</b> history of failure or contraindications (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) <b>OR</b> history of failure or contraindication (after at least a two month trial) or intolerance to not propriod to the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol <b>OR</b> history of failure or contraindication (after at least a two month trial) or intolerance to Atacand (candesartan) <b>AND</b> medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, pain specialist, or headache specialist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Renewal Criteria	Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity <b>AND</b> use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan,

	Criteria Details
	sumatriptan)] has decreased since the start of CGRP therapy <b>AND</b> medication will not be used in combination with another CGRP inhibitor for preventive treatment of migraines.
	* <b>AND For Chronic Migraine only:</b> Patient continues to be monitored for medication overuse headache
Effective Date	
P&T Approval Date	
P&T Revision Date	

# Etrasimod arginine (VELSIPITY)

### **Products Affected**

#### • VELSIPITY TAB

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

• ENBREL SURECLICK

Criteria Details		
	ALL: must have a negative tuberculin test (TB)	
Required Medical Information	<b>AS:</b> Patient has a documented diagnosis of ankylosing spondylitis. Clinical documentation showing an inadequate response, intolerance, or contraindication to one or more non-steroidal anti-inflammatory drugs NSAIDs (trial at maximum dose for at least 2-3 weeks before considering them as failures) or analgesic agents if NSAIDs do not completely control the pain, or sulfasalazine (if peripheral joint involvement is present).	
	<b>CD:</b> Clinical documentation showing an inadequate response, intolerance, or contraindication to budesonide, mesalamine, or corticosteroids, or non-biologic DMARDs (i.e., azathioprine, methotrexate, mercaptopurine. JIA: Clinical documentation showing inadequate response, intolerance, or contraindication to one or more NSAID <b>AND</b> one or more non-biologic DMARD (i.e., methotrexate, sulfasalazine).	
	<b>PP:</b> Patient has documented diagnosis of moderate to severe plaque psoriasis for at least 6 months with at least one of the following: Incapacitation due to plaque location (e.g., head and neck, palms, soles, or genitalia) <b>OR</b> Involvement of at least 10 percent of body surface area (BSA) <b>OR</b> Psoriasis Area and Severity Index (PASI) score of 12 or greater, <b>AND</b> patient is free of any clinically important active infections <b>AND</b> clinical documentation of inadequate or non-candidate to a 3-month minimum trial of at least 1 systemic agent (e.g., immunosuppressive, retinoic acid derivatives, and/or methotrexate, <b>AND</b> did not respond or non-candidate to a 3-month minimum trial of phototherapy.	
Age Restrictions		

Criteria Details	
Prescriber Restrictions	
Coverage Duration	Initial: 12 months. Renewal: 12 months.
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

# Fezolinetant (VEOZAH)

### **Products Affected**

• VEOZAH TAB 45MG

	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	09/01/2023
P&T Approval Date	7/11/2023
P&T Revision Date	

# Fingolimod (GILENYA)

### **Products Affected**

#### • GILENYA

Criteria Details	
Required Medical Information	Diagnosis of relapsing forms of multiple sclerosis
Age Restrictions	
Prescriber Restrictions	Neurologist
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

# Fremanezumab-vfrm (AJOVY)

### **Products Affected**

• AJOVY

	Criteria Details
	<b>Diagnosis of episodic migraines:</b> Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month <b>OR</b>
	<b>Diagnosis of chronic migraines</b> : Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months <b>AND</b> medication overuse headache has been considered and potentially offending medication(s) have been discontinued
	AND
Required Medical Information	<b>Two of the following:</b> History of failure or contraindication (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine) <b>OR</b> history of failure or contraindications (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) <b>OR</b> history of failure or contraindication (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol <b>OR</b> history of failure or contraindication (after at least a two month trial) or intolerance to Atacand (candesartan) <b>AND</b> medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, pain specialist, or headache specialist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Renewal Criteria	Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity <b>AND</b> use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy <b>AND</b>

	Criteria Details
	medication will not be used in combination with another CGRP inhibitor for preventive treatment of migraines.
	* <b>AND For Chronic Migraine only:</b> Patient continues to be monitored for medication overuse headache
Effective Date	
P&T Approval Date	
P&T Revision Date	

# Fruquintinib (FRUZAQLA)

#### **Products Affected**

• Fruzaqla

	Criteria Details
Required Medical Information	<ul> <li>Metastatic colorectal cancer (mCRC):</li> <li>Patient has been previously treated with both of the following: <ul> <li>Fluoropyrimidine-, oxaliplatin-, irinotecan-based</li> <li>chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI)</li> <li>Anti-VEGF biological therapy (e.g., Avastin [bevacizumab], Zaltrap [ziv-aflibercept])</li> </ul> </li> <li>One of the following: <ul> <li>Patient has RAS mutant tumors</li> <li>Patient has RAS wild-type tumors</li> <li>Patient has been previously treated with both of the following: An anti-EGFR biological therapy (e.g., Vectibix [panitumumab], Erbitux [cetuximab])</li> <li>One of the following: <ul> <li>Lonsurf [trifluridine/tipiracil]</li> <li>Stivarga [regorafenib]</li> </ul> </li> </ul></li></ul>
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 12 months Renewal: 12 months
Renewal Criteria	Patient does not show evidence of progressive disease while on therapy
Effective Date	03/01/2024
P&T Approval Date	
P&T Revision Date	

# Galcanezumab-gnlm (EMGALITY)

#### **Products Affected**

• Emgality 100mg/mL

	Criteria Details
Required Medical Information	Diagnosis of episodic cluster headache <b>AND</b> patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least 3 months <b>AND</b> medication will not be used in combination with another CGRP inhibitor.
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, pain specialist, or headache specialist.
<b>Coverage Duration</b>	Initial: 3 months Renewal: 12 months
Renewal Criteria	Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity <b>AND</b> Medication will not be used in combination with another CGRP inhibitor.
Effective Date	
P&T Approval Date	
P&T Revision Date	

## **General Oncology**

#### **Products Affected**

- AKEEGA TAB
- AUGTYRO TAB
- CALQUENCE TAB
- COTELLIC TAB
- EMCYT CAP
- EVEROLIMUS
- FRUZAQLA CAP
- GLEOSTINE CAP
- HYCAMTIN CAP
- IBRANCE CAP
- IBRANCE TAB
- ITOVEBI
- KRAZATI TAB

- LENALIDOMIDE
- LEUKERAN TAB
- LONSURF TAB
- LYNPARZA TAB
- LYTGOBI TAB
- MEKINIST TAB
- NINLARO CAP
- ORSERDU
- OSGIVEO
- PEMAZYRE TAB
- RETEVMO TAB
- REZLIDHIA CAP
- RYLAZE

- SORAFENIB TAB
- SPRYCEL TAB
- TABRECTA
- TALZENNA CAP
- TAFINLAR CAP
- THALOMID CAP
- TRUQAP TAB
- TUKYSA
- VANFLYTA TAB
- VONJO CAP
- VOTRIENT TAB
- ZOLINZA TAB

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	Documentation of positive clinical response to therapy.
Effective Date	5/1/2024
P&T Approval Date	3/12/2024
P&T Revision Date	9/12/2023

# **Glatiramer (GLATOPA)**

### **Products Affected**

• GLATIRAMER INJ 20MG/ML

• GLATIRAMER INJ 40MG/ML

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	Documentation of positive clinical response to therapy
Effective Date	
P&T Approval Date	
P&T Revision Date	

### **Glucagon-Like Peptide-1 (GLP1s) Receptor Agonist**

#### **Products Affected**

- BYDUREON BCISE
- BYETTA 10 MCG PEN

- TRULICITY
- VICTOZA

• BYETTA 5MCG PEN

	Criteria Details
Required Medical Information	Patient must have clinically diagnosed Type 2 Diabetes <b>AND</b> patient must have adequate trial of, or contraindication to an SGLT-2 if patient has HF or high risk/established ASCVD or a DPP-4 if no high risk/established ASCVD <b>AND</b> a maximal tolerated doses of metformin.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 12 months, Renewal: 12 months.
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

### Golimumab (SIMPONI)

#### **Products Affected**

• SIMPONI INJ 50/0.5ML

• SIMPONI INJ 100MG/ML

	Criteria Details
Required Medical Information	<b>Rheumatoid Arthritis (RA):</b> Diagnosis of moderately to severely active RA AND trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine <b>AND</b> patient is receiving concurrent therapy with methotrexate <b>OR</b> has a contraindication or intolerance to methotrexate.
	<b>Psoriatic Arthritis (PsA):</b> Diagnosis of active PsA with one of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, active skin and/or nail involvement.
	<b>Ankylosing Spondylitis (AS):</b> Diagnosis of active ankylosing spondylitis <b>AND</b> minimum duration of one month trial and failure, contraindication, or intolerance to two NSAIDs (e.g., diclofenac, ibuprofen, indomethacin, meloxicam, naproxen).
	<b>Polyarticular Juvenile Idiopathic Arthritis (PJIA):</b> Diagnosis of moderate to severely active PJIA AND trial and failure, contraindication, or intolerance to one of the following non-biologic disease-modifying antirheumatic drugs (DMARDs): leflunomide, methotrexate.
	<b>Ulcerative Colitis (UC):</b> Diagnosis of moderately to severely active ulcerative colitis with one of the following: 1) Greater than 6 stools per day, 2) frequent blood in the stools, 3) frequent urgency, 4) presence of ulcers, 5) abnormal lab values (e.g. hemoglobin, ESR, CRP), 6) dependent on, or refractory to, corticosteroids. AND trial and failure, contraindication, or intolerance to one of the following conventional therapies: 6-mercaptopurine, aminosalicylate [e.g., mesalamine sulfasalazine, azathioprine, Corticosteroids (e.g., prednisone, methylprednisolone).
Age Restrictions	

	Criteria Details
Prescriber Restrictions	RA, AS, PJIA: Prescribed by or in consultation with a rheumatologist PsA: Prescribed by or in consultation with one of the following: Dermatologist or Rheumatologist UC: Prescribed by or in consultation with a gastroenterologist
Coverage Duration	<b>RA, PsA, AS, PJIA: Initial:</b> 6 months; <b>Renewal:</b> 12 months <b>UC: Initial:</b> 10 weeks; <b>Renewal</b> : 12 months
Renewal Criteria	<ul> <li>RA, PJIA: Documentation of a positive clinical response to therapy as evidenced by one of the following: reduction in the total active (swollen and tender) joint count from baseline, or improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline.</li> <li>PsA: Documentation of a positive clinical response to therapy as evidenced by one of the following: reduction in the total active (swollen and tender) joint count from baseline, or reduction in the total active (swollen service devidenced by one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline, or reduction in the body</li> </ul>
	surface area (BSA) involvement from baseline. <b>AS:</b> Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following: disease activity (e.g., pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (e.g., lumbar spine motion, chest expansion), or total active (swollen and tender) joint count.
	<b>UC:</b> Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, or reversal of high fecal output state.
Effective Date	
P&T Approval Date	
P&T Revision Date	

# **Gonadotropin-Releasing Hormone Agonists**

#### **Products Affected**

Lupron Depot

Lupron •

. Eligard •

. Leuprorelin •

Criteria Details	
	<ul> <li>Endometriosis</li> <li>Diagnosis of endometriosis</li> <li>One of the following:         <ul> <li>History of inadequate pain control response following a trial of at least 6 months, or history of intolerance or contraindication to one of the following:                 <ul> <li>Danazol</li> <li>Combination (estrogen/progestin) oral contraceptive</li> <li>Progestins</li> </ul> </li> <li>Progestins</li> </ul> <li>One of the following:</li></li></ul>
Required Medical Information	<ul> <li>Patient has had surgical ablation to prevent recurrence</li> <li>Uterine Leiomyomata (Fibroids) - For the reduction of the size of fibroids [off-label]</li> <li>For use prior to surgery to reduce the size of fibroids to facilitate a surgical procedure (e.g., myomectomy, hysterectomy)</li> </ul>
	<ul> <li>Uterine Leiomyomata (Fibroids) - Anemia</li> <li>For the treatment of anemia</li> <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>
	<ul> <li>Central Precocious Puberty (CPP)         <ul> <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> </ul> </li> </ul>

	Criteria Details
	<ul> <li>Advanced bone age of at least one year compared with chronological age</li> <li>One of the following:         <ul> <li>Both of the following:</li> <li>Patient has undergone gonadotropin-releasing hormone agonist (GnRHa) testing</li> <li>Peak luteinizing hormone (LH) level above prepubertal range</li> <li>Patient has a random LH level in the pubertal range</li> <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> <li>Prostate Cancer</li> <li>Diagnosis of advanced or metastatic prostate cancer</li> <li>Trial and failure, contraindication, or intolerance to any brand Lupron formulation</li> <li>Or of mulation</li> <li>Or state to the foilowing for the state cancer</li> <li>Trial and failure, contraindication, or intolerance to any brand</li> <li>Contraindication, or intolerance to any brand</li> <li>Contraindication, or intolerance to any brand</li></ul></li></ul></li></ul>
	<ul> <li>Gender Dysphoria/Gender Incongruence (off-label)</li> <li>Using gonadotropin for suppression of puberty</li> </ul>
	Diagnosis of gender dysphoria/gender incongruence
Age Restrictions	
Prescriber Restrictions	Central Precocious Puberty (CPP): Pediatric endocrinologist
Coverage Duration	Endometriosis: Initial: 6 months; Renewal: 6 months Uterine Leiomyomata (Fibroids): Initial: 4 months; Renewal: 3 months Uterine Leiomyomata (Fibroids) – Anemia Initial: 3 months Central Precocious Puberty (CPP): Initial: 12 months; Renewal: 12 months Prostate Cancer: Initial: 12 months; Renewal: 12 months Gender Dysphoria/Gender Incongruence: Initial: 12 months; Renewal: 12 months
Renewal Criteria	Endometriosis

	Criteria Details
	<ul> <li>Recurrence of symptoms following a trial of at least 6 months with leuprolide acetate</li> <li>Used in combination with one of the following:         <ul> <li>Norethindrone 5 mg daily</li> <li>Other "add-back" sex-hormones (e.g., estrogen, medroxyprogesterone)</li> <li>Other bone-sparing agents (e.g., bisphosphonates)</li> </ul> </li> <li>Central Precocious Puberty (CPP)         <ul> <li>LH levels have been suppressed to pre-pubertal levels</li> <li>Prescribed by or in consultation with a pediatric endocrinologist</li> </ul> </li> <li>Prostate Cancer         <ul> <li>Diagnosis of advanced or metastatic prostate cancer</li> </ul> </li> </ul>
Effective Date	8/1/2024
P&T Approval Date	5/13/2024
P&T Revision Date	

### **Grass Pollen Allergen Extract – Timothy Grass (GRASTEK)**

#### **Products Affected**

#### • GRASTEK

	Criteria Details
Required Medical Information	Grass pollen-induced allergic rhinitis.
Age Restrictions	
Prescriber Restrictions	Prescribed by Allergy and Immunology specialist.
Coverage Duration	Initial: 3 months. Renewal: 3 months.
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

### Guselkumab (TREMFYA)

#### **Products Affected**

• TREMFYA INJ 100MG/ML

	Quitoria Dataila
	Criteria Details
Required Medical Information	<b>Plaque Psoriasis (PsO):</b> Diagnosis of moderate-to-severe plaque psoriasis with one of the following: 1) greater than or equal to 3% body surface area involvement, 2) severe scalp psoriasis, 3) palmoplantar, facial, or genital involvement <b>AND</b> a minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids, vitamin D analogs, tazarotene, calcineurin inhibitors, anthralin, coal tar.
	<b>Psoriatic Arthritis (PsA):</b> Diagnosis of active psoriatic arthritis with one of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, active skin and/or nail involvement.
Age Restrictions	
Prescriber Restrictions	<b>Ps0:</b> Prescribed by or in consultation with a dermatologist <b>PsA:</b> Prescribed by or in consultation with one of the following: dermatologist or rheumatologist
Coverage Duration	Initial: 6 months; Renewal: 12 months
Renewal Criteria	<ul> <li>Ps0: Documentation of positive clinical response to therapy as evidenced by ONE of the following: reduction the body surface area (BSA) involvement from baseline OR improvement in symptoms (e.g., pruritus, inflammation) from baseline</li> <li>PsA: Documentation of positive clinical response to therapy as evidenced by one of the following: Reduction in BSA from baseline, reduction in total active joint count, improvement in symptoms (e.g.,</li> </ul>
Effective Date	improvement in number of swollen/tender joints, pain, or stiffness).

	Criteria Details
P&T Approval Date	
P&T Revision Date	

## Ibrutinib (IMBRUVICA)

#### **Products Affected**

#### • IMBRUVICA

	Criteria Details
Required Medical Information	<ul> <li>Documentation of one of the following: <ul> <li>Diagnosis of Mantle Cell Lymphoma (MCL) AND patient has relapsed or is refractory to at least one prior therapy for the treatment of MCL.</li> <li>Diagnosis of Chronic Lymphocytic Leukemia (CLL) OR Small Lymphocytic Lymphoma (SLL).</li> <li>Diagnosis of Marginal Zone Lymphoma (MZL) AND patient has received at least one prior anti-CD20- based therapy.</li> </ul> </li> <li>Diagnosis of Waldenstrms macroglobulinemia (WM) of Waldenstrms macroglobulinemia/lymphoplasmacytic lymphoma.</li> </ul>
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist.
Coverage Duration	Initial: 12 months. Renewal: 12 months.
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

# Inclisiran (LEQVIO)

#### **Products Affected**

• LEQVIO SOLUTION

	Criteria Details
Required Medical Information	<ul> <li>Established clinical ASCVD:</li> <li>Documentation of very high risk ASCVD as evidenced by either: <ul> <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> </ul>
	<ul> <li>Primary or familial hyperlipidemia:</li> <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> <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.

Criteria Details	
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

### Infigratinib (TRUSELTIQ)

#### **Products Affected**

- TRUSELTIQ (100MG DAILY DOSE)
- TRUSELTIQ (125MG DAILY DOSE)

• TRUSELTIQ (50MG DAILY DOSE) TRUSELTIQ (75MG DAILY DOSE)

Criteria Details	
Required Medical Information	Confirmation of trial and failure of guideline directed therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	Initial: 3 months. Renewal: 3 months.
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

# Insulin Degludec (TRESIBA)

#### **Products Affected**

• TRESIBA FLEXTOUCH U-100 & U-200

	Criteria Details
Required Medical Information	<b>U-100 &amp; *U-200:</b> Must have tried and failed formulary long-acting insulin analogues <b>OR</b> have documented intolerance or contraindication to formulary long-acting insulin analogues <b>AND</b> have significant barriers to sardized administration requiring flexibility in dose timing.
	*( <b>U-200</b> ) Patient must require greater than 160 units of insulin per dose <b>AND</b> have difficulty with multiple daily injections.
Age Restrictions	
Prescriber Restrictions	
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	3/12/2024

# Interferon Alfa-2b (INTRON A)

#### **Products Affected**

#### • INTRON A

	Criteria Details
	<b>Chronic hepatitis B:</b> Diagnosed with chronic hepatitis B infection <b>AND</b> patient is without decompensated liver disease.
	<b>Chronic hepatitis C:</b> Diagnosed with chronic hepatitis C infection <b>AND</b> patient is without decompensated liver disease <b>AND</b> patient has not previously been treated with interferon <b>AND</b> is prescribed for use with ribavirin <b>OR</b> patient has intolerance or contraindication to ribavirin.
	<b>Metastatic renal cell carcinoma (RCC):</b> Diagnosed with metastatic RCC <b>AND</b> prescribed in combination with Avastin (bevacizumab).
Required Medical Information	AIDS-related Kaposi sarcoma (KS): Diagnosed with AIDS-related KS.
mornation	<b>Condylomata acuminata (CA)</b> : Diagnosed with CA involving external surfaces of the genital & perianal areas.
	<b>Follicular lymphoma (FL):</b> Diagnosed with clinically aggressive follicular non-Hodgkin lymphoma. Prescribed in conjunction with anthracycline-containing combination chemotherapy.
	<b>Hairy cell leukemia (HCL)</b> : Diagnosed with HCL. Melanoma: Diagnosed with malignant melanoma. Prescribed as adjuvant to surgical treatment who are free of disease but at high risk for systemic recurrence <b>AND</b> must be administered within 56 days of surgery.
Age Restrictions	Patient must be 18 years or older.
Prescriber Restrictions	Prescribed by a specialist.
Coverage Duration	Initial: 12 months. Renewal: 12 months.

Criteria Details	
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

# Interferon beta-1a (AVONEX)

### **Products Affected**

• AVONEX PEN

• AVONEX PREFILLED

	Criteria Details
Required Medical Information	Diagnosis of a relapsing form 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	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	Initial: 12 months. Renewal: 12 months.
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

### Interferon beta-1a (REBIF)

#### **Products Affected**

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

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

	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	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

## Interferon beta-1b (EXTAVIA)

#### **Products Affected**

• EXTAVIA INJ 0.3MG

	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	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

# Ivacaftor (KALYDECO)

#### **Products Affected**

• KALYDECO

	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 positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

# Ivermectin (STROMECTOL)

#### **Products Affected**

#### • IVERMECTIN

	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	Initial: 6 months, Renewals: reinfection 6 months
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

# Ivosidenib (TIBSOVO)

#### **Products Affected**

• TIBSOVO

	Criteria Details
Required Medical Information	Acute Myeloid Leukemia (AML): Test confirmed IDH1 mutation Cholangiocarcinoma: Test confirmed IHD1 mutation AND previous treatment with at least one chemotherapy regimen (e.g. FOLFOX)
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by an oncologist
Coverage Duration	Initial: 3 months. Renewal: 6 months.
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

# Ixekizumab (TALTZ)

#### **Products Affected**

#### • TALTZ

Criteria Details		
Required Medical Information	<b>Plaque Psoriasis (PsO):</b> Diagnosis of moderate to severe chronic plaque psoriasis with one of the following: 1) greater than or equal to 3% body surface area involvement, 2) severe scalp psoriasis, 3) palmoplantar, facial, or genital involvement <b>AND</b> a minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids, vitamin D analogs, tazarotene, calcineurin inhibitors, anthralin, coal tar <b>AND</b> trial and failure, contraindication, or intolerance to ONE of the following: Cimzia, adalimumab, Skyrizi, Stelara, or Tremya.	
	<b>Psoriatic Arthritis (PsA):</b> Diagnosis of active psoriatic arthritis with one of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, active skin and/or nail involvement <b>AND</b> trial and failure, contraindication, or intolerance to ONE of the following: Cimzia, Enbrel, adalimumab, Simponi, Stelara, Tremfya, Skyrizi, Rinvoq, or Xeljanz	
	<b>Ankylosing Spondylitis (AS):</b> Diagnosis of active ankylosing spondylitis <b>AND</b> minimum duration of one month trial and failure, contraindication, or intolerance to <b>TWO</b> non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., diclofenac, ibuprofen, indomethacin, meloxicam, naproxen) <b>AND</b> trial and failure, contraindication, or intolerance to ONE of the following: Cimzia, Enbrel, adalimumab, Simponi, Rinvoq, Xeljanz.	
	<b>Non-radiographic Axial Spondyloarthritis (nr-axSpA):</b> Diagnosis of active non-radiographic axial spondyloarthritis <b>AND</b> patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) <b>AND</b> minimum duration of one month trial and failure, contraindication, or intolerance to <b>TWO</b> non-steroidal anti-inflammatory drugs (NSAIDs) (e.g.,	

	Criteria Details diclofenac, ibuprofen, meloxicam, naproxen) AND trial and failure,
	contraindication, or intolerance to Cimzia.
Age Restrictions	
Prescriber Restrictions	<ul> <li>Plaque Psoriasis (PP): Prescribed by or in consultation with a dermatologist</li> <li>Psoriatic Arthritis (PsA): Prescribed by or in consultation with a dermatologist or rheumatologist</li> <li>Ankylosing Spondylitis (AS): Prescribed by or in consultation with a rheumatologist</li> <li>Non-radiographic Axial Spondyloarthritis: Prescribed by or in consultation with a rheumatologist</li> </ul>
Coverage Duration	Initial: 12 months; Renewal: 12 months
Renewal Criteria	<ul> <li>Ps0: Documentation of a positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, or improvement in symptoms (e.g., pruritus, inflammation) from baseline.</li> <li>PsA: Documentation of a positive clinical response to therapy as evidenced by one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline, or reduction in the body surface area (BSA) involvement from baseline.</li> <li>AS, nr-axSpA: Documentation of positive clinical response to therapy as evidenced by improvement from baseline.</li> <li>AS, nr-axSpA: Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following: disease activity (e.g., pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (e.g., lumbar spine motion, chest expansion), or total active (swollen and tender) joint count.</li> </ul>
Effective Date	
P&T Approval Date	
P&T Revision Date	

### Lacosamide (VIMPAT)

#### **Products Affected**

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

	Criteria Details
Required Medical Information	Focal seizures OR Primary generalized tonic-clonic seizures: Documented epilepsy or seizure disorder
Age Restrictions	<ul> <li>Solution only</li> <li>One of the following:</li> <li>Pediatric member age 10 or under</li> <li>Documentation inability of the member to use the preferred tablet formulation</li> </ul>
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	3/12/2024
P&T Revision Date	7/11/2023

## Lanthanum Carbonate (FOSRENOL)

#### **Products Affected**

- Lanthanum carbonate 500MG •
- Lanthanum carbonate 1000MG
- Lanthanum carbonate 750MG •

	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	Initial: 6 months Renewal: 12 months
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	
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### Lasmiditan (REYVOW)

#### **Products Affected**

• REYVOW 100MG TAB

• REYVOW 50MG TAB

	Criteria Details
Required Medical Information	Medication intended for use for acute use for the treatment of migraine headaches <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) <b>OR</b> trial and failure to intolerance to NSAID treatment alone if triptans contraindicated <b>OR</b> contraindication to all triptans and NSAIDs
Age Restrictions	Patient is 18 years of age or older
Prescriber Restrictions	Prescribed by neurologist or headache specialist
<b>Coverage Duration</b>	Initial: 3 months Renewal: 6 months
Renewal Criteria	Documented positive clinical response to therapy
Effective Date	
P&T Approval Date	
P&T Revision Date	

# Lebrikizumab (EBGLYSS)

#### **Products Affected**

• Ebglyss autoinjector

• Ebglyss prefilled syringe

Criteria Details	
Required Medical Information	<ul> <li>Atopic dermatitis:</li> <li>Diagnosed with severe atopic dermatitis defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's Dermatology Life Quality Index (CDLQI) ≥ 13 (or severe score on another validated tool)</li> <li>One or more of the following: <ul> <li>At least 10% of body surface area involvement</li> <li>Hand, foot, 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> <li>Topical calcineurin inhibitor (e.g. tacrolimus)</li> <li>Oral immunomodulator therapy (e.g. cyclosporine, methotrexate, azathioprine, mycophenolate mofetil) OR the member is oral corticosteroid dependent.</li> </ul> </li> </ul>
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist.
Coverage Duration	Initial: 6 months Renewal: 12 months
Renewal Criteria	Documentation of positive clinical response to therapy
Effective Date	1/1/2025
P&T Approval Date	11/12/2024
P&T Revision Date	11/12/2024

## Lenvatinib (LENVIMA)

#### **Products Affected**

#### • LENVIMA

	Criteria Details
	<b>Endometrial carcinoma (EC):</b> Has advanced EC that is not microsatellite instability-high (MIS-H) or mismatch repair deficient (dMMR) <b>AND</b> has tried at least one systemic therapy <b>AND</b> is not a candidate for curative therapy.
<b>Required Medical</b>	Hepatocellular Cancer (HCC): Has unresectable or metastatic disease
Information	<b>Renal Cell Carcinoma (RCC):</b> Has advanced disease <b>AND</b> is either being used in combination with Keytruda <b>OR</b> an everolimus.
	<b>Thyroid Carcinoma, differentiated (DTC):</b> Diagnosed with differentiated thyroid carcinoma AMD disease is refractory to radioactive iodine therapy.
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by oncologist
Coverage Duration	Initial: 3 months Renewal: 6 months
Renewal Criteria	Documentation of positive clinical response to therapy
Effective Date	
P&T Approval Date	
P&T Revision Date	

# Lidocaine Topical Anesthetic (LIDODERM)

#### **Products Affected**

• LIDOCAINE EXTERNAL PATCH 5%

Criteria Details	
Required Medical Information	Diagnosis of post-herpetic neuralgia.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 3 months. Renewal: 3 months.
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

## Lifitegrast (XIIDRA)

#### **Products Affected**

#### • XIIDRA

	Criteria Details
Required Medical Information	<ul> <li>The patient has a diagnosis of lack of tear production due to ocular inflammation associated with keratoconjunctivitis sicca AND ONE of the following: <ul> <li>The patient is not currently using a topical ophthalmic anti-inflammatory drug or punctal plug OR</li> <li>The patients current use of topical ophthalmic anti-inflammatory drug or punctal plug will be discontinued before starting the requested agent AND The patient has previously tried or is currently using aqueous enhancements (e.g. artificial tears, gels, ointments) OR</li> <li>The patient has a documented intolerance, contraindication, or hypersensitivity to aqueous enhancements.</li> </ul> </li> <li>The patient is not currently using Restasis OR the patients current use of Restasis will be discontinued before starting Xiidra.</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	
P&T Approval Date	
P&T Revision Date	

# Linezolid (ZYVOX)

#### **Products Affected**

• LINEZOLID

• LINEZOLID IN SODIUM CHLORIDE

	Criteria Details
Required Medical Information	Clinically documented infection that is susceptible to linezolid if the patient has a severe allergy to beta lactamase inhibitors or any antibiotic that the organism is susceptible <b>OR</b> clinically documented infection that is susceptible to linezolid if the patient has failed treatment with antibiotics that the organism is susceptible <b>OR</b> clinically documented Vancomycin-Resistant Enterococcus faecium infection <b>OR</b> clinically documented MRSA <b>AND</b> has failed or is intolerant to Vancomycin if the organism is susceptible to Vancomycin.
Age Restrictions	<ul> <li>Solution only</li> <li>One of the following: <ul> <li>Pediatric member age 10 or under</li> <li>Documentation inability of the member to use the preferred tablet formulation</li> </ul> </li> </ul>
Prescriber Restrictions	Prescribed by or in consultation with an Infectious Disease specialist.
Coverage Duration	Initial: length of treatment. Renewal: length of treatment.
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	3/12/2024

### Long Acting Opiates AND Dolophine

#### **Products Affected**

- FENTANYL PATCH 72 HOUR 100 MCG/HR TRANSDERMAL
- FENTANYL PATCH 72 HOUR 12 MCG/HR TRANSDERMAL
- FENTANYL PATCH 72 HOUR 25 MCG/HR TRANSDERMAL
- FENTANYL PATCH 72 HOUR 37.5 MCG/HR TRANSDERMAL
- FENTANYL PATCH 72 HOUR 50 MCG/HR TRANSDERMAL
- FENTANYL PATCH 72 HOUR 62.5 MCG/HR TRANSDERMAL
- FENTANYL PATCH 72 HOUR 75 MCG/HR TRANSDERMAL
- FENTANYL PATCH 72 HOUR 87.5 MCG/HR TRANSDERMAL
- HYDROCODONE BITARTRATE ER
- HYDROMORPHONE HCL ER
- METHADONE HCL
- MORPHINE SULFATE ER BEADS CAPSULE EXTENDED RELEASE 24 HOUR 120 MG ORAL

- MORPHINE SULFATE ER BEADS CAPSULE EXTENDED RELEASE 24 HOUR 30 MG ORAL
- MORPHINE SULFATE ER BEADS CAPSULE EXTENDED RELEASE 24 HOUR 45 MG ORAL
- MORPHINE SULFATE ER BEADS CAPSULE EXTENDED RELEASE 24 HOUR 60 MG ORAL
- MORPHINE SULFATE ER BEADS CAPSULE EXTENDED RELEASE 24 HOUR 75 MG ORAL
- MORPHINE SULFATE ER BEADS CAPSULE EXTENDED RELEASE 24 HOUR 90 MG ORAL
- 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**

Criteria Details	
	Cancer, end of life, or palliative care: No coverage restrictions.
Required Medical Information	<b>Non-cancer/end of life care:</b> Documented use of current and/or recent usage of short-acting opioids for at least 15 days prior to long-acting opioids.
	• For opioid naive (14 or fewer days filled in previous 120 days): 7-day maximum quantity limit, equal to or less than 50 MED [morphine equivalents per day].

Criteria Details	
	<ul> <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	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

## Lorlatinib (LORBRENA)

#### **Products Affected**

#### LORBRENA

	Criteria Details
Required Medical Information	<ul> <li>Treatment being prescribed or supervised by a hematologist, or oncologist as appropriate for the type of cancer AND treatment supported for the diagnosis in NCCN guidelines AND treatment being used according to FDA indication AND trial and failure of one of the following agents: <ul> <li>For diagnosis of ALK-positive arrangement-positive NSCLC, no prior treatment:</li> <li>Alecensa (alectinib) OR Alunbrig (brigatinib)</li> </ul> </li> <li>For diagnosis of ALK-positive arrangement-positive NSCLC when the ALK-rearrangment is discovered during first-line systemic therapy:</li> <li>Alunbrig (brigatnib), OR Zykadia (ceritinib)</li> </ul>
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Renewal Criteria	Clinical documentation showing continued adherence and toleration of Lorbrena with lack of disease progression
Effective Date	02/01/2022
P&T Approval Date	01/11/2022
P&T Revision Date	

# Lotilaner (XDEMVY)

#### **Products Affected**

• Xdemvy 0.25% Ophthalmic solution

	Criteria Details
Required Medical Information	<ul> <li>Diagnosis: Demodex Blepharitis</li> <li>Documentation of at least mild erythema of the upper eyelid margin</li> <li>Presence of mites upon examination of eyelashes by light microscopy or presence of collarettes on slit lamp examination</li> </ul>
Age Restrictions	18 years of age or older
Prescriber Restrictions	Optometrist or Ophthalmologist
Coverage Duration	Initial: 6 weeks. Renewal: No renewals allowed
Renewal Criteria	
Effective Date	5/1/2024
P&T Approval Date	3/12/2024
P&T Revision Date	3/12/2024

# Lumacaftor/ivacaftor (ORKAMBI)

#### **Products Affected**

• ORKAMBI ORAL PACKET

• ORKAMBI ORAL TABLET

	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	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

# Methylphenidate solution/chewable

#### **Products Affected**

METHYLPHENIDATE HCL ORAL SOLUTION

 METHYLPHENIDATE HCL ORAL TABLET CHEWABLE

	Criteria Details
Required Medical Information	Documentation that the patient has difficulty swallowing pills and/or has tried and failed methylphenidate tablets.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 12 months. Renewal: 12 months.
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

# **Midostaurin (RYDAPT)**

#### **Products Affected**

• Rydapt

#### **Criteria Details** Acute Myeloid Leukemia: FMS-like tyrosine kinase 3 (FLT3) mutation-positive as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments **Required Medical** (CLIA) Information Used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation Diagnosis of Aggressive Systemic Mastocytosis, Systemic Mastocytosis with Associated Hematological Neoplasm, or Mast Cell Leukemia Age Restrictions Prescriber Restrictions **Coverage Duration** Initial: 12 months. Renewal: 12 months. **Renewal Criteria** Patient does not show evidence of progressive disease while on therapy Effective Date 03/01/2024 **P&T Approval Date P&T Revision Date**

# Mitapivat (PYRUKYND)

### **Products Affected**

#### • PYRUKYND

	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	
P&T Approval Date	
P&T Revision Date	

# Mirikizumab-mrkz (OMVOH)

### **Products Affected**

• Omvoh

	Oritoria Dataila
Required Medical Information	<ul> <li>Criteria Details</li> <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> <li>Mesalamine, sulfasalazine OR</li> <li>Mercaptopurine, azathioprine, OR</li> <li>Corticosteroids (prednisone, methylprednisolone)</li> </ul> </li> </ul>
Ano Doctrictions	Trial and failure of both infliximab and adalimumab
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultations with a Gastroenterologist.
<b>Coverage Duration</b>	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	7/1/2024
P&T Approval Date	5/14/2024

Criteria Details	
P&T Revision Date	

# Mobocertinib (EXKIVITY)

### **Products Affected**

• Exkivity

	Criteria Details
Required Medical Information	Treatment supported for the diagnosis in NCCN guidelines <b>AND</b> treatment being used according to FDA indication <b>AND</b> prior trial and failure of contraindication to Rybrevant (amivantamab).
Age Restrictions	18 and older
Prescriber Restrictions	Oncologist or Hematologist
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Renewal Criteria	Clinical documentation showing continued adherence and toleration with lack of disease progression
Effective Date	
P&T Approval Date	
P&T Revision Date	

# Naltrexone (VIVITROL)

### **Products Affected**

• VIVITROL INJ.

	Criteria Details
Required Medical Information	The medication will be sent directly to the administering provider and will not be dispensed directly to the member
Age Restrictions	
Prescriber Restrictions	
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	3/12/2024

# Nilotinib (TASIGNA)

#### **Products Affected**

• TASIGNA CAP 50MG

• TASIGNA CAP 200MG

• TASIGNA **CAP 150MG** 

	Criteria Details
Required Medical Information	Ph+ CML: Newly diagnosed Ph+ CML in chronic phase OR Chronic phase AND accelerated phase Ph+ CML that is resistant or intolerant to prior therapy, including imatinib or the patient has a Sokal risk score >1.2 (High risk)
Age Restrictions	At least one year of age
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	Initial: 3 months Renewal: 3 months
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

# Omalizumab (XOLAIR)

#### **Products Affected**

• XOLAIR AUTO-INJECTOR

• XOLAIR PREFILLED SYRINGE

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> <li>Chronic Rhinosinusitis with Nasal Polyps (CRSwNP): <ul> <li>Confirmed diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP).</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></li>
	• Documentation of chronic spontaneous of holpathic utilicatia.

Criteria Details	
	<ul> <li>Documented trial and failure of at least 6 weeks of maximally tolerated doses of all the following:         <ul> <li>1<sup>st</sup> generation antihistamine - (e.g., doxepin, hydroxyzine)</li> <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> </li> </ul>
	<ul> <li>IgE-Mediated Food Allergy:</li> <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> <li>Clinical history of IgE mediated food allergy.</li> <li>Used in conjunction with food allergen avoidance.</li> </ul> </li> </ul>
	<ul> <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	<ul> <li>Asthma: Prescribed by or in consultation with a pulmonologist or immunologist.</li> <li>CIU: Prescribed by or in consultation with an immunologist.</li> <li>CRSwNP: Prescribed by or in consultation with an allergist or ENT.</li> <li>IgE Mediated Food Allergy: Prescribed by or in consultation with an allergist or immunologist.</li> </ul>
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.

	Criteria Details	
Renewal Criteria	<ul> <li>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> </li> <li>All Other Diagnoses:         <ul> <li>Documentation of clinically significant improvement in symptoms.</li> </ul> </li> </ul>	
Effective Date	9/1/2024	
P&T Approval Date	7/9/2024	
P&T Revision Date	7/9/2024	

# Paliperidone (INVEGA HAFYERA)

#### **Products Affected**

#### • INVEGA HAFYERA

	Criteria Details
Required Medical Information	Clinical documentation of a diagnosis of schizophrenia <b>AND</b> trial and failure (defined by at least 6 months of treatment) of Invega Trinza <b>OR</b> Invega Sustenna <b>AND</b> clinical need or concern for adherence which could be improved upon with twice yearly dosing.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Initial: 12 months. Renewal: 12 months.
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

# Pancrelipase (CREON) (PANCREAZE)

#### **Products Affected**

• PANCREAZE

CREON

	Criteria Details
Required Medical Information	<ul> <li>Confirmed diagnosis of cystic fibrosis OR history of pancreatectomy OR diagnosis of exocrine pancreatic cancer OR diagnosis of chronic pancreatitis confirmed by imaging OR confirmed diagnosis of pancreatic insufficiency confirmed with one of the following methods: <ul> <li>Steatorrhea with fecal fat determination OR</li> <li>Measurement of fecal elastase OR Secretin or CCK pancreatic function testing OR</li> </ul> </li> <li>Two of the following CFTR mutations (G542X, W1282X, R553X, 621+1G&gt;T, 1717-1G&gt;A, 3120+1G&gt;A, R1162X, 3659delC, 1898+1G&gt;A, 2184delA, 711+1G&gt;T, F508del, I507del, G551D, N1303K, R560T).</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	
P&T Approval Date	
P&T Revision Date	

## **PCSK9** inhibitors

#### **Products Affected**

• PRALUENT

• REPATHA

Criteria Details	
Required Medical Information	<ul> <li>Established clinical atherosclerotic cardiovascular disease (ASCVD):</li> <li>Confirmed diagnosis of atherosclerotic cardiovascular disease (ASCVD).</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>Primary or familial hyperlipidemia: <ul> <li>Documentation of current LDL greater than 100 mg/dL.</li> </ul> </li> <li>Documentation of current LDL greater than 100 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 a ezetimibe.</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).

Criteria Details	
Effective Date	11/1/2024
P&T Approval Date	1/11/2022
P&T Revision Date	01/11/2022, 09/10/2024

## **Peanut Powder (PALFORZIA)**

#### **Products Affected**

- PALFORZIA (12 MG DAILY DOSE)
- PALFORZIA (120 MG DAILY DOSE)
- PALFORZIA (160 MG DAILY DOSE)
- PALFORZIA (20 MG DAILY DOSE)
- PALFORZIA (200 MG DAILY DOSE)
- PALFORZIA (240 MG DAILY DOSE)
- PALFORZIA (3 MG DAILY DOSE)

- PALFORZIA (300 MG MAINTENANCE)
- PALFORZIA (300 MG TITRATION)
- PALFORZIA (40 MG DAILY DOSE)
- PALFORZIA (6 MG DAILY DOSE)
- PALFORZIA (80 MG DAILY DOSE)
- PALFORZIA INITIAL ESCALATION

	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	Currently receiving medication byway of previously approved SHP authorization or documents showing <b>Initial</b> approval criteria was/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 greater than 18 years old, must have medical justification that supports continued need for oral immunotherapy despite peanut avoidance and documentation that Initial dose escalation happened between age 4 and 17.
Effective Date	
P&T Approval Date	
P&T Revision Date	

# Pirtobrutinib (JAYPIRCA)

### **Products Affected**

• JAYPIRCA 50MG

• JAYPIRCA 100MG

	Criteria Details
Required Medical Information	<ul> <li>Mantle Cell Lymphoma (MCL):</li> <li>Diagnosis of MCL confirmed by histology</li> <li>Tried and failed at least 2 prior therapies of which one was with a BTKi</li> <li>ECOG performance status score of 0 to 2</li> <li>Other Diagnosis</li> <li>Diagnosis as supported in National Comprehensive Cancer Network (NCCN) guidelines.</li> </ul>
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by oncologist
Coverage Duration	Initial: 2 months. Renewal: 4 months
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	09/01/2023
P&T Approval Date	07/11/2023
P&T Revision Date	

# Pitolisant (WAKIX)

### **Products Affected**

• WAKIX 4.45MG TAB

• WAKIX 17.8NG TAB

	Criteria Details
Required Medical Information	<ul> <li>Confirmation of diagnosis of narcolepsy based on polysomnography AND a multiple sleep latency test.</li> <li>Documentation that CYP2D6 testing has been done, and the dosing will be adjusted if the patient is a poor metabolizer.</li> <li>For Excessive Daytime Sleepiness (EDS) the following is required: <ul> <li>Documentation of fatigue severity using a validated measure</li> <li>(e.g. Epworth score, Brief Fatigue Inventory, or other validated measure</li> <li>Trial and failure or contraindication to ALL the following:</li> <li>Modafinil (at least 200mg dose) AND armodafinil</li> <li>Mixed amphetamine salts, methylphenidate or dexmethylphenidate, AND dextroamphetamine</li> <li>Sunosi (solriamfetol)</li> <li>A sodium oxybate product</li> </ul> </li> <li>For Cataplexy the following is required: <ul> <li>Diagnosis of Cataplexy confirmed by a specialist.</li> <li>Trial and failure or contraindication to ALL the following:</li> <li>SSRI antidepressant (e.g. fluoxetine)</li> <li>SNRI antidepressant (e.g. clomipramine)</li> <li>Sodium oxybate product titrated to maximally tolerated dose.</li> </ul> </li> </ul>
Age Restrictions	18 years of age and older
Exclusions	<ul> <li>Severe renal or hepatic impairment</li> <li>Pregnant or actively trying to conceive</li> </ul>
Prescriber Restrictions	Prescribed by Sleep Specialist or Neurologist
Coverage Duration	Initial: 3 months. Renewal: 6 months
Renewal Criteria	Documentation of positive clinical response to therapy.

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

# Pramlintide Acetate (SYMLIN)

### **Products Affected**

• SYMLINPEN 60

• SYMLINPEN 120

	Oritoria Dataila
	Criteria Details Coverage is provided for the use of pramlintide as an adjunct treatment
Required Medical Information	<ul> <li>in type 1 and type 2 diabetic patients 18 or older who use mealtime insulin therapy AND who meet all of the following criteria: <ul> <li>Are currently on mealtime insulin.</li> <li>Have an HbA1c less than or equal to 9%.</li> </ul> </li> <li>Are monitoring blood glucose levels regularly AND reliably (3 or more times per day).</li> <li>Are capable of monitoring blood glucose levels pre- AND postmeals AND at bedtime.</li> <li>Have failed to achieve adequate control of blood glucose levels despite individualized management of their insulin therapy.</li> </ul> Are receiving ongoing care under the guidance of a health care provider skilled in use of insulin AND supported by the services of a diabetes educator.
Age Restrictions	Patient must be 18 years or older.
Prescriber Restrictions	
Coverage Duration	Initial: 12 months. Renewal: 12 months.
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

# Priftin (rifapentine)

### **Products Affected**

• Priftin

	Criteria Details
Required Medical Information	<ul> <li>Latent tuberculosis:         <ul> <li>Used in combination with isoniazid</li> </ul> </li> <li>Active tuberculosis:         <ul> <li>One of the following:                 <ul> <li>The member does NOT have multidrug resistant disease</li> <li>The member has multidrug resistant disease and the drug is prescribed by or in consultation with infectious disease specialist.                     <ul> <li>Priftin will be used as part of multi-drug regimen</li> <li>The drug will NOT be prescribed by a county clinic with a state funded TB program(for these programs the drug is funded directly through the state).</li> </ul> </li> </ul> </li> </ul></li></ul>
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Latent TB Initial: 3 months. Renewal: N/A Active TB Initial: 6 months. Renewal: N/A
Renewal Criteria	
Effective Date	5/1/2024
P&T Approval Date	3/12/2024
P&T Revision Date	3/12/2024

# Ranolazine (RANEXA)

### **Products Affected**

• RANOLAZINE ER

	Criteria Details
Required Medical Information	Diagnosis of chronic angina not controlled with other antianginal therapy. May be used with beta-blockers, nitrates, calcium channel blockers, anti-platelet therapy, lipid-lowering therapy, ACE inhibitors, and angiotensin receptor blockers.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 12 months. Renewal: 12 months.
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

# **Resmetirom (REZDIFFRA)**

### **Products Affected**

• Rezdiffra 60MG/80MG/100MG TAB

	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>FibroScan</li> <li>FibroScan</li> <li>Submission of medical records (FIB-4)</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 used as an adjunct to lifestyle modification (e.g., dietary or</li> </ul>
	caloric restriction, exercise, behavioral support, community based program)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by 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

Criteria Details	
	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	7/1/2024
P&T Approval Date	5/14/2024
P&T Revision Date	

# **Ribavirin (VIRAZOLE)**

### **Products Affected**

• **RIBAVIRIN INHALATION** 

Criteria Details	
Required Medical Information	<b>Respiratory Syncytial Virus (RSV) Infection:</b> Chart notes / written medical summary documenting diagnosis of RSV.
Age Restrictions	
Prescriber Restrictions	Request is initiated by an infectious disease specialist.
Coverage Duration	Initial: 3 months.
Renewal Criteria	
Effective Date	
P&T Approval Date	
P&T Revision Date	

# **Ribociclib Succinate (KISQALI)**

### **Products Affected**

#### • KISQALI

	Criteria Details
Required Medical Information	<b>Breast Cancer in Women:</b> Has recurrent or metastatic disease <b>AND</b> has hormone receptor positive (HR+) <b>AND</b> has human epidermal growth factor receptor 2 (HER2)-negative breast cancer <b>AND</b> is either post- menopausal <b>OR</b> is pre/perimenopausal <b>AND</b> is receiving gonadotropin- releasing hormone agonist <b>OR</b> has had bilateral oophorectomy or ovarian irradiation <b>AND</b> medication will be used in combination with anastrozole, exemestane, or letrozole <b>OR w</b> ill be used in combination with fulvestrant.
	<b>Breast Cancer in Men:</b> Has recurrent or metastatic disease <b>AND</b> has hormone receptor positive (HR+) <b>AND</b> has human epidermal growth factor receptor 2 (HER2)-negative breast cancer <b>AND</b> is receiving gonadotropin-releasing hormone analog <b>AND</b> medication will be used in combination with anastrozole, exemestane, or letrozole <b>OR</b> will be used in combination with fulvestrant.
Age Restrictions	At least 18 years of age
Prescriber Restrictions	Prescribed by or in consultations with an oncologist
Coverage Duration	Initial: 3 months. Renewal: 3 months.
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

# **Rifaximin (XIFAXAN)**

### **Products Affected**

• XIFAXAN

	Critorio Dotoilo
	Criteria Details IBS-D: Diagnosis of IBS with diarrhea
Required Medical Information	Hepatic Encephalopathy: must have one of the following: used as add-on therapy to lactulose AND unable to achieve an optimal clinical response with lactulose monotherapy OR a history of contraindication or intolerance to lactulose.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	<b>IBS-D Initial</b> : 14 Days. <b>Renewal</b> : 30 Days. <b>HE Initial</b> : 12 months. <b>Renewal</b> : 12 months.
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

# **Rimegepant (NURTEC)**

### **Products Affected**

#### NURTEC ODT

Criteria Details	
Required Medical Information	Acute treatment: Diagnosis of migraine with or without aura AND will be used for the acute treatment of migraine AND patient has fewer than 15 headache days per month AND trial and failure or intolerance to 3 generic triptans or contraindications to all triptans and NSAID combined treatment OR trial and failure or intolerance to NSAID treatment alone if triptans contraindicated OR contraindication to all triptans and NSAIDs AND medication will not be used in combination with another CGRP inhibitor AND if patient has 4 or more headache days per month, then patient must currently be treated with amitriptyline, venlafaxine, divalproex, topiramate, candesartan or a beta-blocker or have a contraindication or intolerance to all of these medications. Prophylaxis treatment: Diagnosis of episodic migraines AND patient has 4 to 18 migraine days per month but no more than 18 headache days per month AND trial and failure of at least 2 months intolerance or contraindication of two of the following sets: 1) amitriptyline or venlafaxine; 2) divalproex or topiramate; 3) one of the following beta blocker: atenolol, propranolol, nadolol, timolol, or metoprolol; 4) candesartan AND not used in combination with another CGRP inhibitor.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, pain specialist, or headache specialist
Coverage Duration	<b>Acute Initial</b> : 3 months; <b>Renewal</b> : 12 months <b>Prophylaxis Initial</b> : 6 months; <b>Renewal</b> 12 months
Renewal Criteria	Documentation of positive clinical response to therapy
Effective Date	

Criteria Details	
P&T Approval Date	
P&T Revision Date	

# Risankizumab (SKYRIZI)

### **Products Affected**

• SKYRIZI

Criteria Details	
	<b>Plaque Psoriasis (PsO):</b> Diagnosis of moderate to severe chronic plaque psoriasis with one of the following: 1) greater than or equal to 3% body surface area involvement, 2) severe scalp psoriasis, 3) palmoplantar, facial, or genital involvement <b>AND</b> a minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids, vitamin D analogs, tazarotene, calcineurin inhibitors, anthralin, coal tar.
	<b>Psoriatic Arthritis (PsA):</b> Diagnosis of active PsA with one of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, active skin and/or nail involvement.
Required Medical Information	<b>Crohn's disease (CD):</b> Diagnosis of moderately to severely active Crohn's disease with one of the following: 1) frequent diarrhea and abdominal pain, 2) at least 10% weight loss, 3) complications such as obstruction, fever, abdominal mass, 4) abnormal lab values (e.g. C-reactive protein), CD Activity Index greater than 220 <b>AND</b> trial and failure, contraindication, or intolerance to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroids (e.g., prednisone, methylprednisolone), methotrexate.*induction dose is IV, maintenance is subcutaneous.
	<b>Ulcerative Colitis (UC):</b> Diagnosis of moderately to severely active ulcerative colitis with one of the following: 1) greater than 6 stools per day, 2) frequent blood in the stools, 3) frequent urgency, 4) presence of ulcers, 5) abnormal lab values (e.g., hemoglobin, erythrocyte sedimentation rate, C-reactive protein), 6) dependent on, or refractory to, corticosteroids. <b>AND</b> trial and failure, contraindication, or intolerance to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroids (e.g., prednisone, methylprednisolone), aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine). *induction dose is IV. maintenance is subcutaneous.

Criteria Details	
Age Restrictions	
Prescriber Restrictions	<b>PsA:</b> Prescribed by or in consultation with one of the following: Dermatologist or Rheumatologist. <b>CD/UC:</b> Prescribed by or in consultation with a gastroenterologist <b>PsO:</b> Prescribed by or in consultation with a dermatologist
Coverage Duration	Initial: 6 months. Renewal: 12 months
Renewal Criteria	<ul> <li>Ps0: Documentation of positive clinical response to therapy as evidenced by ONE of the following: Reduction in the body surface area (BSA) involvement from baseline OR improvement in symptoms (e.g., pruritus, inflammation) from baseline.</li> <li>PsA: Documentation of a positive clinical response to therapy as evidenced by one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline, or reduction in the body surface area (BSA) involvement from baseline, or reduction in the body surface area (BSA) involvement from baseline.</li> <li>CD/UC: Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, or reversal of high fecal output state.</li> </ul>
Effective Date	10/1/2024
P&T Approval Date	
P&T Revision Date	7/9/2024

# Risdiplam (EVRYSDI)

### **Products Affected**

• EVRYSDI SOL 0.75MG/ML

Criteria Details	
Required Medical Information	<ul> <li>Spinal Muscular Atrophy (SMA):</li> <li>Confirmed (via genetic testing) diagnosis of 5q-autosomal recessive SMA (type 1, 2 or 3)</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	09/01/2023
P&T Approval Date	7/11/2023
P&T Revision Date	

# Sacubitril/Valsartan (ENTRESTO)

### Products Affected

#### • ENTRESO

	Critorio Dotoilo
Required Medical Information	Criteria Details The patient has a diagnosis of New York Heart Association class II to IV heart failure AND patient is receiving concomitant therapy with one of the following beta blockers: carvedilol, bisoprolol, sustained-released metoprolol, unless unable to tolerate or contraindicated AND 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	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

# Sargramostin (LEUKINE)

### **Products Affected**

#### • LEUKINE

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).
	<b>Bone marrow transplant (allogeneic or autologous):</b> For graft failure or engraftment delay.
	<b>Myeloid reconstitution after allogeneic bone marrow transplantation:</b> 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.
	<b>Peripheral stem cell transplantation:</b> Mobilization of hematopoietic progenitor cells for leukapheresis <b>AND</b> 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 specialist.
Coverage Duration	Initial: 12 months. Renewal: 12 months.
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	

Criteria Details	
P&T Approval Date	
P&T Revision Date	

# Secukinumab (COSENTYX)

#### **Products Affected**

• COSENTYX (200 MG DOSE)

• COSENTYX SENSOREADY (300 MG)

Criteria Details	
	<b>All:</b> patient has a negative tuberculin test (TB) prior to initiating therapy.
Required Medical Information	<ul> <li>PP: Patient has documented diagnosis of moderate to severe plaque psoriasis for at least 6 months with at least one of the following: incapacitation due to plaque locations (e.g., head and neck, palms, soles, or genitalia), OR involvement of at least 10% of body surface area (BSA) OR psoriasis area AND severity index (PASI) score of 12 or greater, AND patient is free of any clinically important active infections, AND patient did not respond adequately (or is not a candidate) to a 3-month trial of at least 1 systemic agent AND patient did not respond adequately (or is not a candidate) to a 3-month trial of at least 1 systemic agent AND patient did not respond adequately (or is not a candidate) to a 3 month trial of phototherapy AND patient has had a trial AND failure of adalimumab AND Enbrel with clinical documentation.</li> <li>PA: Patient has active psoriatic arthritis for at least 6 months defined as: greater than 3 swollen joints AND greater than 3 tender joints AND patient has had an inadequate response, intolerance or contraindication (clinical documentation required) with the following, one or more nonsteroidal anti-inflammatory drugs (NSAIDS) trialed at a max dose for at least 2 weeks AND one or more non-biologic disease modifying anti-</li> </ul>
	rheumatic drugs <b>AND</b> patient has had a trial <b>AND</b> failure of adalimumab OR Xeljanz OR Orencia.
	<b>AS</b> : Patient has had an inadequate response, intolerance or contraindication with the following, one or more non-steroidal anti-inflammatory drugs (NSAIDS) trialed at a max dose for at least 2 weeks <b>OR</b> analgesic agents if NSAIDs do not control pain OR sulfasalazine (if peripheral joint involvement is present).
	<ul> <li>Hidradenitis Suppurativa (HS):</li> <li>Documentation of one of the following:</li> <li>Moderate to severe hidradenitis suppurative (Hurley Stage II or</li> </ul>

	Criteria Details
	<ul> <li>Hurley Stage III)</li> <li>Patient is on a current biologic product and experiencing intolerable side effects.</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> <li>Trial and failure of both infliximab and adalimumab</li> </ul> </li> </ul>
Age Restrictions	Patient must be 18 years or older.
Prescriber Restrictions	
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	

## Seladelpar (LIVDELZI)

### **Products Affected**

• Livdelzi Capsules

	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>Documentation of at least 12 months of inadequate response to ursodiol</li> <li>No current decompensated cirrhosis</li> </ul>
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a hepatologist or gastroenterologist
Coverage Duration	Initial: 6 months. Renewal: up to 12 months.
Renewal Criteria	Documented adherence to medication regimen and clinical benefit
Effective Date	01/01/2025
P&T Approval Date	11/12/2024
P&T Revision Date	11/12/2024

## Semaglutide (WEYGOVY)

#### **Products Affected**

• Weygovy

	Criteria Details
Required Medical Information	<ul> <li>Reduction of Major Adverse Cardiovascular Events <ul> <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 aterial 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> </ul> </li> </ul>
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Renewal Criteria	<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>
Effective Date	7/1/2024
P&T Approval Date	5/14/2024

Criteria Details	
P&T Revision Date	

## Sildenafil Citrate (REVATIO)

#### **Products Affected**

• SILDENAFIL CITRATE INTRAVENOUS

SILDENAFIL CITRATE ORAL TABLET

 SILDENAFIL CITRATE ORAL SUSPENSION RECONSTITUTED

Criteria Details	
Required Medical Information	Clinical diagnosis of pulmonary arterial hypertension (PAH).
Age Restrictions	<ul> <li>Solution only</li> <li>One of the following: <ul> <li>Pediatric member age 10 or under</li> <li>Documentation inability of the member to use the preferred tablet formulation</li> </ul> </li> </ul>
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist.
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	3/12/2024

### Somatropins

#### **Products Affected**

- **GENOTROPIN**
- **GENOTROPIN MINIQUICK**
- HUMATROPE
- NORDITROPIN FLEXPRO
- NUTROPIN AQ NUSPIN 10
- NUTROPIN AQ NUSPIN 20

- NUTROPIN AQ NUSPIN 5
- OMNITROPE
- SAIZEN
- SAIZENPREP
- SEROSTIM
- ZORBTIVE

	Criteria Details
Required Medical Information	<b>For children:</b> Growth hormone deficiency in individuals less than 16 years of age or radiographic evidence of non-closure of epiphyseal plates. Appropriate medical work up: Assessment <b>AND</b> evaluation must indicate absolute growth less than 4.5 cm per year without growth hormone. Subnormal growth, greater than or equal to 2 standard deviations below the mean for age.
	<b>For adults:</b> Biochemical diagnosis of adult growth hormone deficiency by means of a subnormal response to a standard growth hormone stimulation test (peak growth hormone Less than or equal to 5 mcg/L). Confirmatory testing may not be required in patients with congenital/genetic growth hormone deficiency or multiple pituitary hormone deficiencies due to organic diseases.
	<b>Adult-onset:</b> Patients who have adult growth hormone deficiency whether alone or with multiple hormone deficiencies (hypopituitarism) as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma. Turners Syndrome in females is an approved indication.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 12 months. Renewal: 12 months.

Criteria Details	
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

### Sotatercept (WINREVAIR)

#### **Products Affected**

#### • WINREVAIR INJECTION

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	Documentation of positive clinical response to therapy.
Effective Date	11/1/2024
P&T Approval Date	9/10/2024
P&T Revision Date	9/10/2024

## Sotorasib (LUMAKRAS)

#### **Products Affected**

#### • LUMAKRAS

Criteria Details	
Required Medical Information	Trial and failure of at least one prior systemic therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	Initial: 3 months. Renewal: 3 months.
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

### Sparsentan (FILSPARI)

#### **Products Affected**

• FILSPARI TAB 200MG

• FILSPARI TAB 400MG

	Criteria Details
Required Medical Information	<ul> <li>Primary immunoglobulin A nephropathy:</li> <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>
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	09/01/2023
P&T Approval Date	7/11/2023
P&T Revision Date	

## **Tacrolimus (PROTOPIC)**

#### **Products Affected**

• TACROLIMUS EXTERNAL

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

## Tadalafil (ADCIRCA)

#### **Products Affected**

• TADALAFIL (PAH)

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	Documentation of positive response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

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

### Products Affected

• TAZAROTENE 0.1% CREAM

	Criteria Details
Required Medical Information	<ul> <li>Psoriasis: diagnosis of moderate to severe Psoriasis (10% BSA, hand, foot or mucous membrane involvement AND functional impairment) AND trial and failure of high potency topical corticosteroids or medical reason why they would be inappropriate</li> <li>Other FDA approved indications (i.e., severe acne): trial and failure/contraindication to two formulary alternatives used to treat the approved indication.</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	
P&T Approval Date	
P&T Revision Date	

### **Tenapanor (XPHOZA)**

#### **Products Affected**

• XPHOZA 20MG

• XPHOZA 30MG

	Criteria Details
Required Medical Information	<ul> <li>Add on therapy for hyperphosphatemia in chronic kidney disease, on chronic hemodialysis:         <ul> <li>On chronic maintenance hemodialysis 3x per week for at least 3 months or chronic peritoneal dialysis for a minimum of 6 months</li> <li>Other contributing factors for hyperphosphatemia have been addressed:                 <ul> <li>On a stable dose of calcimimetic or active vitamin D for at least 4 weeks</li> <li>Serum parathyroid hormone is &lt;1200 pg/mL</li> <li>Dietary restrictions are in place to limit phosphate intake</li> <li>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)</li> <li>Medication will be used as add-on therapy with phosphate binder treatment</li> </ul> </li> </ul> </li> </ul>
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	

### **Tepotinib (TEPMETKO)**

#### **Products Affected**

#### • TEPMETKO

	Criteria Details
Required Medical Information	Diagnosis of NSCLC containing MET exon 14-skipping alterations <b>AND</b> no EGFR-activating mutations predictive of sensitivity to anti-EGFR therapy <b>AND</b> no ALK rearrangements predictive of sensitivity to anti-ALK therapy <b>AND</b> Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. <b>Maximum daily dose of 2 tablets</b>
Ago Dostrictiono	
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by oncologist
Coverage Duration	Initial: 3 months. Renewal: up to 12 months.
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

# **Terbinafine Hydrochloride (LAMISIL)**

#### **Products Affected**

• TERBINAFINE HCL

	Criteria Details
Required Medical Information	For the treatment of onychomycosis of the toenail or fingernail due to dermatophytes (tinea unguium) <b>AND</b> 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 diseas, <b>OR</b> patient is immunocompromised.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 3 months. Renewal: 3 months.
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

## **Tezacaftor/ivacaftor (SYMDEKO)**

#### **Products Affected**

• SYMDEKO

	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	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

### Ticagrelor (BRILINTA)

#### **Products Affected**

• BRILINTA 60MG

• BRILINTA 90MG

	Criteria Details
Required Medical Information	<ul> <li>Acute Coronary Syndrome</li> <li>Patient has acute coronary syndrome (ACS)         <ul> <li>Either NSTE-ACS or STEMI and has had a coronary stent implanted OR</li> <li>Patient has NSTE-ACS and is treated with medical therapy alone (i.e., has not had revascularization)?</li> </ul> </li> </ul>
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	09/01/2023
P&T Approval Date	7/11/2023
P&T Revision Date	

### Tranexamic Acid

#### **Products Affected**

Tranexamic Acid 650MG TAB

	Criteria Details
	<ul> <li>Hemophilia Diagnosis</li> <li>Intending to use for hemorrhage prophylaxis for tooth extraction(s)</li> </ul>
Required Medical Information	<ul> <li>Abnormal Uterine Bleeding         <ul> <li>Currently using or documented trial and failure or contradiction to ALL the following treatments:                 <ul> <li>Cobombined Oral Contraceptive therapy</li> <li>Profestin therapy (oral or LM) or Levonogrestrel IUD</li> <li>NSAID therapy</li> </ul> </li> </ul> </li> </ul>
Age Restrictions	
Prescriber Restrictions	Prescribed by Hematologist, Hemophilia specialist, Dentist, Gynecologist
<b>Coverage Duration</b>	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	

# Tivozanib (FOTIVDA)

#### **Products Affected**

#### • FOTIVDA

	Criteria Details
Required Medical Information	Diagnosis of metastatic renal cell carcinoma <b>AND</b> tried and failed at least two systemic therapies with at least one including a VEGF-TKI <b>AND</b> Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 <b>AND</b> maximum monthly dose of 21 per 28 days
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by oncologist
Coverage Duration	Initial: 3 months. Renewal: up to 12 months.
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

### **Tobramycin Solution**

#### **Products Affected**

• Tobramycin nebulization solution

	Criteria Details
Required Medical Information	Use must be for cystic fibrosis or any FDA-approved or compendia supported indication.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist, pulmonologist, or cystic fibrosis specialist
Coverage Duration	Cystic Fibrosis: Lifetime Other diagnoses: Initial: 3 months; Renewal: 12 months
Renewal Criteria	Confirmed diagnosis with clinical evidence supporting chronic use
Effective Date	01/01/2025
P&T Approval Date	11/12/2024
P&T Revision Date	11/12/2024

### Tocilizumab SC (ACTEMRA)

#### **Products Affected**

- ACTEMRA INJ PF syringe
- TYENNE INJ PF syringe
- TYENNE INJ AUTO-Inj

- TYENNE IV
- ACTEMRA INJ ACTPEN

Criteria Details	
Required Medical Information	<b>Rheumatoid Arthritis (RA):</b> Diagnosis of moderately to severely active rheumatoid arthritis <b>AND</b> trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine <b>AND</b> trial and failure, contraindication, or intolerance to <b>TWO</b> of the following, or attestation demonstrating a trial may be inappropriate: Cimzia (certolizumab pegol), Enbrel (etanercept), adalimumab, Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/XR (tofacitinib/ER).
	<b>Systemic Juvenile Idiopathic Arthritis (SJIA):</b> Diagnosis of active systemic juvenile idiopathic arthritis <b>AND</b> trial and failure, contraindication, or intolerance to <b>ONE</b> of the following: Non-steroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, naproxen), Systemic glucocorticoid (e.g., prednisone), methotrexate.
	<b>Polyarticular Juvenile Idiopathic Arthritis (PJIA):</b> Diagnosis of active polyarticular juvenile idiopathic arthritis <b>AND</b> trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, <b>AND</b> trial and failure, contraindication, or intolerance to two of the following, or attestation demonstrating a trial may be inappropriate: Enbrel (etanercept), adalimumab, Xeljanz (tofacitinib).
	<b>Giant Cell Arteritis (GCA):</b> Diagnosis of giant cell arteritis <b>AND</b> trial and failure, contraindication, or intolerance to a glucocorticoid.
	<b>Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD):</b> Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) as documented by the following: exclusion of other known causes of

Criteria Details	
	interstitial lung disease (ILD) (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity) <b>AND</b> one of the following: In patients not subjected to surgical lung biopsy, the presence of idiopathic interstitial pneumonia (e.g., fibrotic nonspecific interstitial pneumonia [NSIP], usual interstitial pneumonia [UIP] <b>AND</b> centrilobular fibrosis) pattern on high-resolution computed tomography (HRCT) revealing SSc-ILD or probable SSc-ILD OR In patients subjected to a lung biopsy, both HRCT <b>AND</b> surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD.
	<b>Cytokine Release Syndrome (CRS) Risk due to CAR T-Cell Therapy:</b> Patient will receive or is receiving chimeric antigen receptor (CAR) T-cell immunotherapy (i.e., Kymriah [tisagenlecleucel], Yescarta [axicabtagene ciloleucel])
Age Restrictions	
Prescriber Restrictions	<ul> <li>RA, SJIA, PJIA, GCA: Prescribed by or in consultation with a rheumatologist.</li> <li>SSc-ILD: Prescribed by or in consultation with a pulmonologist or rheumatologist.</li> <li>CRS: Prescribed by or in consultation with an oncologist or hematologist</li> </ul>
Coverage Duration	RA, SJIA, PJIA, GCA, SSc-ILD: Initial: 6 months; Renewal: 12 months Cytokine Release Syndrome (CRS) Risk due to CAR T-Cell Therapy: Initial: 2 months.
	<ul> <li>RA, PJIA: Documentation of a positive clinical response to therapy as evidenced by one of the following: reduction in the total active (swollen AND tender) joint count from baseline, or improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline.</li> <li>SIIA: Documentation of a positive clinical response to therapy as</li> </ul>
Renewal Criteria	<ul> <li>SJIA: Documentation of a positive clinical response to therapy as evidenced by one of the following: reduction in the total active (swollen AND tender) joint count from baseline, or improvement in clinical features or symptoms (e.g., pain, fever, inflammation, rash, lymphadenopathy, serositis) from baseline.</li> <li>GCA, SSc-ILD: Documentation of positive clinical response to therapy.</li> </ul>
Effective Date	9/1/2024
P&T Approval Date	
P&T Revision Date	7/9/2024

### Tofacitinib (XELJANZ)

#### **Products Affected**

• XELJANZ

• XELJANZ XR

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	<b>Rheumatoid Arthritis (RA):</b> Diagnosis of moderately to severely active rheumatoid arthritis <b>AND</b> trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine <b>AND</b> patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia, adalimumab, Simponi) <b>AND</b> patient will not be taking Xeljanz in combination with a potent immunosuppressant (e.g azathioprine or cyclosporine).
Required Medical Information	<b>Psoriatic Arthritis (PsA):</b> Diagnosis of active psoriatic arthritis with one of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, active skin and/or nail involvement <b>AND</b> trial and failure, contraindication, or intolerance to one or more TNF inhibitors (e.g. Cimzia, Enbrel, adalimumab, Simponi) <b>AND</b> patient is will not be taking Xeljanz in combination with a potent immunosuppressant (e.g azathioprine or cyclosporine).
mormation	<b>Ankylosing Spondylitis (AS):</b> Diagnosis of active ankylosing spondylitis <b>AND</b> minimum duration of one month trial and failure, contraindication, or intolerance to <b>TWO</b> non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., diclofenac, ibuprofen, indomethacin, meloxicam, naproxen) AND Trial and failure, contraindication, or intolerance to one or more TNF inhibitors (e.g. Cimzia, Enbrel, adalimumab, Simponi) <b>AND</b> patient will not be taking Xeljanz in combination with a potent immunosuppressant (e.g azathioprine or cyclosporine).
	<b>Ulcerative Colitis (UC):</b> Diagnosis of moderately to severely active ulcerative colitis with one of the following: 1) Greater than 6 stools per day, 2) frequent blood in the stools, 3) frequent urgency, 4) presence of ulcers, 5) abnormal lab values (e.g. hemoglobin, ESR, CRP), 6) dependent on, or refractory to, corticosteroids. AND trial and failure, contraindication, or intolerance to one of the following conventional

	Criteria Details
	therapies: 6-mercaptopurine, aminosalicylate [e.g., mesalamine sulfasalazine, azathioprine, Corticosteroids (e.g., prednisone, methylprednisolone) <b>AND</b> trial and failure, contraindication, or intolerance to one or more TNF inhibitors (e.g. adalimumab, Simponi) <b>AND</b> patient will not be taking Xeljanz in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine).
	<b>Polyarticular Juvenile Idiopathic Arthritis (PJIA):</b> Diagnosis of active polyarticular course juvenile idiopathic arthritis <b>AND</b> trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide <b>AND</b> trial and failure, contraindication, or intolerance to one or more TNF inhibitors (e.g. Enbrel, adalimumab) <b>AND</b> patient will not be taking Xeljanz in combination with a potent immunosuppressant (e.g azathioprine or cyclosporine).
Age Restrictions	<ul> <li>Solution only</li> <li>One of the following:</li> <li>Pediatric member age 10 or under</li> <li>Documentation inability of the member to use the preferred tablet formulation</li> </ul>
Prescriber Restrictions	<ul> <li>RA, AS, PJIA: Prescribed by or in consultation with a rheumatologist</li> <li>PsA: Prescribed by or in consultation with a dermatologist or</li> <li>rheumatologist</li> <li>UC: Prescribed by or in consultation with a gastroenterologist</li> </ul>
Coverage Duration	RA, PsA, AS, PJIA: Initial: 6 months. Renewal 12 months Ulcerative Colitis (UC): Initial: 4 months. Renewal 12 months
Ponowal Critaria	<b>RA, PJIA:</b> Documentation of a positive clinical response to therapy as evidenced by one of the following: reduction in the total active (swollen and tender) joint count from baseline, or improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline <b>AND</b> will not be used in combination with biologic DMARDs or potent immunosuppressants (e.g., azathioprine or cyclosporine).
Renewal Criteria	<b>PsA:</b> Documentation of a positive clinical response to therapy as evidenced by one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline, or reduction in the body surface area (BSA) involvement from baseline <b>AND</b> will not be used in combination with biologic DMARDs or potent immunosuppressants (e.g., azathioprine or cyclosporine).

	Criteria Details
	<b>AS:</b> Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following: disease activity (e.g., pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (e.g., lumbar spine motion, chest expansion), or total active (swollen and tender) joint count. AND will not be used in combination with biologic DMARDs or potent immunosuppressants (e.g., azathioprine or cyclosporine).
	<b>UC:</b> Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, or reversal of high fecal output state <b>AND</b> will not be used in combination with biologic DMARDs or potent immunosuppressants (e.g., azathioprine or cyclosporine).
Effective Date	5/1/2024
P&T Approval Date	3/12/2024
P&T Revision Date	3/12/2024

# **Treprostinil (ORENITRAM)**

#### **Products Affected**

#### ORENITRAM

	Criteria Details
Required Medical Information	Confirmed diagnosis of pulmonary arterial hypertension with right heart catheterization <b>AND</b> 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.
<b>Coverage Duration</b>	Initial: 12 months. Renewal: 12 months.
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

# **Treprostinil (REMODULIN)**

#### **Products Affected**

TREPROSTINIL

Required Medical Information	<b>Criteria Details</b> Confirmed diagnosis of pulmonary arterial hypertension with right heart catheterization <b>AND</b> 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	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

### **Treprostinil (TYVASO)**

#### **Products Affected**

• TYVASO

• TYVASO STARTER

• TYVASO REFILL

Criteria Details				
Required Medical	Confirmed diagnosis of pulmonary hypertension associated with interstitial lung disease (WHO Group 3).			
Information	*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.			
<b>Coverage Duration</b>	Initial: 12 months. Renewal: 12 months.			
Renewal Criteria	Documentation of positive clinical response to therapy.			
Effective Date				
P&T Approval Date				
P&T Revision Date				

### Ubrogepant (UBRELVY)

#### **Products Affected**

#### • UBRELVY

	Criteria Details
Required Medical Information	Diagnosis of migraine with or without aura <b>AND</b> will be used for the acute treatment of migraine <b>AND</b> patient has fewer than 15 headache days per month <b>AND</b> trial and failure or intolerance to 3 generic triptans and NSAID (ibuprofen, naproxen, diclofenac) combined treatment <b>OR</b> trial and failure or intolerance to NSAID treatment alone if triptans contraindicated <b>OR</b> contraindication to all triptans and NSAIDs <b>AND</b> medication will not be used in combination with another CGRP inhibitor <b>AND</b> if patient has 4 or more headache days per month, then patient must currently be treated with amitriptyline, venlafaxine, divalproex, topiramate, candesartan or a beta-blocker or have a contraindication or intolerance to all of these medications.
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with one of the following specialists: Neurologist, pain specialist, headache specialist
Coverage Duration	Initial: 3 months Renewal: 12 months
Renewal Criteria	Documentation of positive clinical response to therapy and will not be used for preventative treatment of migraine.
Effective Date	
P&T Approval Date	
P&T Revision Date	

## Umbralisib (UKONIQ)

#### **Products Affected**

• Ukoniq

	Criteria Details
Required Medical Information	<b>Marginal zone lymphoma (MZL):</b> Diagnosis of relapsed or refractory marginal zone lymphoma (MZL) <b>AND</b> must have received a prior therapy that included an anti-CD20 antibody agent
information	Follicular lymphoma (FL): Must have received at least three prior therapies, including both an anti-CD20 antibody AND an alkylating agent *Maximum daily dose of 4 tablets
Age Restrictions	18 years of age AND older
Prescriber Restrictions	Prescribed by oncologist
Coverage Duration	Initial: 3 months. Renewal: up to 12 months.
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

### Upadacitinib (RINVOQ)

#### **Products Affected**

• RINVOQ TABLETS

• RINVOQ LQ SOLUTION

	<b>Rheumatoid Arthritis (RA):</b> Diagnosis of moderately to severely active rheumatoid arthritis <b>AND</b> trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine <b>AND</b> trial and failure, contraindication, or intolerance to one or more TNF inhibitors (e.g. Cimzia, Enbrel, adalimumab, Simponi) <b>AND</b> not used in combination with other Janus kinase (JAK) inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine).
Required Medical Information	<b>Psoriatic Arthritis (PsA):</b> Diagnosis of active psoriatic arthritis with one of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, active skin and/or nail involvement <b>AND</b> trial and failure, contraindication, or intolerance to one or more TNF inhibitors (e.g. Cimzia, Enbrel, adalimumab, Simponi) <b>AND</b> not used in combination with other Janus kinase (JAK) inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine).
	<b>Ankylosing spondylitis (AS):</b> Diagnosis of active ankylosing spondylitis minimum duration of one month trial and failure, contraindication, or intolerance to two different nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., diclofenac, ibuprofen, indomethacin, meloxicam, naproxen). AND trial and failure, contraindication, or intolerance to one or more TNF inhibitors (e.g. Cimzia, Enbrel, adalimumab, Simponi) <b>AND</b> not used in combination with other Janus kinase (JAK) inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine).
	Atopic Dermatitis (AD): Diagnosis of moderate to severe atopic dermatitis AND one of the following: Involvement of at least 10% body surface area (BSA), SCORing Atopic Dermatitis (SCORAD) index value of at least 25 AND a minimum duration of a 30-day trial and failure, contraindication, or intolerance to at least one of the following: Medium

Criteria Details			
or higher potency topical corticosteroid, Pimecrolimus cream, Tacrolimus ointment, or Eucrisa (crisaborole) ointment <b>AND</b> a minimu duration of 12-week trial and failure, contraindication, or intolerance of least one systemic drug for the treatment of AD (e.g. Dupixent) <b>AND</b> n used in combination with other Janus kinase (JAK) inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine).			
	<b>Crohn's disease (CD):</b> Diagnosis of moderately to severely active Crohn's disease with one of the following: 1) frequent diarrhea and abdominal pain, 2) at least 10% weight loss, 3) complications such as obstruction, fever, abdominal mass, 4) abnormal lab values (e.g. C-reactive protein), CD Activity Index greater than 220 <b>AND</b> trial and failure, contraindication, or intolerance to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroids (e.g., prednisone, methylprednisolone), methotrexate <b>AND</b> trial and failure, contraindication, or intolerance to one or more TNF inhibitors (e.g. adalimumab, Simponi) <b>AND</b> not used in combination with other Janus kinase (JAK) inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine).		
Age Restrictions	AD: Age 12 or older		
Prescriber Restrictions	<ul> <li>RA, AS: Prescribed by or in consultation with a rheumatologist</li> <li>PsA: Prescribed by or in consultation with one of the following:</li> <li>Dermatologist or Rheumatologist.</li> <li>AD: Prescribed by or in consultation with one of the following:</li> <li>Dermatologist or Allergist/Immunologist.</li> <li>UC: Prescribed by or in consultation with a gastroenterologist</li> </ul>		
Coverage Duration	Initial: 6 months. Renewal: 12 months		
Renewal Criteria	<b>RA:</b> Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in total active joint count, improvement in symptoms (e.g., improvement in number of swollen/tender joints, pain, or stiffness). AND Rinvoq will not be used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine).		
	<b>PsA:</b> Documentation of positive clinical response to therapy as evidenced by one of the following: Reduction in BSA from baseline, reduction in total active joint count, improvement in symptoms(e.g., improvement in number of swollen/tender joints, pain, or stiffness) <b>AND</b> Rinvoq will not be used in combination with other JAK inhibitors, biologic		

	Criteria Details
	DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine).
	<b>AS:</b> Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following: disease activity (e.g., pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (e.g., lumbar spine motion, chest expansion), or total active (swollen and tender) joint count <b>AND</b> Rinvoq will not be used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine).
	<b>AD:</b> Documentation of a positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, or reduction in SCORing Atopic Dermatitis (SCORAD) index value from baseline <b>AND</b> Rinvoq will not be used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine).
	<b>UC:</b> Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, or reversal of high fecal output state <b>AND</b> Rinvoq will not be used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine).
Effective Date	
P&T Approval Date	
P&T Revision Date	

### Ustekinumab (STELARA)

#### **Products Affected**

#### • STELARA

Criteria Details	
Required Medical Information	<b>Plaque Psoriasis (Ps0):</b> Diagnosis of moderate to severe chronic plaque psoriasis with one of the following: 1) greater than or equal to 3% body surface area involvement, 2) severe scalp psoriasis, 3) palmoplantar, facial, or genital involvement <b>AND</b> a minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids, vitamin D analogs, tazarotene, calcineurin inhibitors, anthralin, coal tar. For Stelara SC 90mg/1 mL: patient weight is greater than 100 kg (220 lbs).
	<b>Psoriatic Arthritis (PsA):</b> Diagnosis of active psoriatic arthritis with one of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, active skin and/or nail involvement. For Stelara SC 90mg/1 mL: patient weight is greater than 100 kg (220 lbs) and has diagnosis of co-existent moderate to severe psoriasis.
	<b>Crohn's Disease (CD):</b> Diagnosis of moderately to severely active Crohn's disease with one of the following: 1) frequent diarrhea and abdominal pain, 2) at least 10% weight loss, 3) complications such as obstruction, fever, abdominal mass, 4) abnormal lab values (e.g. C- reactive protein), CD Activity Index greater than 220 <b>AND</b> Trial and failure, contraindication, or intolerance to <b>ONE</b> of the following conventional therapies: 6-mercaptopurine, Azathioprine, Corticosteroids (e.g., prednisone, methylprednisolone), Methotrexate.
	<b>Ulcerative Colitis (UC):</b> Diagnosis of moderately to severely active ulcerative colitis with one of the following: 1) Greater than 6 stools per day, 2) frequent blood in the stools, 3) frequent urgency, 4) presence of ulcers, 5) abnormal lab values (e.g. hemoglobin, ESR, CRP), 6) dependent on, or refractory to, corticosteroids <b>AND</b> trial and failure, contraindication, or intolerance to one of the following conventional therapies: 6-mercaptopurine, aminosalicylate [e.g., mesalamine

	Criteria Details
	sulfasalazine, azathioprine, Corticosteroids (e.g., prednisone, methylprednisolone).
Age Restrictions	Ps0/PsA: 6 and older
Prescriber Restrictions	<ul> <li>Ps0: Prescribed by or in consultation with a dermatologist</li> <li>PsA: Prescribed by or in consultation with a dermatologist or rheumatologist</li> <li>CD/UC: Prescribed by or in consultation with a gastroenterologist</li> </ul>
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Renewal Criteria	<ul> <li>Ps0: Documentation of positive clinical response to therapy as evidenced by ONE of the following: Reduction the body surface area (BSA) involvement from baseline OR improvement in symptoms (e.g., pruritus, inflammation) from baseline.</li> <li>PsA: Documentation of positive clinical response to therapy as</li> </ul>
	evidenced by one of the following: Reduction in BSA from baseline, reduction in total active joint count, improvement in symptoms (e.g., improvement in number of swollen/tender joints, pain, or stiffness).
	<b>CD:</b> Documentation of positive clinical response to therapy as evidenced by improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline or reversal of high fecal output state.
	<b>UC:</b> Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, or reversal of high fecal output state.
Effective Date	
P&T Approval Date	
P&T Revision Date	

# Vedolizumab (ENTYVIO)

#### **Products Affected**

#### • ENTYVIO

	Criteria Details
Required Medical Information	<ul> <li>Crohn's Disease</li> <li>Documentation of moderately to severely active Crohn's disease</li> <li>One of the following: <ul> <li>Frequently diarrhea and abdominal pain</li> <li>At least 10% weight loss</li> <li>Complications such as obstruction, fever abdominal mass</li> <li>Abnormal lab values (e.g., C-reactive protein [CRP])</li> </ul> </li> <li>Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies: <ul> <li>6-mercaptopurine</li> <li>azathioprine</li> <li>corticosteroids (e.g., prednisone)</li> <li>methotrexate</li> </ul> </li> <li>One of the following: <ul> <li>Cimzia (certolizumab pegol)</li> <li>Humira (adalimumab), Amjevita, Cyltezo, Hyrimoz, or Brand Adalimumab-adaz</li> <li>Stelara (ustekinumab)</li> <li>Skyrizi (risankizumab-rzaa)</li> <li>For continuation of prior Entyvio therapy, defined as no more than a 45-day gap in therapy</li> </ul> </li> </ul>
	<ul> <li>Ulcerative Colitis</li> <li>Diagnosis of moderately to severely active ulcerative colitis</li> </ul>
	<ul> <li>One of the following:</li> <li>Greater than 6 stools per day</li> </ul>
	<ul> <li>Frequent blood in the stools</li> </ul>
	<ul> <li>Frequent urgency</li> </ul>
	<ul> <li>Presence of ulcers</li> </ul>

	Criteria Details
	<ul> <li>Abnormal lab values (e.g., hemoglobin, ESR, CRP)</li> <li>Dependent on, or refractory to, corticosteroids</li> <li>Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies :         <ul> <li>6-mercaptopurine</li> <li>Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)</li> <li>Azathioprine</li> <li>Corticosteroids (e.g., prednisone)</li> </ul> </li> <li>One of the following:         <ul> <li>Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*:                 <ul> <li>Humira (adalimumab), Amjevita, Cyltezo, Hyrimoz, or Brand Adalimumab)</li> <li>Stelara (ustekinumab)</li> <li>Rinvoq (upadacitinib)</li> <li>Xeljanz/XR (tofacitinib/ER)</li> <li>For continuation of prior Entyvio therapy, defined as no more than a 45-day gap in therapy</li> </ul></li></ul></li></ul>
Age Restrictions	
Prescriber Restrictions	Prescribed by or in collaboration with a Gastroenterologist
Coverage Duration	Initial: 14 weeks. Renewal: 12 months.
Renewal Criteria	<ul> <li>Crohn's Disease: Documentation of positive clinical response to therapy as evidenced by at least one of the following:         <ul> <li>Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline</li> <li>Reversal of high fecal output state</li> </ul> </li> <li>Ulcerative Colitis: Documentation of positive clinical response to therapy as evidenced by at least one of the following:         <ul> <li>Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline</li> <li>Reversal of high fecal output state</li> </ul> </li></ul>
Effective Date	5/1/2024

Criteria Details	
P&T Approval Date	3/12/2024
P&T Revision Date	

### Vonoprazan (VOQUEZNA)

### **Products Affected**

• VOQUEZNA 10MG

• VOQUEZNA 20MG

Criteria Details	
	Erosive esophagitis-
	<ul> <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>
Required Medical Information	<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

Criteria Details	
P&T Revision Date	

# Xanomeline and trospium (COBENFY)

### **Products Affected**

#### • COBENFY CAPS

	Criteria Details
Required Medical Information	<ul> <li>Schizophrenia:</li> <li>Confirmed diagnosis of schizophrenia.</li> <li>Used as monotherapy (not used in combination with 1<sup>st</sup> or 2<sup>nd</sup> generation antipsychotic therapy).</li> <li>Documentation of prior therapy, intolerance, or contraindication to 2 generic antipsychotics indicated for the treatment of schizophrenia (risperidone, olanzapine, quetiapine, ziprasidone, aripiprazole, paliperidone, asenapine, or lurasidone).</li> </ul>
Age Restrictions	18 years of age and older
Prescriber Restrictions	Psychiatry
Coverage Duration	Initial: 12 months. Renewal: 12 months
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	03/01/2025
P&T Approval Date	01/14/2025
P&T Revision Date	01/14/2025

# Zanubrutinib (BRUKINSA)

#### **Products Affected**

• BRUKINSA CAP 80MG

	Criteria Details
Required Medical Information	<b>Follow general oncology criteria with the following parameters:</b> One prior treatment for mantel cell lymphoma( MCL) <b>OR</b> one prior treatment (anti-CD20 based) for refractory marginal zone lymphoma (MZL) <b>OR</b> diagnosis of Waldenstrom's macroglobulinemia (WM).
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by oncologist
Coverage Duration	Initial: 3 months. Renewal: 12 months
Renewal Criteria	Documentation of positive clinical response to therapy.
Effective Date	
P&T Approval Date	
P&T Revision Date	

### Zuranolone (ZURZUVAE)

#### **Products Affected**

#### ZURZUVAE

#### **Criteria Details Postpartum Depression** Physician attestation of moderate to severe postpartum depression • (PPD) diagnosis and submission of validated screening tool result(s) (e.g. EPDS, PHQ-9) that will be used to monitor a patient's response to **Required Medical** Zurzuvae therapy Information Physician attestation that patient has not had a major depressive episode prior to third trimester of pregnancy and no later than the first 4 weeks following delivery Patient has tried/failed generic SSRI or SNIR for PPD Age Restrictions 18 years of age and older Prescriber Prescribed by psychiatrist or OB/GYN Restrictions Initial: 3 months. Renewal: N/A **Coverage Duration Renewal Criteria** Effective Date 7/1/2024 **P&T Approval Date** 5/14/2024 **P&T Revision Date**