### **2021 Prior Authorization Criteria**

#### Formulary ID: 21570, Updated 12/01/2021

## ABIRATERONE

- Abiraterone Acetate
- Zytiga Oral Tablet 500 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Node-positive (N1), non-metastatic (M0) prostate cancer

## ACITRETIN

### **Products Affected**

• Acitretin

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	Psoriasis: The patient has experienced an inadequate treatment response, intolerance, or contraindication to methotrexate or cyclosporine.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Prevention of non-melanoma skin cancers in high risk individuals, Lichen planus, Keratosis follicularis (Darier Disease).

## ACTIMMUNE

#### **Products Affected**

• Actimmune

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Mycosis fungoides, Sezary syndrome.

## **ADEMPAS**

#### **Products Affected**

• Adempas

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than or equal to 25 mmHg, AND 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) pretreatment pulmonary vascular resistance is greater than 3 Wood units. For chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4): 1) Patient has persistent or recurrent CTEPH after pulmonary endarterectomy (PEA), OR 2) Patient has inoperable CTEPH with the diagnosis confirmed by right heart catheterization AND by computed tomography (CT), magnetic resonance imaging (MRI), or pulmonary angiography.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## AIMOVIG

### **Products Affected**

• Aimovig

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1) The patient received at least 3 months of treatment with the requested drug, and the patient had a reduction in migraine days per month from baseline, OR 2) The patient experienced an inadequate treatment response with a 4-week trial of any of the following: Antiepileptic drugs (AEDs), Beta-adrenergic blocking agents, Antidepressants, OR 3) The patient experienced an intolerance or has a contraindication that would prohibit a 4-week trial of any of the following: Antiepileptic drugs (AEDs), Beta-adrenergic blocking agents, Antidepressants.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial 3 Months, Reauthorization Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# ALDURAZYME

### **Products Affected**

• Aldurazyme

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	For mucopolysaccharidosis I: Diagnosis of mucopolysaccharidosis I was confirmed by an enzyme assay demonstrating a deficiency of alpha-L- iduronidase enzyme activity or by genetic testing.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## ALECENSA

#### **Products Affected**

• Alecensa

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Recurrent or advanced anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC), brain metastases from ALK-positive NSCLC.

# **ALOSETRON**

#### **Products Affected**

Alosetron HCI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1) The requested drug is being prescribed for a biological female or a person that self-identifies as a female with a diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS) AND 2) Chronic IBS symptoms lasting at least 6 months AND 3) Gastrointestinal tract abnormalities have been ruled out AND 4) Inadequate response to conventional therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **ALPHA1-PROTEINASE INHIBITOR**

- Aralast NP Intravenous Solution Reconstituted 1000 MG, 500 MG
- Prolastin-C
- Zemaira

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For alpha1-proteinase inhibitor deficiency: Patient must have 1) clinically evident emphysema, 2) pretreatment serum alpha1-proteinase inhibitor level less than 11 micromol/L (80 mg/dL by radial immunodiffusion or 50 mg/dL by nephelometry), and 3) pretreatment post-bronchodilation forced expiratory volume in 1 second (FEV1) greater than or equal to 25 percent and less than or equal to 80 percent of predicted.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **ALUNBRIG**

#### **Products Affected**

• Alunbrig

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Recurrent or advanced anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC), brain metastases from ALK-positive NSCLC.

# AMBRISENTAN

### **Products Affected**

• Ambrisentan

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): Diagnosis was confirmed by right heart catheterization. For PAH new starts only: 1) Pretreatment mean pulmonary arterial pressure is greater than or equal to 25 mmHg, 2) Pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, and 3) Pretreatment pulmonary vascular resistance is greater than 3 Wood units.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **AMPHETAMINES**

- Amphetamine-Dextroamphet ER Amphetamine-Dextroamphetamine

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1) The patient has a diagnosis of Attention-Deficit Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD) OR 2) The patient has the diagnosis of narcolepsy confirmed by a sleep study.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# **APOKYN**

## **Products Affected**

• Apokyn Subcutaneous Solution Cartridge

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# ARCALYST

#### **Products Affected**

Arcalyst

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For prevention of gout flares in patients initiating or continuing urate-lowering therapy (e.g., allopurinol) (new starts): 1) two or more gout flares within the previous 12 months, AND 2) inadequate response, intolerance or contraindication to maximum tolerated doses of a non-steroidal anti-inflammatory drug and colchicine, AND 3) concurrent use with urate-lowering therapy. For prevention of gout flares in patients initiating or continuing urate-lowering therapy (e.g., allopurinol) (continuation): 1) patient must have achieved or maintained a clinical benefit (i.e., a fewer number of gout attacks or fewer flare days) compared to baseline, AND 2) continued use of urate-lowering therapy with the requested drug.
Age Restrictions	For Cryopyrin-Associated Periodic Syndromes (CAPS) and recurrent pericarditis: 12 years of age or older.
Prescriber Restrictions	
Coverage Duration	For prevention of gout flares: 4 months. Other: Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Prevention of gout flares in patients initiating or continuing urate-lowering therapy.

# ARMODAFINIL

### **Products Affected**

• Armodafinil

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1) Diagnosis is narcolepsy confirmed by sleep lab evaluation OR 2) Diagnosis is Shift Work Disorder (SWD) OR 3) Diagnosis is obstructive sleep apnea (OSA) confirmed by polysomnography.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **ATYPICAL ANTIPSYCHOTICS**

- FanaptFanapt Titration Pack

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following: aripiprazole, lurasidone, olanzapine, paliperidone, quetiapine, risperidone, or ziprasidone.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# AURYXIA

### **Products Affected**

• Auryxia

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	The requested drug is not being prescribed for treatment of iron deficiency anemia in adult patients with chronic kidney disease not on dialysis
Indications	All FDA-approved Indications.
Off Label Uses	

# **AUSTEDO**

#### **Products Affected**

Austedo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Tourette's syndrome

## **AVASTIN**

#### **Products Affected**

• Avastin

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. For FDA-approved indications and off-label uses that overlap: the patient had an intolerable adverse event to both Mvasi AND Zirabev and that adverse event was NOT attributed to the active ingredient as described in the prescribing information.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	Breast cancer, central nervous system (CNS) tumor types: adult low-grade (WHO Grade II) infiltrative supratentorial astrocytoma/oligodendroglioma, adult intracranial and spinal ependymoma, anaplastic gliomas, adult medulloblastoma, primary central nervous system lymphoma, meningiomas, limited and extensive brain metastases, leptomeningeal metastases and metastatic spine tumors, malignant pleural mesothelioma, ovarian cancer/fallopian tube cancer/primary peritoneal cancer types: carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma, mucinous carcinoma, grade 1 endometrioid carcinoma, low-grade serous carcinoma, ovarian borderline epithelial tumors (low malignant potential) with invasive implants, and malignant sex cord-stromal tumors, soft tissue sarcoma types: angiosarcoma and solitary fibrous tumor/hemangiopericytoma, AIDS-related Kaposi sarcoma, uterine cancer, endometrial cancer, vulvar cancer, and ophthalmic-related disorders: diabetic macular edema, neovascular (wet) age-related macular degeneration including polypoidal choroidopathy and retinal angiomatous proliferation subtypes, macular edema following retinal vein occlusion, proliferative diabetic retinopathy, choroidal neovascularization, neovascular glaucoma and retinopathy of prematurity.

# AYVAKIT

### **Products Affected**

• Ayvakit

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For advanced systemic mastocytosis (AdvSM): 1) the patient has a diagnosis of advanced systemic mastocytosis including aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL) AND 2) the patient has a platelet count of greater than or equal to 50,000/mcL.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

- Abelcet
- Abraxane
- Acetylcysteine Inhalation
- Acyclovir Sodium Intravenous Solution
- Adriamycin Intravenous Solution
- Albuterol Sulfate Inhalation Nebulization Solution (2.5 MG/3ML) 0.083%, 0.63 MG/3ML, 1.25 MG/3ML, 2.5 MG/0.5ML
- Alimta
- AmBisome
- Aminosyn-PF Intravenous Solution 7 %
- Amphotericin B Intravenous
- Aprepitant Oral Capsule
- Arformoterol Tartrate
- AzaCITIDine
- azaTHIOprine Oral Tablet 50 MG
- Bendeka
- Brovana
- Budesonide Inhalation Suspension 0.25 MG/2ML,
   0.5 MG/2ML
- Calcitonin (Salmon) Nasal
- Calcitriol Intravenous Solution 1 MCG/ML
- Calcitriol Oral
- CARBOplatin Intravenous Solution
- Cinacalcet HCI
- CISplatin Intravenous Solution 100 MG/100ML, 200 MG/200ML, 50 MG/50ML
- Clinimix/Dextrose (4.25/10)
- Clinimix/Dextrose (4.25/5)
- Clinimix/Dextrose (5/15)
- Clinimix/Dextrose (5/20)
- Clinimix/Dextrose (6/5)
- Clinimix/Dextrose (8/10)
- Clinimix/Dextrose (8/14)
- Clinisol SF
- Clinolipid
- Cromolyn Sodium Inhalation
- Cyclophosphamide Injection
- Cyclophosphamide Intravenous
- Cyclophosphamide Oral Capsule
- Cyclophosphamide Oral Tablet

- CycloSPORINE Intravenous
- CycloSPORINE Modified
- CycloSPORINE Oral Capsule
- Cytarabine Injection Solution
- Dextrose Intravenous Solution 50 %, 70 %
- Diphtheria-Tetanus Toxoids DT
- DOCEtaxel CONCENTRATE 160 MG/8ML Intravenous
- DOCEtaxel CONCENTRATE 80 MG/4ML Intravenous
- DOCEtaxel Intravenous Concentrate 160 MG/8ML, 20 MG/ML, 80 MG/4ML
- DOCEtaxel Intravenous Solution 160 MG/16ML, 20 MG/2ML, 80 MG/8ML
- DOCEtaxel SOLUTION 160 MG/16ML Intravenous
- DOCEtaxel SOLUTION 20 MG/2ML Intravenous
- DOCEtaxel SOLUTION 80 MG/8ML Intravenous
- Doxercalciferol Oral
- DOXOrubicin HCI Intravenous Solution
- DOXOrubicin HCI Liposomal
- Dronabinol
- Emend Oral Suspension Reconstituted
- Engerix-B Injection
- EpiRUBicin HCl Intravenous Solution 200 MG/100ML, 50 MG/25ML
- Etoposide Intravenous Solution 100 MG/5ML, 500 MG/25ML
- Everolimus Oral Tablet 0.25 MG, 0.5 MG, 0.75 MG
- Fluorouracil Intravenous
- Formoterol Fumarate Inhalation
- FreAmine III Intravenous Solution 10 %
- Fulvestrant
- GamaSTAN S/D
- Ganciclovir Sodium Intravenous Solution Reconstituted
- Gemcitabine HCI Intravenous Solution 1 GM/26.3ML, 2 GM/52.6ML, 200 MG/5.26ML
- Gemcitabine HCI Intravenous Solution Reconstituted
- Gengraf Oral Capsule 100 MG, 25 MG

- Gengraf Oral Solution
- Granisetron HCI Oral
- Heparin Sodium (Porcine) Injection Solution 1000 UNIT/ML, 10000 UNIT/ML, 20000 UNIT/ML, 5000 UNIT/ML
- Hepatamine
- HumuLIN R U-500 (CONCENTRATED)
- Ibandronate Sodium
- Imovax Rabies
- Intralipid
- Intron A
- Ipratropium Bromide Inhalation
- Ipratropium-Albuterol
- Irinotecan HCI
- Kadcyla
- Leucovorin Calcium Injection Solution 500
   MG/50ML
- Leucovorin Calcium Injection Solution Reconstituted
- Levalbuterol HCI Inhalation
- levOCARNitine Oral Solution
- levOCARNitine Oral Tablet
- Lidocaine HCI (PF) Injection Solution 0.5 %, 1 %, 1.5 %
- Lidocaine HCI Injection Solution 0.5 %, 1 %, 2 %
- Methotrexate Sodium (PF) Injection Solution 1 GM/40ML, 250 MG/10ML, 50 MG/2ML
- Methotrexate Sodium Injection Solution 250
   MG/10ML, 50 MG/2ML
- Methotrexate Sodium Injection Solution Reconstituted
- Morphine Sulfate (PF) Injection Solution 10
   MG/ML, 2 MG/ML, 4 MG/ML, 5 MG/ML, 8 MG/ML
- Morphine Sulfate (PF) Intravenous Solution 10 MG/ML
- Morphine Sulfate (PF) Intravenous Solution 2 MG/ML, 4 MG/ML, 8 MG/ML
- Morphine Sulfate (PF) SOLUTION 10 MG/ML Intravenous
- Morphine Sulfate Intravenous Solution 1 MG/ML, 4 MG/ML, 8 MG/ML
- Mycophenolate Mofetil Oral
- Mycophenolate Sodium

- Nulojix
- Nutrilipid
- Oxaliplatin
- PACLitaxel Intravenous Concentrate 100 MG/16.7ML, 150 MG/25ML, 30 MG/5ML, 300 MG/50ML
- Pamidronate Disodium Intravenous Solution 30 MG/10ML, 90 MG/10ML
- Pamidronate Disodium Intravenous Solution 6 MG/ML
- Pamidronate Disodium Intravenous Solution Reconstituted
- Paraplatin Intravenous Solution 1000 MG/100ML
- Paricalcitol Oral
- Pentamidine Isethionate Inhalation
- Perforomist
- Plenamine
- Premasol Intravenous Solution 10 %
- Procalamine
- Prograf Oral Packet
- Prosol
- RabAvert
- Recombivax HB
- SandIMMUNE Oral Solution
- Sirolimus Oral
- Tacrolimus Oral
- TDVAX
- Tenivac
- Toposar Intravenous Solution 1 GM/50ML, 100 MG/5ML
- TPN Electrolytes Intravenous Concentrate
- Travasol
- Trexall
- TrophAmine Intravenous Solution 10 %
- vinCRIStine Sulfate Intravenous
- Vinorelbine Tartrate
- Xatmep
- Zoledronic Acid Intravenous Concentrate
- Zoledronic Acid Intravenous Solution
- Zortress Oral Tablet 1 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	N/A
Other Criteria	This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.
Indications	All Medically-accepted Indications.
Off Label Uses	

## BALVERSA

#### **Products Affected**

• Balversa

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## BANZEL

- Banzel Oral Tablet
- Rufinamide

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	1 year of age or older
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## **BENLYSTA**

#### **Products Affected**

• Benlysta

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	For patients new to therapy: severe active central nervous system lupus.
Required Medical Information	For systemic lupus erythematosus (SLE): 1) Patient is currently receiving a stable standard therapy regimen (e.g., corticosteroid or antimalarial) for SLE OR 2) patient is not currently receiving stable standard therapy regimen for SLE because patient tried and had an inadequate response or intolerance to stable standard therapy regimen. For lupus nephritis: 1) Patient is currently receiving a stable standard therapy regimen (e.g., corticosteroid) for lupus nephritis OR 2) patient is not currently receiving a stable standard therapy regimen for lupus nephritis patient is not currently receiving a stable standard therapy regimen for lupus nephritis because patient tried and had an inadequate response or intolerance to a stable standard therapy regimen.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## BERINERT

#### **Products Affected**

• Berinert

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For hereditary angioedema (HAE): patient has hereditary angioedema (HAE) with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing OR patient has hereditary angioedema with normal C1 inhibitor confirmed by laboratory testing. For patients with HAE with normal C1 inhibitor, EITHER 1) Patient tested positive for an F12, angiopoietin-1, or plasminogen gene mutation OR 2) Patient has a family history of angioedema and the angioedema was refractory to a trial of an antihistamine for at least one month.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## **BETASERON**

### **Products Affected**

• Betaseron Subcutaneous Kit

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# BEXAROTENE

- Bexarotene
- Targretin External

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Mycosis fungoides, Sezary syndrome (capsules only), primary cutaneous CD30- positive T-cell lymphoproliferative disorder types: primary cutaneous anaplastic large cell lymphoma (capsules only) and lymphomatoid papulosis (capsules only), chronic or smoldering adult T-cell leukemia/lymphoma (gel only), primary cutaneous B-cell lymphoma types: primary cutaneous marginal zone lymphoma (gel only) and primary cutaneous follicle center lymphoma (gel only).

## BOSENTAN

#### **Products Affected**

• Bosentan

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): Diagnosis was confirmed by right heart catheterization. For PAH new starts only: 1) Pretreatment mean pulmonary arterial pressure is greater than or equal to 25 mmHg, 2) Pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, and 3) Pretreatment pulmonary vascular resistance is greater than 3 Wood units. For Eisenmenger's syndrome: Patient is diagnosed with Eisenmenger's syndrome, WHO functional class III PAH.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Eisenmenger's syndrome

## BOSULIF

#### **Products Affected**

• Bosulif

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For chronic myeloid leukemia (CML) or acute lymphoblastic leukemia (ALL): Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR- ABL gene. For CML, patient meets one of the following: 1) patient received a hematopoietic stem cell transplant, OR 2) patient has accelerated or blast phase CML, OR 3) patient has chronic phase CML (high, intermediate, or low risk for disease progression). If patient has low risk for disease progression (includes newly diagnosed), patient has experienced resistance, intolerance or toxicity to imatinib or an alternative tyrosine kinase inhibitor. If patient experienced resistance to imatinib or an alternative tyrosine kinase inhibitor for CML, patient is negative for T315I mutation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL).

## BRAFTOVI

## **Products Affected**

• Braftovi Oral Capsule 75 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For colorectal cancer, patient must meet all of the following criteria: 1) Tumor is positive for BRAF V600E mutation, 2) The disease is advanced or metastatic, and 3) The requested drug will be used as subsequent therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## BRIVIACT

### **Products Affected**

• Briviact

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	1 month of age or older
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **BRIVIACT INJ**

## **Products Affected**

• Briviact

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	1 month of age or older
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## BRUKINSA

#### **Products Affected**

• Brukinsa

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# BUPRENORPHINE

### **Products Affected**

• Buprenorphine HCI Sublingual

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1) The requested drug is being prescribed for the treatment of opioid use disorder AND 2) The patient is pregnant or breastfeeding, and the requested drug is being prescribed for induction therapy and/or subsequent maintenance therapy for treatment of opioid use disorder OR 3) The requested drug is being prescribed for induction therapy for transition from opioid use to treatment of opioid use disorder OR 4) The requested drug is being prescribed for maintenance therapy for treatment of opioid use disorder in a patient who is intolerant to naloxone.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# CABOMETYX

### **Products Affected**

Cabometyx

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For renal cell carcinoma: The disease is relapsed, unresectable, or metastatic. For non-small cell lung cancer: The disease is rearranged during transfection (RET) positive. For hepatocellular carcinoma: The patient has been previously treated with sorafenib.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Non-small cell lung cancer

# **CALCIPOTRIENE**

#### **Products Affected**

- Calcipotriene External CreamCalcipotriene External Ointment
- Calcipotriene External Solution
- Calcipotriene-Betameth Diprop External ٠

Suspension

Calcitrene

- Enstilar •

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	1) The requested drug is being prescribed for the treatment of psoriasis AND 2) The patient experienced an inadequate treatment response, intolerance, or contraindication to a generic topical steroid.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# CALQUENCE

#### **Products Affected**

• Calquence

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# CAPRELSA

#### **Products Affected**

Caprelsa

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For NSCLC: the requested medication is used for NSCLC when the patient's disease expresses rearranged during transfection (RET) gene rearrangements.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Non-small cell lung cancer (NSCLC), differentiated thyroid carcinoma: papillary, follicular, and Hurthle cell.

# CARBAGLU

#### **Products Affected**

• Carbaglu

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For N-acetylglutamate synthase (NAGS) deficiency: Diagnosis of NAGS deficiency was confirmed by enzymatic or genetic testing.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

### CAYSTON

#### **Products Affected**

Cayston

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For treatment of respiratory symptoms in cystic fibrosis patients: 1) Pseudomonas aeruginosa is present in the patient's airway cultures OR 2) The patient has a history of pseudomonas aeruginosa infection or colonization in the airways.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## CERDELGA

#### **Products Affected**

• Cerdelga

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	For Gaucher disease, the diagnosis was confirmed by an enzyme assay demonstrating a deficiency of beta-glucocerebrosidase enzyme activity or by genetic testing. The patient's CYP2D6 metabolizer status has been established using an FDA-cleared test. The patient is a CYP2D6 extensive metabolizer, an intermediate metabolizer, or a poor metabolizer.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# CEREZYME

### **Products Affected**

Cerezyme Intravenous Solution Reconstituted
 400 UNIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	For Gaucher disease, the diagnosis was confirmed by an enzyme assay demonstrating a deficiency of beta-glucocerebrosidase enzyme activity or by genetic testing.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Type 3 Gaucher disease

## CLOBAZAM

#### **Products Affected**

CloBAZam

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	2 years of age or older
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **CLOMIPRAMINE**

### **Products Affected**

• clomiPRAMINE HCI Oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1) The requested drug is being prescribed for one of the following: the treatment of Obsessive-Compulsive Disorder (OCD) or Panic Disorder AND 2) The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to any of the following: a serotonin and norepinephrine reuptake inhibitor (SNRI), a selective serotonin reuptake inhibitor (SSRI), mirtazapine OR 3) The requested drug is being prescribed for the treatment of Depression AND 4) The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to TWO of the following: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Depression, Panic Disorder

# **CLORAZEPATE**

### **Products Affected**

• Clorazepate Dipotassium

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1) For the management of anxiety disorders, the requested drug is being used with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) until the antidepressant becomes effective for the symptoms of anxiety OR The patient has experienced an inadequate treatment response, intolerance, or a contraindication to AT LEAST TWO agents from the following classes: A) selective serotonin reuptake inhibitors (SSRIs), B) serotonin-norepinephrine reuptake inhibitors (SNRIs) OR 2) For adjunctive therapy in the management of partial seizures OR 3) Symptomatic relief in acute alcohol withdrawal OR 4) For the short-term relief of the symptoms of anxiety.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Short-term relief anxiety-1 month, Anxiety Disorders-4 months, All other Diagnoses-Plan Year
Other Criteria	This Prior Authorization requirement only applies to patients 65 years of age or older. The benefit of therapy with the prescribed medication outweighs the potential risk in a patient 65 years of age or older. (Note: The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
Indications	All FDA-approved Indications.
Off Label Uses	

# **CLOZAPINE ODT**

### **Products Affected**

• CloZAPine Oral Tablet Dispersible

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **COMETRIQ**

### **Products Affected**

- Cometriq (100 MG Daily Dose) Oral Kit 80 & 20 Cometriq (60 MG Daily Dose) MG
- Cometriq (140 MG Daily Dose) Oral Kit 3 x 20 MG & 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For NSCLC: The requested medication is used for NSCLC when the patient's disease expresses rearranged during transfection (RET) gene rearrangements.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Non-small cell lung cancer (NSCLC), differentiated thyroid carcinoma: papillary, follicular, and Hurthle cell.

# **COPIKTRA**

#### **Products Affected**

• Copiktra

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For follicular lymphoma: the requested drug will be used as second-line or subsequent therapy. For gastric MALT lymphoma, non-gastric MALT lymphoma, nodal marginal zone lymphoma, and splenic marginal zone lymphoma: the requested drug will be used as subsequent therapy after at least 2 prior therapies.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Gastric MALT lymphoma, non-gastric MALT lymphoma, nodal marginal zone lymphoma, splenic marginal zone lymphoma

# COTELLIC

#### **Products Affected**

Cotellic

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **CYSTADROPS**

#### **Products Affected**

Cystadrops

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For cystinosis: 1) Diagnosis of cystinosis was confirmed by the presence of increased cystine concentration in leukocytes or by genetic testing, and 2) The patient has corneal cystine crystal accumulation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## **CYSTAGON**

#### **Products Affected**

Cystagon

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For nephropathic cystinosis: Diagnosis of nephropathic cystinosis was confirmed by the presence of increased cystine concentration in leukocytes or by genetic testing.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## **CYSTARAN**

#### **Products Affected**

• Cystaran

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For cystinosis: 1) Diagnosis of cystinosis was confirmed by the presence of increased cystine concentration in leukocytes or by genetic testing, and 2) The patient has corneal cystine crystal accumulation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## DALFAMPRIDINE

### **Products Affected**

• Dalfampridine ER

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For multiple sclerosis, patient must meet the following: For new starts, prior to initiating therapy, patient meets the following: patient demonstrates sustained walking impairment. For continuation of therapy, patient meets the following: patient must have experienced an improvement in walking speed OR other objective measure of walking ability since starting the requested drug.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## DAURISMO

#### **Products Affected**

• Daurismo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For acute myeloid leukemia: 1) the requested medication must be used in combination with cytarabine, 2) the patient is 75 years of age or older OR has comorbidities that preclude intensive chemotherapy, and 3) the requested medication will be used as treatment for induction therapy, post-remission therapy, or relapsed or refractory disease.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Post remission therapy following response to previous therapy with the same regimen for acute myeloid leukemia (AML). Relapsed/refractory disease as a component of repeating the initial successful induction regimen for AML.

# DEFERASIROX

### **Products Affected**

- Deferasirox Granules
- Deferasirox Oral Tablet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For chronic iron overload due to blood transfusions: pretreatment serum ferritin level is greater than 1000 mcg/L.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## DEMSER

### **Products Affected**

metyroSINE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# DESVENLAFAXINE

### **Products Affected**

• Desvenlafaxine Succinate ER

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to TWO of the following: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **DHE NASAL**

### **Products Affected**

• Dihydroergotamine Mesylate Nasal

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	The patient experienced an inadequate treatment response, intolerance, or contraindication to one triptan 5-HT1 receptor agonist
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## DIACOMIT

#### **Products Affected**

• Diacomit

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

### DIAZEPAM

#### **Products Affected**

- Diazepam Oral Concentrate
- diazePAM Oral Solution 5 MG/5ML
- diazePAM Oral Tablet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1) For the management of anxiety disorders, the requested drug is being used with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) until the antidepressant becomes effective for the symptoms of anxiety OR The patient has experienced an inadequate treatment response, intolerance, or a contraindication to AT LEAST TWO agents from the following classes: A) selective serotonin reuptake inhibitors (SSRIs), B) serotonin-norepinephrine reuptake inhibitors (SNRIs) OR 2) For symptomatic relief in acute alcohol withdrawal OR 3) For use as an adjunct for the relief of spasticity caused by upper motor neuron disorders (e.g., cerebral palsy and paraplegia), athetosis, or stiff-man syndrome OR 4) For use as an adjunct for the relief of the muscles or joints, or secondary to trauma) OR 5) For adjunctive therapy in the treatment of convulsive disorders OR 6) For the short-term relief of the symptoms of anxiety.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Short-term relief anx-1 mo, skeletal muscles spasm-3 mo, Anx Disorders-4 mo, Other Diagnoses-PlanYR
Other Criteria	This Prior Authorization requirement only applies to patients 65 years of age or older. The benefit of therapy with the prescribed medication outweighs the potential risk in a patient 65 years of age or older. (Note: The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
Indications	All FDA-approved Indications.
Off Label Uses	

## DOPTELET

#### **Products Affected**

• Doptelet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For thrombocytopenia associated with chronic liver disease: Baseline platelet (plt) count prior to a scheduled procedure is less than 50,000/mcL. For chronic or persistent immune thrombocytopenia (ITP): 1) For new starts: a) Patient has had an inadequate response or is intolerant to prior therapy such as corticosteroids or immunoglobulins, AND b) Untransfused plt count at any point prior to the initiation of the requested medication is less than 30,000/mcL OR 30,000-50,000/mcL with symptomatic bleeding or risk factor(s) for bleeding. 2) For continuation of therapy, plt count response to the requested drug: a) Current plt count is less than or equal to 200,000/mcL OR b) Current plt count is greater than 200,000/mcL and dosing will be adjusted to a plt count sufficient to avoid clinically important bleeding.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	Chronic liver disease: 1 month, ITP initial: 6 months, ITP reauthorization: Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## DRIZALMA

### **Products Affected**

• Drizalma Sprinkle

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	The patient has tried duloxetine capsules or the patient is unable to take duloxetine capsules for any reason (e.g., difficulty swallowing capsules, requires nasogastric administration)
Age Restrictions	Generalized Anxiety Disorder - 7 years of age or older
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Cancer pain, chemotherapy-induced neuropathic pain

### **EMSAM**

#### **Products Affected**

• Emsam

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1) The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to TWO of the following: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion OR 2) Patient is unable to swallow oral formulations.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## **ENBREL**

#### Products Affected

- Enbrel Mini
- Enbrel Subcutaneous Solution 25 MG/0.5ML
- Enbrel Subcutaneous Solution Prefilled Syringe
- Enbrel Subcutaneous Solution Reconstituted
- **PA Criteria Criteria Details Exclusion Criteria Required Medical** For moderately to severely active rheumatoid arthritis (new starts only):1) Information Inadequate response, intolerance or contraindication to methotrexate (MTX) OR 2) Inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis (new starts only): Inadequate response to a non-steroidal anti-inflammatory drug (NSAID) trial OR intolerance or contraindication to NSAIDs. For chronic moderate to severe plaque psoriasis (new starts only): 1) At least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) Patient meets any of the following: a) Patient has experienced an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin OR b) Pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated OR c) Patient has severe psoriasis that warrants a biologic DMARD as first-line therapy (i.e. at least 10% of the BSA or crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected). Age Restrictions Prescriber Restrictions **Coverage Duration** Plan Year **Other Criteria** Indications All FDA-approved Indications, Some Medically-accepted Indications. **Off Label Uses** Severe, refractory hidradenitis suppurativa, graft versus host disease
- Enbrel SureClick Subcutaneous Solution Auto-Injector

## **ENDARI**

### **Products Affected**

• Endari

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	5 years of age or older
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## **EPCLUSA**

### **Products Affected**

• Epclusa Oral Tablet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For chronic hepatitis C: Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [Child Turcotte Pugh class B or C]), presence or absence of HIV coinfection, presence or absence of resistance-associated substitutions where applicable, liver and kidney transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current AASLD treatment guidelines.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Criteria will be applied consistent with current AASLD-IDSA guidance.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## **EPIDIOLEX**

#### **Products Affected**

• Epidiolex

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

#### **Products Affected**

• Procrit

PA Criteria	Criteria Details
Exclusion Criteria	Patients receiving chemotherapy with curative intent. Patients with myeloid cancer.
Required Medical Information	For all uses except surgery: Pretreatment (no erythropoietin treatment in previous month) hemoglobin (Hgb) is less than 10 g/dL (less than 9 g/dL for anemia in congested heart failure only). For surgery: 1) Patient is scheduled for elective, noncardiac, nonvascular surgery. 2) Pretreatment Hgb is greater than 10 but not more than 13 g/dL.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	16 weeks
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual (e.g., used for treatment of anemia for a patient with chronic renal failure who is undergoing dialysis, or furnished from physician's supply incident to a physician service). Coverage includes use in anemia in patients whose religious beliefs forbid blood transfusions. Requirements regarding Hgb values exclude values due to a recent transfusion. For reauthorizations (patient received erythropoietin treatment in previous month): 1) For all uses except surgery, there is an increase in Hgb of at least 1 g/dL after at least 12 weeks of therapy. 2) For anemia in chronic kidney disease, MDS, CHF, RA, human immunodeficiency virus (HIV), hepatitis C treatment, anemia due to myelosuppressive cancer chemotherapy, or patients whose religious beliefs forbid blood transfusions: current Hgb is less than 12 g/dL.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	Anemia due to myelodysplastic syndromes (MDS), anemia in congestive heart failure (CHF), anemia in rheumatoid arthritis (RA), anemia due to hepatitis C treatment (ribavirin in combination with either interferon alfa or peginterferon alfa).

### **ERIVEDGE**

### **Products Affected**

• Erivedge

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Adult medulloblastoma: patient has received chemotherapy previously AND has tumor(s) with mutations in the sonic hedgehog pathway
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Adult medulloblastoma

### **ERLEADA**

### **Products Affected**

• Erleada

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For all indications: The requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

### **ERLOTINIB**

### **Products Affected**

• Erlotinib HCl

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For NSCLC (including brain metastases from NSCLC): 1) the disease is recurrent, advanced, or metastatic and 2) the member has sensitizing EGFR mutation-positive disease. For pancreatic cancer: the disease is locally advanced, unresectable, or metastatic.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Recurrent or advanced non-small cell lung cancer (NSCLC), recurrent chordoma, renal cell carcinoma (RCC), brain metastases from NSCLC.

# **ESBRIET**

### **Products Affected**

• Esbriet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For idiopathic pulmonary fibrosis (Initial Review Only): 1) a high-resolution computed tomography (HRCT) study of the chest or a lung biopsy reveals the usual interstitial pneumonia (UIP) pattern, OR 2) HRCT study of the chest reveals a result other than the UIP pattern (e.g., probable UIP, indeterminate for UIP) and the diagnosis is supported either by a lung biopsy or by a multidisciplinary discussion between at least a radiologist and pulmonologist who are experienced in idiopathic pulmonary fibrosis if a lung biopsy has not been conducted.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **EVEROLIMUS**

- Afinitor Disperz
- Afinitor Oral Tablet 10 MG
- Everolimus Oral Tablet 10 MG, 2.5 MG, 5 MG, 7.5 MG
- **PA Criteria Criteria Details Exclusion Criteria Required Medical** For breast cancer: 1) The disease is recurrent or metastatic hormone receptor Information (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, and 2) The requested medication is prescribed in combination with exemestane. fulvestrant, or tamoxifen, AND 3) The patient has received endocrine therapy within 1 year. For renal cell carcinoma: The disease is relapsed or metastatic. For subependymal giant cell astrocytoma (SEGA): The requested drug is given as adjuvant treatment. **Age Restrictions** Prescriber **Restrictions** Plan Year **Coverage Duration Other Criteria** All FDA-approved Indications, Some Medically-accepted Indications. Indications **Off Label Uses** Classic Hodgkin lymphoma, thymomas and thymic carcinomas, Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma, soft tissue sarcoma (perivascular epithelioid cell tumors (PEComa) and lymphangioleiomyomatosis subtypes), gastrointestinal stromal tumors, neuroendocrine tumors of the thymus, thyroid carcinoma (papillary, Hurthle cell, and follicular), endometrial carcinoma.
- Everolimus Oral Tablet Soluble

## **EXKIVITY**

### **Products Affected**

• Exkivity

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## FABRAZYME

### **Products Affected**

• Fabrazyme

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Fabry disease: diagnosis of Fabry disease was confirmed by an enzyme assay demonstrating a deficiency of alpha-galactosidase enzyme activity or by genetic testing, or the patient is a symptomatic obligate female carrier.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# FARYDAK

### **Products Affected**

• Farydak

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **FASENRA**

- Fasenra
- Fasenra Pen

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For severe asthma: For initial therapy: 1) Either a) Patient has baseline blood eosinophil count of at least 150 cells per microliter OR b) Patient is dependent on systemic corticosteroids, and 2) Patient has a history of severe asthma despite current treatment with both of the following medications at optimized doses: a) inhaled corticosteroid and b) additional controller (long acting beta2-agonist, leukotriene modifier, or sustained release theophylline). For continuation of therapy: Asthma control has improved on treatment with the requested drug, as demonstrated by a reduction in the frequency and/or severity of symptoms and exacerbations or a reduction in the daily maintenance oral corticosteroid dose.
Age Restrictions	12 years of age or older
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **FENTANYL PATCH**

- FentaNYL Transdermal Patch 72 Hour 100 MCG/HR, 25 MCG/HR, 50 MCG/HR, 75 MCG/HR
- fentaNYL Transdermal Patch 72 Hour 12 MCG/HR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1) The requested drug is being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through palliative care OR 2) The requested drug is being prescribed for pain severe enough to require daily, around-the-clock, long-term treatment in a patient who has been taking an opioid AND 3) The patient can safely take the requested dose based on their history of opioid use [Note:This drug should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain.] AND 4) The patient has been evaluated and the patient will be monitored for the development of opioid use disorder AND 5) This request is for continuation of therapy for a patient who has been receiving an extended-release opioid agent for at least 30 days OR the patient has taken an immediate-release opioid for at least one week.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

### **FETZIMA**

- Fetzima
- Fetzima Titration

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to TWO of the following: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

### **FINTEPLA**

### **Products Affected**

• Fintepla

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **FORTEO**

### **Products Affected**

 Forteo Subcutaneous Solution Pen-Injector 620 MCG/2.48ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For postmenopausal osteoporosis: patient has ONE of the following (1 or 2): 1) A history of fragility fractures, OR 2) A pre-treatment T-score of less than or equal to -2.5 or pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment Fracture Risk Assessment Tool (FRAX) fracture probability AND patient has ANY of the following: a) Indicators for higher fracture risk (e.g., advanced age, frailty, glucocorticoid therapy, very low T-scores, or increased fall risk), OR b) Patient has failed prior treatment with or is intolerant to a previous injectable osteoporosis therapy OR c) Patient has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate. For primary or hypogonadal osteoporosis in men: patient has one of the following: 1) a history of osteoporotic vertebral or hip fracture, OR 2) pre-treatment T-score of less than -1 with a high pre-treatment FRAX fracture probability. For glucocorticoid-induced osteoporosis: 1) patient has had an oral bisphosphonate trial of at least 1-year duration or intolerance to an oral bisphosphonate, AND 2) patient has one of the following: a) a history of fragility fracture, OR b) a pre-treatment T-score greater than -2.5, OR c) pre-treatment T-score greater than -2.5, or glucocorticoid-induced osteoporosis: 1) patient has had an oral bisphosphonate trial of at least 1-year duration unless patient has no er of the following: a) a history of fragility fracture, OR b) a pre-treatment T-score greater than -2.5, OR c) pre-treatment T-score greater than -2.5, OR c) pre-treatment T-score greater than -2.5, or core greater than -2.5, and less than -1 with a high pre-treatment T-score greater than -2.5, or pre-treatment T-sco
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	24 months lifetime total for parathyroid hormone analogs (e.g., abaloparatide or teriparatide)

PA Criteria	Criteria Details
Other Criteria	Patient has high FRAX fracture probability if the 10 year probability is either greater than or equal to 20 percent for any major osteoporotic fracture or greater than or equal to 3 percent for hip fracture. If glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day, the estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture and 1.2 for hip fracture.
Indications	All FDA-approved Indications.
Off Label Uses	

# FOTIVDA

### **Products Affected**

• Fotivda

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## **FYCOMPA**

### **Products Affected**

• Fycompa

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Partial-onset seizures: 4 years of age or older, Primary generalized tonic-clonic seizures: 12 years of age or older.
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# GATTEX

### **Products Affected**

• Gattex

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For short bowel syndrome (SBS) initial therapy: Adult patients were dependent on parenteral support for at least 12 months. Pediatric patients were dependent on nutrition/IV fluids to account for at least 30 percent of caloric and/or fluid/electrolyte needs. For SBS continuation: Requirement for parenteral support has decreased from baseline while on therapy with the requested medication.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **GAVRETO**

#### **Products Affected**

• Gavreto

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-small cell lung cancer, patient must meet all of the following: 1) The disease is recurrent, advanced, or metastatic, and 2) The tumor is rearranged during transfection (RET) fusion-positive or RET rearrangement-positive.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Recurrent or advanced rearranged during transfection (RET) rearrangement- positive non-small cell lung cancer

# GILENYA

### **Products Affected**

• Gilenya Oral Capsule 0.5 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# GILOTRIF

#### **Products Affected**

• Gilotrif

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-small cell lung cancer (NSCLC): Patient meets either of the following: 1) Patient has metastatic squamous NSCLC that progressed after platinum-based chemotherapy, or 2) Patient has a known sensitizing EGFR mutation. For brain metastases from NSCLC: Patient has a known sensitizing EGFR mutation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Brain metastases from non-small cell lung cancer.

# **GLATIRAMER**

- Glatiramer Acetate
- Glatopa

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# GRALISE

### **Products Affected**

• Gralise Oral Tablet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	The patient has experienced an inadequate treatment response or intolerance to immediate-release gabapentin.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **GROWTH HORMONE**

- GenotropinGenotropin MiniQuick

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pediatric patients with closed epiphyses (except in patients with PWS).
Required Medical Information	Pediatric GHD: 1) Younger than 2.5 yrs old, when applicable: a) Pre-treatment (pre-tx) height (ht) more than 2 SD below mean and slow growth velocity. 2) 2.5 yrs old or older: a) Pre-tx 1-year ht velocity more than 2 SD below mean OR b) Pre-tx ht more than 2 SD below mean and 1-year ht velocity more than 1 SD below mean. Pediatric GHD: 1) Failed 2 stimulation tests (peak below 10 ng/mL) prior to starting treatment, OR 2) Pituitary/CNS disorder (eg, genetic defects, CNS tumors, congenital structural abnormalities) and pre-tx IGF-1 more than 2 SD below mean, OR 3) Patient is a neonate or was diagnosed with GHD as a neonate. TS: 1) Confirmed by karyotyping AND 2) Pre-treatment height is less than the 5th percentile for age. SGA: 1) Birth weight (wt) below 2500g at gestational age (GA) more than 37 weeks OR birth wt or length below 3rd percentile for GA or at least 2 SD below mean for GA, AND 2) Did not manifest catch-up growth by age 2. Adult GHD: 1) Failed 2 stimulation tests (peak below 5 ng/mL) or test with Macrilen (peak below 2.8 ng/ml) prior to starting tx, OR 2) Structural abnormality of the hypothalamus/pituitary AND 3 or more pituitary hormone deficiencies, OR 3) Childhood-onset GHD with congenital (genetic or structural) abnormality of the hypothalamus/pituitary/CNS, OR 4) Low pre-tx IGF- 1 and failed 1 stimulation test prior to starting tx.
Age Restrictions	SGA: 2 years of age or older
Prescriber Restrictions	Endocrinologist, pediatric endocrinologist, pediatric nephrologist, infectious disease specialist, gastroenterologist/nutritional support specialist, geneticist.
Coverage Duration	Plan Year
Other Criteria	Renewal for pediatric GHD, TS, SGA, and adult GHD: patient is experiencing improvement.
Indications	All Medically-accepted Indications.
Off Label Uses	

# HAEGARDA

### **Products Affected**

• Haegarda

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For hereditary angioedema (HAE): The requested drug is being used for the prevention of acute angioedema attacks. Patient has HAE with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing OR patient has HAE with normal C1 inhibitor confirmed by laboratory testing. For patients with HAE with normal C1 inhibitor, EITHER 1) Patient tested positive for an F12, angiopoietin-1, or plasminogen gene mutation, OR 2) Patient has a family history of angioedema and the angioedema was refractory to a trial of an antihistamine for at least one month.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

### HARVONI

### **Products Affected**

• Harvoni

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For chronic hepatitis C: Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [Child Turcotte Pugh class B or C]), presence or absence of HIV coinfection, presence or absence of resistance-associated substitutions where applicable, liver and kidney transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current AASLD treatment guidelines.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Criteria applied consistent w/ current AASLD-IDSA guidance. Reminder for 8wk option if appropriate.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# HERCEPTIN

### **Products Affected**

Herceptin Intravenous Solution Reconstituted
 150 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Neoadjuvant therapy for breast cancer: 6 months. Other: Plan Year.
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. For FDA-approved indications and off-label uses that overlap: the patient had an intolerable adverse event to Trazimera and that adverse event was NOT attributed to the active ingredient as described in the prescribing information.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Neoadjuvant treatment for human epidermal growth factor receptor 2 (HER2)- positive breast cancer, recurrent HER2-positive breast cancer, leptomeningeal metastases from breast cancer, HER2-positive esophageal and esophagogastric junction cancer, HER2-positive advanced and recurrent uterine serous carcinoma, HER2-amplified colorectal cancer in combination with pertuzumab or lapatinib.

# **HERCEPTIN HYLECTA**

### **Products Affected**

• Herceptin Hylecta

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Neoadjuvant therapy for breast cancer: 6 months, Other: Plan Year.
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Neoadjuvant treatment for human epidermal growth factor receptor 2 (HER2)- positive breast cancer.

### HERZUMA

### **Products Affected**

• Herzuma

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Neoadjuvant therapy for breast cancer: 6 months. Other: Plan Year.
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. For FDA-approved indications and off-label uses that overlap: the patient had an intolerable adverse event to Trazimera and that adverse event was NOT attributed to the active ingredient as described in the prescribing information.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Neoadjuvant treatment for human epidermal growth factor receptor 2 (HER2)- positive breast cancer, recurrent HER2-positive breast cancer, leptomeningeal metastases from breast cancer, HER2-positive esophageal and esophagogastric junction cancer, HER2-positive advanced and recurrent uterine serous carcinoma, HER2-amplified colorectal cancer in combination with pertuzumab or lapatinib.

# **HETLIOZ**

### **Products Affected**

• Hetlioz

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-24-Hour Sleep-Wake Disorder: 1) For initial therapy and continuation of therapy: a) diagnosis of total blindness in both eyes (e.g., nonfunctioning retinas) and b) unable to perceive light in both eyes, AND 2) If currently on therapy with the requested drug, patient must meet at least one of the following: a) increased total nighttime sleep or b) decreased daytime nap duration. For nighttime sleep disturbances in Smith-Magenis Syndrome (SMS): 1) for initial therapy and continuation of therapy, the patient has a confirmed diagnosis of SMS AND 2) if currently on therapy with the requested drug, the patient experiences improvement in the quality of sleep since starting therapy.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Initiation: 6 Months, Renewal: Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **HRM-ANTICONVULSANTS**

- PHENobarbital Oral Elixir
- PHENobarbital Oral Tablet
- PHENobarbital Sodium Injection

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	This Prior Authorization requirement only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Epilepsy

# **HRM-ANTIPARKINSON**

- Benztropine Mesylate OralTrihexyphenidyl HCl

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	EPS (extrapyramidal symptoms): 1) The patient has not tried the non-HRM alternative drug amantadine AND 2) The patient has a contraindication to the non-HRM alternative drug amantadine AND 3) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient OR 4) The patient has tried the non-HRM alternative drug amantadine AND 5) The patient experienced an inadequate treatment response OR intolerance to the non-HRM alternative drug amantadine AND 6) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient is patient. Parkinson's: 1) The patient has tried two of the following non-HRM alternative drugs: amantadine, carbidopa/levodopa, pramipexole, or ropinirole AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: amantadine, carbidopa/levodopa, pramipexole, or ropinirole AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: amantadine, carbidopa/levodopa, pramipexole, or ropinirole AND 3) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization requirement only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
Indications	All FDA-approved Indications.
Off Label Uses	

# **HRM-CYPROHEPTADINE**

### **Products Affected**

• Cyproheptadine HCI Oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For rhinitis: 1) The patient has tried two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	This Prior Authorization requirement only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) The prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Pruritus, spasticity due to spinal cord injury

# **HRM-DIPYRIDAMOLE**

### **Products Affected**

• Dipyridamole Oral

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization requirement only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.
Indications	All FDA-approved Indications.
Off Label Uses	

## **HRM-GUANFACINE ER**

### **Products Affected**

• GuanFACINE HCI ER

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization requirement only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.
Indications	All FDA-approved Indications.
Off Label Uses	

# **HRM-GUANFACINE IR**

### **Products Affected**

• guanFACINE HCI Oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	This Prior Authorization requirement only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.
Indications	All FDA-approved Indications.
Off Label Uses	

# **HRM-HYDROXYZINE**

- HydrOXYzine HCl Oral SyruphydrOXYzine HCl Oral Tablet
- hydrOXYzine Pamoate Oral Capsule 25 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For anxiety: 1) The patient has tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline, or venlafaxine extended-release AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline, or venlafaxine extended-release AND 3) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient OR 4) The patient has not tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline or venlafaxine extended-release AND 5) The patient has acute anxiety AND 6) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient OR 7) If being requested for pruritus, prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient the benefit of therapy with this prescribed medication outweighs the potential risks for this patient OR 7) If being requested for pruritus, prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization requirement only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
Indications	All FDA-approved Indications.
Off Label Uses	

# HRM-HYDROXYZINE INJ

### **Products Affected**

• HydrOXYzine HCI Intramuscular

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	Alcohol Withdrawal Syndrome: 1) The patient has not tried one of the following alternative drugs: clorazepate or lorazepam AND 2) The patient has a contraindication to one of the following alternative drugs: clorazepate or lorazepam AND 3) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient OR 4) The patient has tried one of the following alternative drugs: clorazepate or lorazepam AND 5) The patient experienced an inadequate treatment response OR intolerance to one of the following alternative drugs: clorazepate or lorazepam AND 6) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. Anxiety: 1) The patient has tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline or venlafaxine extended-release AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline or venlafaxine extended-release AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline or venlafaxine extended-release AND 3) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient OR 4) The patient has not tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline or venlafaxine extended-release AND 3) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient OR 4) The patient has acute anxiety AND 6) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient OR 7) If being requested for nausea/vomiting, prescriber must acknowledge that the benefit of therapy with this pres
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year

PA Criteria	Criteria Details
Other Criteria	This Prior Authorization requirement only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
Indications	All FDA-approved Indications.
Off Label Uses	

## **HRM-HYPNOTICS**

### **Products Affected**

• Zolpidem Tartrate Oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1) The patient has a contraindication to the non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) AND 2) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient OR 3) The non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) has been tried AND 4) The patient experienced an inadequate treatment response OR intolerance to the non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) has been tried and the potential risks for the potential risks for the non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) has been tried AND 4) The patient experienced an inadequate treatment response OR intolerance to the non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) AND 5) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization requirement only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) APPLIES TO GREATER THAN CUMULATIVE 90 DAYS OF THERAPY PER YEAR.
Indications	All FDA-approved Indications.
Off Label Uses	

# **HRM-METHYLDOPA**

### **Products Affected**

• Methyldopa Oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization requirement only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.
Indications	All FDA-approved Indications.
Off Label Uses	

# **HRM-PROMETHAZINE**

#### **Products Affected**

- Promethazine HCI InjectionPromethazine HCI Oral Syrup
- Promethazine HCI Oral Tablet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Rhinitis: 1) The patient has tried two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal AND 3) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient OR 4) The requested drug is being prescribed for urticaria AND 5) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient OR 6) The drug is being requested for antiemetic therapy in postoperative patients or motion sickness AND 7) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient OR 8) The requested drug is being prescribed for any of the following: allergic conjunctivitis, dermatographism, allergic reaction to blood or plasma, sedation, adjunct therapy with analgesics for postoperative pain, angioedema, or adjunct therapy with epinephrine for anaphylaxis after acute symptoms are controlled AND 9) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization requirement only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off Label Uses	

# **HRM-SCOPOLAMINE**

### **Products Affected**

• Scopolamine

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization requirement only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Excessive salivation

# **HRM-SKELETAL MUSCLE RELAXANTS**

### **Products Affected**

• Cyclobenzaprine HCl Oral Tablet 10 MG, 5 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	3 months
Other Criteria	This Prior Authorization requirement only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.
Indications	All FDA-approved Indications.
Off Label Uses	

# **HUMIRA**

### **Products Affected**

- Humira Pediatric Crohns Start Subcutaneous Prefilled Syringe Kit 80 MG/0.8ML, 80 MG/0.8ML & 40MG/0.4ML
- Humira Pen Subcutaneous Pen-Injector Kit
- Humira Pen-CD/UC/HS Starter
- Humira Pen-Pediatric UC Start

- Humira Pen-Ps/UV/Adol HS Start Subcutaneous Pen-Injector Kit 40 MG/0.8ML
- Humira Pen-Psor/Uveit Starter
- Humira Subcutaneous Prefilled Syringe Kit 10 MG/0.1ML, 20 MG/0.2ML, 40 MG/0.4ML, 40 MG/0.8ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	For moderately to severely active rheumatoid arthritis (new starts only): 1) Inadequate response, intolerance or contraindication to methotrexate (MTX) OR 2) Inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis and axial spondyloarthritis (new starts only): Inadequate response to a non-steroidal anti-inflammatory drug (NSAID) trial OR intolerance or contraindication to NSAIDs. For moderate to severe chronic plaque psoriasis (new starts only): 1) At least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) Patient meets any of the following: a) Patient has experienced an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) Patient has severe psoriasis that warrants a biologic DMARD as first-line therapy (i.e. at least 10% of the body surface area (BSA) or crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected). For moderately to severely active Crohn's disease (new starts only): 1) Inadequate response to at least one conventional therapy (e.g., corticosteroids), OR 2) Intolerance or contraindication to conventional therapy. For moderately to severely active ulcerative colitis (new starts only): 1) Inadequate response to at least one conventional therapy (e.g., corticosteroids, aminosalicylates), OR 2) Intolerance or contraindication to conventional therapy.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year

PA Criteria	Criteria Details
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Axial spondyloarthritis.

# **HYPNOTIC BENZODIAZEPINES**

### **Products Affected**

• Temazepam Oral Capsule 15 MG, 7.5 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	<ol> <li>The non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) has been tried AND 2) The patient experienced an inadequate treatment response OR intolerance to the non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) AND 3) The benefit of therapy with this prescribed medication outweighs the potential risk in a patient 65 years of age or older OR</li> <li>The patient has a contraindication to the non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) AND 5) The benefit of therapy with this prescribed medication outweighs the potential risk in a patient 65 years of age or older OR</li> </ol>
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization requirement only applies to patients 65 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) APPLIES TO GREATER THAN CUMULATIVE 90 DAYS OF THERAPY PER YEAR.
Indications	All FDA-approved Indications.
Off Label Uses	

# **IBRANCE**

#### **Products Affected**

• Ibrance

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Unresectable well-differentiated/dedifferentiated liposarcoma, recurrent hormone receptor (HR)-positive human epidermal growth factor receptor 2 (HER2)-negative breast cancer in combination with an aromatase inhibitor or fulvestrant.

# **ICATIBANT**

### **Products Affected**

- Icatibant Acetate
- Sajazir

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For hereditary angioedema (HAE): The requested drug is being used for the treatment of acute angioedema attacks. Patient has hereditary angioedema (HAE) with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing OR patient has hereditary angioedema with normal C1 inhibitor confirmed by laboratory testing. For patients with HAE with normal C1 inhibitor, EITHER 1) Patient tested positive for an F12, angiopoietin-1, or plasminogen gene mutation OR 2) Patient has a family history of angioedema and the angioedema was refractory to a trial of an antihistamine for at least one month.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# ICLUSIG

### **Products Affected**

• Iclusig

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL): diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Follow-up therapy after hematopoietic stem cell transplant (HSCT) for chronic myeloid leukemia (CML) and ALL patients.

# **IDHIFA**

#### **Products Affected**

• IDHIFA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation: 1) patient is 60 years of age or older with newly-diagnosed AML and meets one of the following: a) patient has comorbidities that preclude use of intensive induction chemotherapy, or b) patient declines intensive induction chemotherapy, or b) patient declines intensive induction chemotherapy, OR 2) patient is 60 years of age or older and the requested drug will be used as post-remission therapy following response to previous lower intensity therapy with the same regimen, OR 3) patient has relapsed or refractory AML.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Newly-diagnosed acute myeloid leukemia

### **IMATINIB**

### **Products Affected**

• Imatinib Mesylate

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL): diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene. For CML: patient did not fail (excluding failure due to intolerance) prior therapy with a tyrosine kinase inhibitor. For melanoma: c-Kit mutation is positive.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Desmoid tumors, pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT), chordoma, melanoma, AIDS-related Kaposi sarcoma, and chronic myelomonocytic leukemia.

# **IMBRUVICA**

#### **Products Affected**

• Imbruvica

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For mantle cell lymphoma: 1) the requested drug will be used in a patient who has received at least one prior therapy, OR 2) the requested drug will be used in combination with rituximab as pretreatment to induction therapy with RHyperCVAD (cyclophosphamide, vincristine, doxorubicin, and dexamethasone) regimen. For gastric MALT lymphoma and non-gastric MALT lymphoma: the requested drug will be used as second-line or subsequent therapy. For hairy cell leukemia: the requested drug will be used as a single agent for disease progression. For primary central nervous system lymphoma: 1) the disease is relapsed or refractory and 2) the requested drug is used as a single agent. For nodal marginal zone lymphoma or splenic marginal zone lymphoma: the requested drug will be used as second-line or subsequent therapy. For histologic transformation of marginal zone lymphoma to diffuse large B-cell lymphoma: the requested drug will be used in patients who have received prior chemoimmunotherapy. For diffuse large B-cell lymphoma: the requested drug will be used disease. For post-transplant lymphoma: the requested drug will be used as a single agent and as second-line or subsequent therapy. For follicular lymphoma: the requested drug will be used as second-line or subsequent therapy. For follicular lymphoma: the requested drug will be used as a single agent and as second-line or subsequent therapy. For AIDS-related B-cell lymphoma: the requested drug will be used disease. For post-transplant lymphoproliferative disorders: the requested drug will be used in patients who have received prior chemoimmunotherapy. For high-grade B-cell lymphoma: the requested drug will be used as second-line or subsequent therapy. For follicular lymphoma: the requested drug will be used as a single agent.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	Gastric mucosa-associated lymphoid tissue (MALT) lymphoma, non-gastric MALT lymphoma, hairy cell leukemia, lymphoplasmacytic lymphoma, follicular lymphoma, primary central nervous system lymphoma, AIDS-related B-cell lymphoma, histologic transformation of marginal zone lymphoma to diffuse large B-cell lymphoma, diffuse large B-cell lymphoma, post-transplant lymphoproliferative disorders, high-grade B-cell lymphoma.

## **INCRELEX**

### **Products Affected**

• Increlex

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For growth failure due to severe primary insulin-like growth factor-1 (IGF-1) deficiency or growth hormone gene deletion in patients who have developed neutralizing antibodies to growth hormone, must meet all of the following prior to beginning therapy with the requested drug (new starts only): 1) height 3 or more standard deviations below the mean for children of the same age and gender AND 2) basal IGF-1 level 3 or more standard deviations below the mean for children of the same age and gender AND 3) provocative growth hormone test showing a normal or elevated growth hormone level.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	For renewal, patient is experiencing improvement.
Indications	All FDA-approved Indications.
Off Label Uses	

### INGREZZA

#### **Products Affected**

• Ingrezza

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# INLYTA

### **Products Affected**

• Inlyta

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For renal cell carcinoma, the disease is relapsed, metastatic, or unresectable.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Papillary, Hurthle cell, or follicular thyroid carcinoma.

# INQOVI

### **Products Affected**

• Inqovi

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## **INREBIC**

### **Products Affected**

• Inrebic

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **IR BEFORE ER**

#### **Products Affected**

- Hysingla ER
- Methadone HCI Intensol
- Methadone HCI Oral Solution
- Methadone HCI Oral Tablet

 Morphine Sulfate ER Oral Tablet Extended Release

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1) The requested drug is being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through palliative care OR 2) The requested drug is being prescribed for pain severe enough to require daily, around-the-clock, long-term treatment in a patient who has been taking an opioid AND 3) The patient can safely take the requested dose based on their history of opioid use [Note: This drug should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain.] AND 4) The patient has been evaluated and the patient will be monitored for the development of opioid use disorder AND 5) This request is for continuation of therapy for a patient who has been receiving an extended-release opioid agent for at least 30 days OR the patient has taken an immediate-release opioid for at least one week.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# IRESSA

#### **Products Affected**

• Iressa

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For NSCLC (including brain metastases from NSCLC), patient has a sensitizing EGFR mutation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Recurrent or advanced non-small cell lung cancer (NSCLC), brain metastases from epidermal growth factor receptor (EGFR) mutation-positive NSCLC.

# **ISOTRETINOIN**

#### **Products Affected**

- Accutane Oral Capsule 20 MG, 30 MG, 40 MG
- Amnesteem
- Claravis
- ISOtretinoin Oral Capsule 10 MG, 20 MG, 30 MG,

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Refractory acne vulgaris, severe refractory rosacea, neuroblastoma, cutaneous T-cell lymphoma (CTCL) (e.g., mycosis fungoides, Sezary syndrome), high risk for developing skin cancer (squamous cell cancers), transient acantholytic dermatosis (Grover's Disease), keratosis follicularis (Darier Disease), lamellar ichthyosis, pityriasis rubra pilaris.

- 40 MG
- Myorisan
- Zenatane

# ITRACONAZOLE

### **Products Affected**

• Itraconazole Oral Capsule

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	If for the treatment of onychomycosis due to tinea, the diagnosis has been confirmed by a fungal diagnostic test.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	6 months
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Coccidioidomycosis, Cryptococcosis, Microsporidiosis, Penicilliosis, Sporotrichosis, Pityriasis versicolor/Tinea versicolor, Tinea corporis/Tinea cruris, Tinea capitis, Tinea manuum/Tinea pedis.

# **IVERMECTIN TAB**

### **Products Affected**

• Ivermectin Oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	The requested drug is not being prescribed for the prevention or treatment of coronavirus disease 2019 (COVID-19).
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	1 month
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Ascariasis, Cutaneous Iarva migrans, Mansonelliasis, Scabies, Gnathostomiasis, Pediculosis

#### **Products Affected**

- Bivigam Intravenous Solution 5 GM/50ML
- Flebogamma DIF Intravenous Solution 10 GM/100ML, 10 GM/200ML, 2.5 GM/50ML, 20 GM/200ML, 20 GM/400ML, 5 GM/100ML, 5 GM/50ML
- Gammagard
- Gammagard S/D Less IgA
- Gammaked Injection Solution 1 GM/10ML, 10

GM/100ML, 20 GM/200ML, 5 GM/50ML

- Gammaplex Intravenous Solution 10 GM/100ML, 10 GM/200ML, 20 GM/200ML, 20 GM/400ML, 5 GM/100ML, 5 GM/50ML
- Gamunex-C
- Octagam
- Panzyga
- Privigen

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For B-cell chronic lymphocytic leukemia (CLL): 1) serum IgG less than 500 mg/dL OR 2) a history of recurrent bacterial infections. For bone marrow transplant/hematopoietic stem cell transplant (BMT/HSCT): 1) IVIG is requested within the first 100 days post-transplant OR 2) serum IgG less than 400 mg/dL. For pediatric human immunodeficiency virus (HIV) infection: 1) Serum IgG less than 400 mg/dL, OR 2) History of recurrent bacterial infections. For dermatomyositis and polymyositis: 1) at least one standard first-line treatment (corticosteroids or immunosuppressants) has been tried but was unsuccessful or not tolerated OR 2) patient is unable to receive standard therapy because of a contraindication or other clinical reason. For pure red cell aplasia (PRCA): PRCA is secondary to parvovirus B19 infection.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
Indications	All Medically-accepted Indications.
Off Label Uses	

# **JAKAFI**

### **Products Affected**

• Jakafi

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For polycythemia vera: patients with inadequate response or intolerance to interferon therapy or hydroxyurea. For pediatric acute lymphoblastic leukemia: patient has a cytokine receptor-like factor 2 (CRLF2) mutation or a mutation associated with activation of the Janus kinase/signal transducers and activators of transcription (JAK/STAT) pathway.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Low-risk myelofibrosis, accelerated phase myelofibrosis, blast phase myelofibrosis/acute myeloid leukemia, or pediatric acute lymphoblastic leukemia (ALL).

# JUXTAPID

### **Products Affected**

Juxtapid Oral Capsule 10 MG, 20 MG, 30 MG, 5 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	For initiation of therapy to treat homozygous familial hypercholesterolemia: 1) Patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) confirmed by genetic analysis or clinical criteria (see Other Criteria), AND 2) Prior to initiation of treatment with the requested drug, patient is/was receiving a combination lipid-lowering regimen consisting of at least 2 of the following treatment options: high-intensity statin or experienced statin-intolerance, fibrate, bile acid sequestrant, ezetimibe, or niacin, at maximally tolerated doses or at the maximum doses approved by the Food and Drug Administration (FDA), AND 3) Prior to initiation of treatment with the requested drug, patient is/was experiencing an inadequate response to such combination regimen as demonstrated by treated low-density lipoprotein cholesterol (LDL-C) greater than 100 mg/dL (or greater than 70 mg/dL with clinical atherosclerotic cardiovascular disease). For renewal of therapy to treat HoFH: 1) Patient meets all initial criteria AND 2) Has responded to therapy as demonstrated by a reduction in LDL-C.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year

PA Criteria	Criteria Details
Other Criteria	Diagnosis of HoFH must be confirmed by one of the following: 1) Genetic diagnosis: Mutations in both alleles at LDL receptor, apolipoprotein B (ApoB), proprotein convertase subtilisin/kexin type 9 (PCSK9), or LDL receptor adaptor protein/ARH gene locus, OR 2) Clinical diagnosis: Untreated LDL-C greater than 500 mg/dL or unknown untreated LDL-C with treated LDL-C greater than 300 mg/dL plus one of the following: a) Tendon or cutaneous xanthomas at age 10 or younger, or b) Diagnosis of familial hypercholesterolemia (FH) by genetic analysis, Simon-Broome Diagnostic Criteria or Dutch Lipid Clinic Network Criteria in both parents, or c) Evidence of FH in both parents with a history including any of the following: Total cholesterol greater than or equal to 310 mg/dL, premature atherosclerotic cardiovascular disease (ASCVD) [before 55 years in men and 60 years in women], tendon xanthoma, or sudden premature cardiac death. Diagnosis of FH must be confirmed by one of the following: 1) Genetic diagnosis: An LDL-receptor mutation, familial defective apo B-100, or a PCSK9 gain-of-function mutation, or 2) Simon-Broome Diagnostic Criteria for FH: Total cholesterol greater than 190 mg/dL, plus tendon xanthoma in patient, first-degree (parent, sibling or child) or second-degree relative (grandparent, uncle or aunt), or family history of myocardial infarction in a first degree relative 60 years of age or younger or in a second degree relative 50 years of age or younger, or total cholesterol greater than 290 mg/dL in an adult first or second degree relative, or total cholesterol greater than 290 mg/dL in a child, brother, or sister aged younger than 16 years, or 3) Dutch Lipid Clinic Network Criteria for FH: Total score greater than 5 points.
Indications	All FDA-approved Indications.
Off Label Uses	

# **KALYDECO**

### **Products Affected**

• Kalydeco

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For cystic fibrosis (CF): The patient has one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data.
Age Restrictions	4 months of age or older
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	The requested medication will not be used in combination with other medications containing ivacaftor.
Indications	All FDA-approved Indications.
Off Label Uses	

# KANJINTI

### **Products Affected**

• Kanjinti

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Neoadjuvant therapy for breast cancer: 6 months. Other: Plan Year.
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. For FDA-approved indications and off-label uses that overlap: the patient had an intolerable adverse event to Trazimera and that adverse event was NOT attributed to the active ingredient as described in the prescribing information.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Neoadjuvant treatment for human epidermal growth factor receptor 2 (HER2)- positive breast cancer, recurrent HER2-positive breast cancer, leptomeningeal metastases from breast cancer, HER2-positive esophageal and esophagogastric junction cancer, HER2-positive advanced and recurrent uterine serous carcinoma, HER2-amplified colorectal cancer in combination with pertuzumab or lapatinib.

# **KETOCONAZOLE**

### **Products Affected**

Ketoconazole Oral

PA Criteria	Criteria Details
Exclusion Criteria	Acute or chronic liver disease. Current use with dofetilide, quinidine, pimozide, cisapride, methadone, disopyramide, dronedarone, ranolazine, ergot alkaloids, alprazolam or simvastatin.
Required Medical Information	1) Patient has one of the following diagnoses: blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, or paracoccidioidomycosis, OR 2) The requested drug is being prescribed for a patient with Cushing's syndrome who cannot tolerate surgery or surgery has not been curative.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Cushing's syndrome.

# **KEYTRUDA**

### **Products Affected**

• Keytruda Intravenous Solution

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For cutaneous melanoma: Disease is unresectable or metastatic. For adjuvant treatment of melanoma: 1) The disease has spread to lymph nodes and 2) The requested drug will be used following complete lymph node resection or complete resection of metastatic disease. For NSCLC: Patient must meet any of the following conditions: 1) Will be used in combination with pemetrexed and carboplatin or cisplatin following epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) therapy (if EGFR or ALK positive) for recurrent, advanced, or metastatic nonsquamous NSCLC, OR 2) Will be used with carboplatin or cisplatin and paclitaxel or paclitaxel protein-bound for recurrent, advanced, or metastatic squamous NSCLC, OR 3) Will be used as a single agent for recurrent, advanced, or metastatic NSCLC expressing programmed death ligand 1 (PD-L1) (Tumor Proportion Score [TPS] greater than or equal to 1%) following EGFR or ALK therapy (if EGFR or ALK positive), OR 4) Will be used for continuation maintenance therapy for recurrent, advanced or metastatic disease. For head and neck squamous cell carcinoma: Disease is unresectable, metastatic, or second primary. For classical Hodgkin lymphoma: The disease is relapsed or refractory. For urothelial carcinoma (other than non-muscle invasive bladder cancer [NMIBC] with carcinoma in situ [CIS]): 1) Patient is not eligible for cisplatin and tumor expresses PD-L1 (Combined Positive Score [CPS] greater than or equal to 10, OR 2) Patient is not eligible for any platinum-containing chemotherapy, OR 3) Disease has progressed during, following, or within 12 months of neoadjuvant or adjuvant platinum therapy. For colorectal cancer: 1) Disease is unresectable or metastatic, AND 2) Tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).
Age Restrictions	
Prescriber Restrictions	

PA Criteria	Criteria Details
Coverage Duration	Plan Year
Other Criteria	For solid tumors (including Ewing sarcoma, osteosarcoma, adrenal gland tumors, penile cancer): 1) Disease is unresectable or metastatic, AND 2) Tumor is MSI-H or dMMR or tumor mutational burden-high (greater than or equal to 10 mutations per megabase), AND 3) Disease has progressed following prior treatment and patient has no satisfactory alternative treatment options. For gastric, esophagogastric junction, and esophageal cancer: 1) Member is not a surgical candidate or disease is recurrent, locally advanced, or metastatic, AND 2) Tumor is MSI-H or dMMR OR tumor expresses PD-L1 (CPS greater than or equal to 1) OR the requested drug will be used in combination with chemotherapy. For cervical cancer: Disease is recurrent or metastatic AND one of the following: 1) Tumor is MSI-H or dMMR, OR 2) Tumor expresses PD-L1 (CPS greater than or equal to 1) and disease has progressed on or after chemotherapy. For primary mediastinal large B-cell lymphoma: Disease is relapsed or refractory. For hepatocellular carcinoma: Patient was previously treated with sorafenib. For kidney cancer: The requested drug will be used in combination with axitinib or lenvatinib. For small cell lung cancer: Disease is relapsed, primary progressive, or metastatic. For CNS brain metastases: The requested drug will be used for treatment of brain metastases in patients with melanoma or NSCLC.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer, uveal melanoma, Ewing sarcoma, osteosarcoma, testicular cancer, anal carcinoma, adrenal gland tumors, penile cancer, central nervous system (CNS) brain metastases in patients with melanoma or non-small cell lung cancer (NSCLC), pancreatic adenocarcinoma, hepatobiliary cancers (extrahepatic cholangiocarcinoma, intrahepatic cholangiocarcinoma, gallbladder cancer), malignant pleural mesothelioma, vulvar cancer, thymic carcinoma, Mycosis Fungoides/Sezary syndrome, T-cell lymphomas (extranodal natural killer [NK]/T- cell lymphoma, nasal type), gestational trophoblastic neoplasia, poorly differentiated neuroendocrine carcinoma/large or small cell carcinoma.

# **KISQALI**

- Kisqali (200 MG Dose) Kisqali (400 MG Dose) ٠
- ٠
- Kisqali (600 MG Dose)
- Kisqali Femara (400 MG Dose) ٠

- Kisqali Femara (600 MG Dose)Kisqali Femara(200 MG Dose)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	For treatment of breast cancer using Kisqali (ribociclib) in combination with an aromatase inhibitor or Kisqali Femara Co-Pack (ribociclib and letrozole) as initial endocrine-based therapy, one the following criteria must be met: 1) the patient is pre- or peri-menopausal, OR 2) the patient is postmenopausal and the patient has experienced disease progression on Ibrance (palbociclib) or Verzenio (abemaciclib) or an intolerable adverse event to Ibrance (palbociclib) AND Verzenio (abemaciclib). For treatment of breast cancer with Kisqali (ribociclib) in combination with fulvestrant, one of the following criteria must met: 1) the requested drug is being used with fulvestrant as initial endocrine-based therapy in a postmenopausal patient, OR 2) the requested drug is being used following disease progression on Ibrance (palbociclib) OR Verzenio (abemaciclib) OR an intolerable adverse event to Ibrance (palbociclib) AND terzenio (abemaciclib).
Indications	All FDA-approved Indications.
Off Label Uses	

## KORLYM

### **Products Affected**

• Korlym

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **KUVAN**

- Sapropterin Dihydrochloride Oral Packet
  Sapropterin Dihydrochloride Oral Tablet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For phenylketonuria: For patients who have not yet received a therapeutic trial of the requested drug, the patient's pretreatment, including before dietary management, phenylalanine level is greater than 6 mg/dL (360 micromol/L). For patients who completed a therapeutic trial of the requested drug, the patient must have experienced a reduction in blood phenylalanine level of greater than or equal to 30 percent from baseline OR the patient has demonstrated an improvement in neuropsychiatric symptoms.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Initial: 2 months. All others: Plan Year.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## **KYNMOBI**

## **Products Affected**

• Kynmobi

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# LENVIMA

- Lenvima (10 MG Daily Dose)
- Lenvima (12 MG Daily Dose)
- Lenvima (14 MG Daily Dose)
- Lenvima (18 MG Daily Dose)

- Lenvima (20 MG Daily Dose)
- Lenvima (24 MG Daily Dose)
- Lenvima (4 MG Daily Dose)
- Lenvima (8 MG Daily Dose)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For differentiated thyroid cancer (follicular, papillary, or Hurthle cell): disease is radioactive iodine-refractory and unresectable, locally recurrent, or metastatic. For hepatocellular carcinoma: disease is unresectable or inoperable, local, metastatic or with extensive liver tumor burden. For renal cell carcinoma: disease is advanced or relapsed.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Medullary thyroid carcinoma, anaplastic thyroid carcinoma

# **LIDOCAINE PATCHES**

## **Products Affected**

• Lidocaine External Patch 5 %

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Pain associated with diabetic neuropathy, pain associated with cancer-related neuropathy (including treatment-related neuropathy [e.g., neuropathy associated with radiation treatment or chemotherapy]).

# LONSURF

#### **Products Affected**

• Lonsurf

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For colorectal cancer: The disease is unresectable advanced or metastatic. For gastric or gastroesophageal junction adenocarcinoma, all of the following criteria must be met: 1) The disease is unresectable locally advanced, recurrent, or metastatic, and 2) The patient has been previously treated with at least two prior lines of chemotherapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# LORBRENA

#### **Products Affected**

• Lorbrena

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Repressor of silencing (ROS)-1 rearrangement-positive metastatic NSCLC following progression on crizotinib, entrectinib, or ceritinib.

# LUMAKRAS

## **Products Affected**

• Lumakras

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# LUMIZYME

## **Products Affected**

• Lumizyme

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Pompe disease, the diagnosis was confirmed by an enzyme assay demonstrating a deficiency of acid alpha-glucosidase (GAA) enzyme activity or by genetic testing.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# LUPRON

### **Products Affected**

- Leuprolide Acetate Injection
- Lupron Depot (1-Month) Intramuscular Kit 3.75
   MG
- Lupron Depot (3-Month) Intramuscular Kit 11.25

## MG

- Lupron Depot-Ped (1-Month)
- Lupron Depot-Ped (3-Month)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For central precocious puberty (CPP), patients not currently receiving therapy must meet all of the following criteria: 1) Diagnosis of CPP confirmed by: a) a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test OR a pubertal level of a third generation luteinizing hormone (LH) assay AND b) Assessment of bone age versus chronological age, and 2) The onset of secondary sexual characteristics occurred prior to 8 years of age for female patients OR prior to 9 years of age for male patients. For uterine fibroids, patient must meet one of the following: 1) Diagnosis of anemia (eg, hematocrit less than or equal to 30 percent and/or hemoglobin less than or equal to 10g/dL), OR 2) the requested medication will be used prior to surgery for uterine fibroids.
Age Restrictions	CPP: Patient must be less than 12 years old if female and less than 13 years old if male.
Prescriber Restrictions	
Coverage Duration	Fibroids: 3 months (mo), max 6 mo total. Endometriosis: 6 mo, max 12 mo total. Others: Plan Year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# LYNPARZA

## **Products Affected**

• Lynparza Oral Tablet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For breast cancer the disease must be: 1) BRCA 1/2-germline mutated, and 2) recurrent or metastatic
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Recurrent HER2-negative, BRCA 1/2-germline mutated breast cancer, recurrent or metastatic HER2-positive, BRCA 1/2-germline mutated breast cancer

# LYRICA CR

## **Products Affected**

• Lyrica CR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	The patient has experienced an inadequate treatment response, intolerance, or contraindication to gabapentin.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# MAVYRET

## **Products Affected**

• Mavyret Oral Tablet

PA Criteria	Criteria Details
Exclusion Criteria	Decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh class B or C).
Required Medical Information	For chronic hepatitis C: Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [Child Turcotte Pugh class B or C]), presence or absence of HIV coinfection, presence or absence of resistance-associated substitutions where applicable, liver and kidney transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current AASLD treatment guidelines.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Criteria will be applied consistent with current AASLD-IDSA guidance.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# MEGESTROL

## **Products Affected**

Megestrol Acetate Oral Suspension 625 MG/5ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## **MEKINIST**

#### **Products Affected**

• Mekinist

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For brain metastasis from melanoma or for adjuvant treatment of melanoma, the tumor is positive for a BRAF V600 activating mutation and the requested drug will be used in combination with dabrafenib. For unresectable or metastatic melanoma, the tumor is positive for a BRAF V600 activating mutation and the requested drug will be used as a single agent or in combination with dabrafenib. For non-small cell lung cancer or for anaplastic thyroid cancer, the tumor is positive for a BRAF V600E mutation and the requested drug will be used in combination with dabrafenib. For uveal melanoma, the requested drug will be used in combination with dabrafenib. For uveal melanoma, the requested drug will be used as a single agent. For unresectable advanced or metastatic colorectal cancer, the tumor is positive for a BRAF V600E activating mutation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Brain metastases from melanoma, uveal melanoma, colorectal cancer.

# **MEKTOVI**

#### **Products Affected**

• Mektovi

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For colorectal cancer, patient must meet all of the following criteria: 1) The requested drug is used in combination with encorafenib, 2) Tumor is positive for BRAF V600E mutation, and 3) The requested drug will be used as subsequent therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Colorectal cancer

# MEMANTINE

- Memantine HCI ER
- Memantine HCI Oral Solution 2 MG/ML
- Memantine HCI Oral Tablet 10 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	This edit only applies to patients less than 30 years of age.
Indications	All FDA-approved Indications.
Off Label Uses	

# **METHYLPHENIDATE**

#### **Products Affected**

- Dexmethylphenidate HCI ٠
- Metadate ER Oral Tablet Extended Release 20 ٠ MG
- Methylphenidate HCI ER Oral Tablet Extended ٠

Release 10 MG, 20 MG

Methylphenidate HCl Oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1) The patient has a diagnosis of Attention-Deficit Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD) OR 2) The patient has the diagnosis of narcolepsy confirmed by a sleep study and the request is not for a dexmethylphenidate product OR 3) The requested drug is being prescribed for the treatment of cancer-related fatigue after other causes of fatigue have been ruled out.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# MIGLUSTAT

## **Products Affected**

• Miglustat

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	For Gaucher disease, the diagnosis was confirmed by an enzyme assay demonstrating a deficiency of beta-glucocerebrosidase enzyme activity or by genetic testing.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# MODAFINIL

#### **Products Affected**

Modafinil

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1) Diagnosis is narcolepsy confirmed by sleep lab evaluation OR 2) Diagnosis is shift work disorder (SWD) OR 3) Diagnosis is obstructive sleep apnea (OSA) confirmed by polysomnography.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## MONJUVI

## **Products Affected**

• Monjuvi

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## **MVASI**

## **Products Affected**

• Mvasi

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	Breast cancer, central nervous system (CNS) tumor types: adult low-grade (WHO Grade II) infiltrative supratentorial astrocytoma/oligodendroglioma, adult intracranial and spinal ependymoma, anaplastic gliomas, adult medulloblastoma, primary central nervous system lymphoma, meningiomas, limited and extensive brain metastases, leptomeningeal metastases and metastatic spine tumors, malignant pleural mesothelioma, epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer, including the following cancer types: carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma, mucinous carcinoma, grade 1 endometrioid carcinoma, low-grade serous carcinoma, ovarian borderline epithelial tumors (low malignant potential) with invasive implants, and malignant sex cord-stromal tumors, soft tissue sarcoma types: angiosarcoma and solitary fibrous tumor/hemangiopericytoma, AIDS-related Kaposi sarcoma, uterine cancer, endometrial cancer, vulvar cancer, and ophthalmic-related disorders: diabetic macular edema, neovascular (wet) age-related macular degeneration including polypoidal choroidopathy and retinal angiomatous proliferation subtypes, macular edema following retinal vein occlusion, proliferative diabetic retinopathy, choroidal neovascularization, neovascular glaucoma and retinopathy of prematurity, hepatocellular carcinoma.

# NAGLAZYME

## **Products Affected**

• Naglazyme

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For mucopolysaccharidosis VI disease, the diagnosis was confirmed by an enzyme assay demonstrating a deficiency of N-acetylgalactosamine 4-sulfatase (arylsulfatase B) enzyme activity or by genetic testing.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## NATPARA

#### **Products Affected**

• Natpara

PA Criteria	Criteria Details
Exclusion Criteria	Acute postsurgical hypoparathyroidism (within 6 months of surgery) and expected recovery from the hypoparathyroidism.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## **NERLYNX**

### **Products Affected**

• Nerlynx

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **NEXAVAR**

#### **Products Affected**

• NexAVAR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For thyroid carcinoma: Histology is follicular, papillary, Hurthle cell or medullary. For acute myeloid leukemia, any of the following criteria must be met: 1) The requested drug is used in combination with azactidine or decitabine for low- intensity treatment induction or post-remission therapy AND the patient is 60 years of age or older with FLT3-ITD mutation, OR 2) The disease is relapsed/refractory AND the requested drug is a component of repeating the initial successful induction if late relapse (greater than or equal to 12 months), OR 3) The disease is relapsed/refractory AND the requested drug is used in combination with azactidine or decitabine if the patient is FLT3-ITD mutation positive.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Acute myeloid leukemia, soft tissue sarcoma (angiosarcoma, desmoid tumors/aggressive fibromatosis, solitary fibrous tumor, and hemangiopericytoma subtypes), gastrointestinal stromal tumor, medullary thyroid carcinoma, osteosarcoma, recurrent chordoma, epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer.

## **NINLARO**

#### **Products Affected**

• Ninlaro

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For multiple myeloma: The requested drug will be used in combination with lenalidomide and dexamethasone OR pomalidomide and dexamethasone OR dexamethasone OR cyclophosphamide and dexamethasone OR as a single agent.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Systemic light chain amyloidosis.

# NITISINONE

#### **Products Affected**

• Nitisinone

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For hereditary tyrosinemia type 1: Diagnosis of hereditary tyrosinemia type 1 is confirmed by one of the following: 1) biochemical testing (e.g., detection of succinylacetone in urine) or 2) DNA testing (mutation analysis).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **NORTHERA**

- DroxidopaNorthera

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For neurogenic orthostatic hypotension (NOH): Prior to initial therapy, patient has a persistent, consistent decrease in systolic blood pressure of at least 20 mmHg OR decrease in diastolic blood pressure of at least 10 mmHg within 3 minutes of standing. For continuation of therapy for NOH, patient must experience a sustained decrease in dizziness. For both initial and continuation of therapy for NOH, the requested drug will be used for patients with neurogenic orthostatic hypotension associated with one of the following diagnoses: 1) Primary autonomic failure due to Parkinson's disease, multiple system atrophy, or pure autonomic failure, OR 2) Dopamine beta hydroxylase deficiency, OR 3) Non- diabetic autonomic neuropathy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# NUBEQA

## **Products Affected**

• Nubeqa

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **NUEDEXTA**

## **Products Affected**

• Nuedexta

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# NUPLAZID

- Nuplazid Oral CapsuleNuplazid Oral Tablet 10 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For hallucinations and delusions associated with Parkinson's disease psychosis, the diagnosis of Parkinson's disease must be made prior to the onset of psychotic symptoms.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# OCTREOTIDE

- Octreotide Acetate Injection Solution 100 MCG/ML, 1000 MCG/ML, 200 MCG/ML, 50 MCG/ML, 500 MCG/ML
- Octreotide Acetate Subcutaneous

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For acromegaly (initial): 1) Patient has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range, and 2) Patient had an inadequate or partial response to surgery or radiotherapy OR there is a clinical reason for why the patient has not had surgery or radiotherapy.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	For acromegaly (continuation of therapy): patient's IGF-1 level has decreased or normalized since initiation of therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Meningiomas, thymomas and thymic carcinomas, neuroendocrine tumors (NETs) of the gastrointestinal (GI) tract, lung, thymus (carcinoid tumors) or unresected primary gastrinoma, NETs of the pancreas, and pheochromocytoma/paraganglioma.

# **ODOMZO**

#### **Products Affected**

• Odomzo

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# OFEV

### **Products Affected**

• Ofev

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# OGIVRI

### **Products Affected**

• Ogivri

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Neoadjuvant therapy for breast cancer: 6 months. Other: Plan Year.
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. For FDA-approved indications and off-label uses that overlap: the patient had an intolerable adverse event to Trazimera and that adverse event was NOT attributed to the active ingredient as described in the prescribing information.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Neoadjuvant treatment for human epidermal growth factor receptor 2 (HER2)- positive breast cancer, recurrent HER2-positive breast cancer, leptomeningeal metastases from breast cancer, HER2-positive esophageal and esophagogastric junction cancer, HER2-positive advanced and recurrent uterine serous carcinoma, HER2-amplified colorectal cancer in combination with pertuzumab or lapatinib.

# **OMNIPOD**

### **Products Affected**

- OmniPod 5 Pack
- OmniPod Dash 5 Pack Pods
- OmniPod Starter

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1) The patient has diabetes requiring insulin management with multiple daily injections AND 2) The patient is self-testing glucose levels 4 or more times per day AND 3) The patient has experienced any of the following with the current diabetes regimen: inadequate glycemic control, recurrent hypoglycemia, wide fluctuations in blood glucose, dawn phenomenon with persistent severe early morning hyperglycemia, severe glycemic excursions.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	For continuation of therapy with an insulin pump, the patient has stable or improved glycemic control.
Indications	All FDA-approved Indications.
Off Label Uses	

# **ONTRUZANT**

#### **Products Affected**

• Ontruzant

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Neoadjuvant therapy for breast cancer: 6 months. Other: Plan Year.
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. For FDA-approved indications and off-label uses that overlap: the patient had an intolerable adverse event to Trazimera and that adverse event was NOT attributed to the active ingredient as described in the prescribing information.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Neoadjuvant treatment for human epidermal growth factor receptor 2 (HER2)- positive breast cancer, recurrent HER2-positive breast cancer, leptomeningeal metastases from breast cancer, HER2-positive esophageal and esophagogastric junction cancer, HER2-positive advanced and recurrent uterine serous carcinoma, HER2-amplified colorectal cancer in combination with pertuzumab or lapatinib.

# **ONUREG**

### **Products Affected**

• Onureg

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## **OPSUMIT**

### **Products Affected**

• Opsumit

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	Pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): Diagnosis was confirmed by right heart catheterization. For PAH new starts only: 1) Pretreatment mean pulmonary arterial pressure is greater than or equal to 25 mmHg, 2) Pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, and 3) Pretreatment pulmonary vascular resistance is greater than 3 Wood units.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **ORAL-INTRANASAL FENTANYL**

### **Products Affected**

• FentaNYL Citrate Buccal Lozenge On A Handle

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1) The requested drug is indicated for the treatment of breakthrough CANCER- related pain only. The requested drug is being prescribed for the management of breakthrough pain in a CANCER patient who is currently receiving around-the- clock opioid therapy for underlying CANCER pain. [Note: Ensure that the patient is opioid tolerant. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine per day, at least 25 mcg per hour of transdermal fentanyl, at least 30 mg of oral oxycodone per day, at least 60 mg oral hydrocodone per day, at least 8 mg of oral hydromorphone per day, at least 25 mg oral oxymorphone per day, or an equianalgesic dose of another opioid medication daily for a week or longer.] AND 2) The International Classification of Diseases (ICD) diagnosis code provided supports the CANCER-RELATED diagnosis. [Note: For drug coverage approval, ICD diagnosis code provided MUST support the CANCER-RELATED diagnosis.]
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# ORGOVYX

### **Products Affected**

• Orgovyx

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## ORKAMBI

#### **Products Affected**

• Orkambi

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For cystic fibrosis (CF): The patient is positive for the F508del mutation on both alleles of the cystic fibrosis transmembrane conductance regulator (CFTR) gene.
Age Restrictions	2 years of age or older
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	For cystic fibrosis (CF): The requested medication will not be used in combination with other medications containing ivacaftor.
Indications	All FDA-approved Indications.
Off Label Uses	

## **OSPHENA**

### **Products Affected**

• Osphena

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# OXANDROLONE

### **Products Affected**

• Oxandrolone Oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	6 months
Other Criteria	Coverage will be denied if request is for an indication excluded from Part D.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Cachexia associated with AIDS (HIV wasting) or to enhance growth in patients with Turner's Syndrome.

### PANRETIN

#### **Products Affected**

• Panretin

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Topical treatment of cutaneous lesions in patients with non-AIDS-related Kaposi sarcoma

# PEGASYS

### **Products Affected**

- Pegasys Subcutaneous SolutionPegasys Subcutaneous Solution Prefilled Syringe

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For chronic hepatitis C (CHC): CHC infection confirmed by presence of HCV RNA in serum prior to starting treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [Child Turcotte Pugh class B or C]), presence or absence of HIV coinfection, presence or absence of resistance-associated substitutions where applicable, liver and kidney transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current AASLD- IDSA treatment guidelines.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	HCV=Criteria will be applied consistent with current AASLD-IDSA guidance. HBV=48 wks. Other=Plan Yr
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Myeloproliferative neoplasm (essential thrombocythemia, polycythemia vera, primary myelofibrosis and post-polycythemia vera or post-essential thrombocythemia myelofibrosis), systemic mastocytosis.

## PEMAZYRE

#### **Products Affected**

• Pemazyre

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# PHENYLBUTYRATE

### **Products Affected**

- Sodium Phenylbutyrate Oral Powder 3 GM/TSPSodium Phenylbutyrate Oral Tablet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For urea cycle disorder: Diagnosis of urea cycle disorder (UCD) was confirmed by enzymatic, biochemical or genetic testing.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## **PHESGO**

### **Products Affected**

• Phesgo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Neoadjuvant therapy for breast cancer: 6 months. Other: Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **PIQRAY**

### **Products Affected**

- Piqray (200 MG Daily Dose)Piqray (250 MG Daily Dose)
- Piqray (300 MG Daily Dose)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Recurrent hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated breast cancer in combination with fulvestrant.

## POMALYST

### **Products Affected**

Pomalyst

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For multiple myeloma: The patient has previously received at least two prior therapies for multiple myeloma, including an immunomodulatory agent AND a proteasome inhibitor. For Kaposi sarcoma, patient meets one of the following: 1) patient has acquired immunodeficiency syndrome (AIDS), or 2) patient is negative for human immunodeficiency virus (HIV).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Systemic light chain amyloidosis, primary central nervous system (CNS) lymphoma.

# PRALUENT

### **Products Affected**

• Praluent Subcutaneous Solution Auto-Injector

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# PROMACTA

#### **Products Affected**

• Promacta

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For chronic or persistent immune thrombocytopenia (ITP): 1) For new starts: a) Patient has had an inadequate response or is intolerant to prior therapy such as corticosteroids or immunoglobulins, AND b) Untransfused platelet (plt) count at any point prior to the initiation of the requested medication is less than 30,000/mcL OR 30,000-50,000/mcL with symptomatic bleeding or risk factor(s) for bleeding. 2) For continuation of therapy, plt count response to the requested drug: a) Current plt count is less than or equal to 200,000/mcL OR b) Current plt count is greater than 200,000/mcL and dosing will be adjusted to a plt count sufficient to avoid clinically important bleeding. For thrombocytopenia associated with chronic hepatitis C: 1) For new starts: the requested drug is used for initiation and maintenance of interferon-based therapy. 2) For continuation of therapy: patient is receiving interferon-based therapy. For severe aplastic anemia (AA): For continuation of therapy following the initial 6 month approval for severe aplastic anemia: The patient must meet one of the following: 1) Current plt count is 50,000-200,000/mcL OR 2) Current plt count is less than 50,000/mcL and patient has not received appropriately titrated therapy for at least 16 weeks, OR 3) Current plt count is less than 50,000/mcL and patient, OR 4) Current plt count is greater than 200,000/mcL and patient plt count is less than 50,000/mcL and patient plt c
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	HCV: 6mo, ITP/AA initial: 6mo, ITP reauth: Plan Year, AA reauth: APR-Plan Year, IPR-16 wks
Other Criteria	APR: adequate platelet response (greater than 50,000/mcL), IPR: inadequate platelet response (less than 50,000/mcL)
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off Label Uses	

## PULMOZYME

### **Products Affected**

• Pulmozyme

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For cystic fibrosis: Diagnosis of cystic fibrosis was confirmed by appropriate diagnostic or genetic testing.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
Indications	All FDA-approved Indications.
Off Label Uses	

# QINLOCK

### **Products Affected**

Qinlock

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **QUETIAPINE XR**

### **Products Affected**

• QUEtiapine Fumarate ER

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For schizophrenia, acute treatment of manic or mixed episodes associated with bipolar I disorder, both as monotherapy and as an adjunct to lithium or divalproex, the acute treatment of depressive episodes associated with bipolar disorder, maintenance treatment of bipolar I disorder, as an adjunct to lithium or divalproex, adjunctive treatment of major depressive disorder, or maintenance monotherapy treatment in bipolar I disorder: The patient has had an inadequate treatment response, intolerance or contraindication to one of the following: aripiprazole, lurasidone, olanzapine, paliperidone, quetiapine immediate-release, risperidone, or ziprasidone
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Maintenance monotherapy treatment in bipolar I disorder, monotherapy treatment of generalized anxiety disorder, monotherapy treatment of major depressive disorder

# **QUININE SULFATE**

### **Products Affected**

• QuiNINE Sulfate Oral

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 month
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Babesiosis, uncomplicated Plasmodium vivax malaria.

# REGRANEX

### **Products Affected**

• Regranex

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	20 weeks
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **RELISTOR INJ**

### **Products Affected**

• Relistor Subcutaneous Solution

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	<ol> <li>The requested drug is being prescribed for opioid-induced constipation in an adult patient with advanced illness or pain caused by active cancer who requires opioid dosage escalation for palliative care OR 2) The requested drug is being prescribed for opioid-induced constipation in an adult patient with chronic non- cancer pain, including chronic pain related to prior cancer or its treatment who does not require frequent (e.g., weekly) opioid dosage escalation AND 3) The patient is unable to tolerate oral medications OR 4) An oral drug indicated for opioid-induced constipation in an adult patient with chronic non- cancer pain (Note: An example of an oral drug indicated for opioid-induced constipation includes Movantik) AND 5) The patient experienced an inadequate treatment response or intolerance to an oral drug indicated for opioid-induced constipation in an adult patient with chronic non-cancer pain. (Note: An example of an oral drug indicated for opioid-induced constipation in a adult patient with chronic non-cancer pain. (Note: An example of an oral drug indicated for opioid-induced constipation includes Movantik) OR 6) The patient has a contraindication that would prohibit a trial of an oral drug indicated for opioid-induced constipation in an adult patient with chronic non- cancer pain (Note: An example of an oral drug indicated for opioid-induced constipation includes Movantik).</li> </ol>
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	4 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## REMICADE

### **Products Affected**

• Remicade

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For moderately to severely active Crohn's disease (new starts only): 1) Pt has fistulizing disease, OR 2) Inadequate response to at least one conventional therapy (e.g., corticosteroids), OR 3) Intolerance or contraindication to conventional therapy. For moderately to severely active ulcerative colitis (new starts only): 1) Inadequate response to at least one conventional therapy (e.g., corticosteroids, aminosalicylates) OR 2) Intolerance or contraindication to conventional therapy. For moderately to severely active rheumatoid arthritis (new starts only): 1) Pt meets ANY of the following: a) requested drug will be used in combination with methotrexate (MTX) or leflunomide OR b) intolerance or contraindication to MTX or leflunomide AND 2) pt meets ANY of the following: a) inadequate response, intolerance or contraindication to MTX or leflunomide AND 2) pt meets ANY of b) inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis (new starts only): Inadequate responses to a non-steroidal anti-inflammatory drug (NSAID) trial OR intolerance or contraindication to NSAIDs. For moderate to severe chronic plaque psoriasis (new starts only): 1) At least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at time of diagnosis, AND 2) Pt meets ANY of the following: a) pt has experienced inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with MTX, cyclosporine, or acitretin is contraindicated, OR c) pt has severe psoriasis that warrants a biologic DMARD as first-line therapy. For hidradenitis suppurativa (new starts only): pt has severe, refractory disease. For uveitis (new starts only): Inadequate response or intolerance or has a contraindication to a trial of immunosuppressive therapy for uveitis.
Age Restrictions	
Prescriber Restrictions	

PA Criteria	Criteria Details
Coverage Duration	Plan Year
Other Criteria	For FDA-approved indications and off-label uses that overlap: the patient had an intolerable adverse event to Renflexis and that adverse event was NOT attributed to the active ingredient as described in the prescribing information.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Behcet's syndrome, granulomatosis with polyangiitis (Wegener's granulomatosis), hidradenitis suppurativa, juvenile idiopathic arthritis, pyoderma gangrenosum, sarcoidosis, Takayasu's arteritis, uveitis

## RENFLEXIS

#### **Products Affected**

• Renflexis

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For moderately to severely active Crohn's disease (new starts only): 1) Pt has fistulizing disease, OR 2) Inadequate response to at least one conventional therapy (e.g., corticosteroids), OR 3) Intolerance or contraindication to conventional therapy. For moderately to severely active ulcerative colitis (new starts only): 1) Inadequate response to at least one conventional therapy (e.g., corticosteroids, aminosalicylates) OR 2) Intolerance or contraindication to conventional therapy. For moderately to severely active rheumatoid arthritis (new starts only): 1) Pt meets ANY of the following: a) requested drug will be used in combination with methotrexate (MTX) or leflunomide OR b) intolerance or contraindication to MTX or leflunomide AND 2) pt meets ANY of the following: a) inadequate response, intolerance or contraindication to MTX OR b) inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis (new starts only): Inadequate responses to a non-steroidal anti-inflammatory drug (NSAID) trial OR intolerance or contraindication to NSAIDs. For moderate to severe chronic plaque psoriasis (new starts only): 1) At least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at time of diagnosis, AND 2) Pt meets ANY of the following: a) pt has experienced inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with MTX, cyclosporine, or acitretin, OR b) pharmacologic treatment with MTX, cyclosporine, or acitretin is contraindicated, OR c) pt has severe psoriasis that warrants a biologic DMARD as first-line therapy. For hidradenitis suppurativa (new starts only): pt has severe, refractory disease. For uveitis (new starts only): pt has severe, refractory disease. For uveitis (new starts only): pt has severe proced or has a contraindication to a trial of immunosuppressive therapy for uveitis.
Age Restrictions	
Prescriber Restrictions	

PA Criteria	Criteria Details
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Behcet's syndrome, granulomatosis with polyangiitis (Wegener's granulomatosis), hidradenitis suppurativa, juvenile idiopathic arthritis, pyoderma gangrenosum, sarcoidosis, Takayasu's arteritis, uveitis

### **RETEVMO**

#### **Products Affected**

Retevmo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-small cell lung cancer, patient must meet all of the following: 1) The disease is recurrent, advanced or metastatic, and 2) Tumor is RET fusion-positive or RET rearrangement-positive.
Age Restrictions	Non-small cell lung cancer: 18 years of age or older. Medullary thyroid cancer and thyroid cancer: 12 years of age or older.
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Recurrent or advanced rearranged during transfection (RET)-rearrangement positive non-small cell lung cancer

### REVLIMID

#### **Products Affected**

• Revlimid

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For myelodysplastic syndrome (MDS): Low- to intermediate-1 risk MDS with symptomatic anemia per the International Prognostic Scoring System (IPSS) scale
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Systemic light chain amyloidosis, classical Hodgkin lymphoma, myelodysplastic syndrome without the 5q deletion cytogenetic abnormality, myelofibrosis- associated anemia, POEMS syndrome, myeloproliferative neoplasms, non- Hodgkin's lymphoma with the following subtypes: acquired immunodeficiency syndrome (AIDS)-related diffuse large B-cell lymphoma, primary central nervous system (CNS) lymphoma, monomorphic post-transplant lymphoproliferative disorder, chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), diffuse large B-cell lymphoma, primary cutaneous B-cell lymphoma, multicentric Castleman's disease, adult T-cell leukemia/lymphoma, mycosis fungoides (MF)/Sezary syndrome (SS), angioimmunoblastic T-cell lymphoma (AITL), peripheral T-cell lymphoma not otherwise specified (PTCL NOS), enteropathy-associated T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma, nodal peripheral T-cell lymphoma, primary cutaneous anaplastic large cell lymphoma (ALCL), hepatosplenic gamma-delta T-cell lymphoma, high-grade B-cell lymphomas.

## REZUROCK

#### **Products Affected**

Rezurock

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	12 years of age or older
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
Indications	All FDA-approved Indications.
Off Label Uses	

## **RIABNI**

### **Products Affected**

• Riabni

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For moderately to severely active rheumatoid arthritis (new starts only): 1) patient meets ANY of the following: a) requested drug will be used in combination with methotrexate (MTX) OR b) patient has intolerance or contraindication to MTX, AND 2) patient meets ANY of the following: a) inadequate response, intolerance, or contraindication to MTX OR b) inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. Hematologic malignancies must be CD20-positive. For multiple sclerosis: 1) patient has a diagnosis of relapsing remitting multiple sclerosis and 2) patient has had an inadequate response to two or more disease-modifying drugs indicated for multiple sclerosis despite adequate duration of treatment.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Immune checkpoint inhibitor-related toxicities: 3 months, All other: Plan Year
Other Criteria	For FDA-approved indications and off-label uses that overlap: the patient had an intolerable adverse event to both Truxima AND Ruxience and that adverse event was NOT attributed to the active ingredient as described in the prescribing information.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	Non-Hodgkin's lymphoma subtypes [small lymphocytic lymphoma (SLL), mantle cell lymphoma, marginal zone lymphomas (nodal, splenic, gastric mucosa- associated lymphoid tissue [MALT], nongastric MALT), Burkitt lymphoma, primary cutaneous B-cell lymphoma, high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 (double/triple hit lymphoma), high-grade B-cell lymphoma not otherwise specified, Castleman's disease, acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma, hairy cell leukemia, post-transplant lymphoproliferative disorder (PTLD)], refractory immune or idiopathic thrombocytopenic purpura (ITP), autoimmune hemolytic anemia, Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma, chronic graft-versus-host disease (GVHD), Sjogren syndrome, thrombotic thrombocytopenic purpura, refractory myasthenia gravis, Hodgkin's lymphoma (nodular lymphocyte-predominant), primary central nervous system (CNS) lymphoma, leptomeningeal metastases from lymphomas, acute lymphoblastic leukemia, prevention of Epstein-Barr virus (EBV)-related PTLD, multiple sclerosis, and immune checkpoint inhibitor-related toxicities

## RINVOQ

### **Products Affected**

• Rinvoq

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For moderately to severely active rheumatoid arthritis (new starts only): 1) inadequate response, intolerance or contraindication to methotrexate (MTX) OR 2) inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## RITUXAN

### **Products Affected**

• Rituxan Intravenous Solution

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For moderately to severely active rheumatoid arthritis (new starts only): 1) patient meets ANY of the following: a) requested drug will be used in combination with methotrexate (MTX) OR b) patient has intolerance or contraindication to MTX, AND 2) patient meets ANY of the following: a) inadequate response, intolerance, or contraindication to MTX OR b) inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. Hematologic malignancies must be CD20-positive. For multiple sclerosis: 1) patient has a diagnosis of relapsing remitting multiple sclerosis and 2) patient has had an inadequate response to two or more disease-modifying drugs indicated for multiple sclerosis despite adequate duration of treatment.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Immune checkpoint inhibitor-related toxicities: 3 months, All other: Plan Year
Other Criteria	For FDA-approved indications and off-label uses that overlap: the patient had an intolerable adverse event to both Truxima AND Ruxience and that adverse event was NOT attributed to the active ingredient as described in the prescribing information.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	Non-Hodgkin's lymphoma subtypes [small lymphocytic lymphoma (SLL), mantle cell lymphoma, marginal zone lymphomas (nodal, splenic, gastric mucosa- associated lymphoid tissue [MALT], nongastric MALT), Burkitt lymphoma, primary cutaneous B-cell lymphoma, high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 (double/triple hit lymphoma), high-grade B-cell lymphoma not otherwise specified, Castleman's disease, acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma, hairy cell leukemia, post-transplant lymphoproliferative disorder (PTLD)], refractory immune or idiopathic thrombocytopenic purpura (ITP), autoimmune hemolytic anemia, Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma, chronic graft-versus-host disease (GVHD), Sjogren syndrome, thrombotic thrombocytopenic purpura, refractory myasthenia gravis, Hodgkin's lymphoma (nodular lymphocyte-predominant), primary central nervous system (CNS) lymphoma, leptomeningeal metastases from lymphomas, acute lymphoblastic leukemia, prevention of Epstein-Barr virus (EBV)-related PTLD, multiple sclerosis, and immune checkpoint inhibitor-related toxicities

# **RITUXAN HYCELA**

### **Products Affected**

• Rituxan Hycela

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Malignancies must be CD20 positive. Patient must receive at least one full dose of a rituximab product by intravenous infusion without experiencing severe adverse reactions.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Acquired immune deficiency syndrome (AIDS)-related B-cell lymphoma, Burkitt lymphoma, Castleman's disease (CD), high-grade B-cell lymphoma, small lymphocytic lymphoma (SLL), gastric mucosa-associated lymphoid tissue (MALT) lymphoma, mantle cell lymphoma, nodal marginal zone lymphoma, nongastric MALT lymphoma, primary cutaneous B-cell lymphoma (e.g., cutaneous marginal zone lymphoma or cutaneous follicle center lymphomas), post-transplant lymphoproliferative disorder (PTLD), splenic marginal zone lymphoma

## ROZLYTREK

#### **Products Affected**

Rozlytrek

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## **RUBRACA**

#### **Products Affected**

• Rubraca

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

### **RUXIENCE**

#### **Products Affected**

• Ruxience

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For moderately to severely active rheumatoid arthritis (new starts only): 1) patient meets ANY of the following: a) requested drug will be used in combination with methotrexate (MTX) OR b) patient has intolerance or contraindication to MTX, AND 2) patient meets ANY of the following: a) inadequate response, intolerance, or contraindication to MTX OR b) inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. Hematologic malignancies must be CD20-positive. For multiple sclerosis: 1) patient has a diagnosis of relapsing remitting multiple sclerosis and 2) patient has had an inadequate response to two or more disease-modifying drugs indicated for multiple sclerosis despite adequate duration of treatment.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Immune checkpoint inhibitor-related toxicities: 3 months, All other: Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	Non-Hodgkin's lymphoma subtypes [small lymphocytic lymphoma (SLL), mantle cell lymphoma, marginal zone lymphomas (nodal, splenic, gastric mucosa- associated lymphoid tissue [MALT], nongastric MALT), Burkitt lymphoma, primary cutaneous B-cell lymphoma, high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 (double/triple hit lymphoma), high-grade B-cell lymphoma not otherwise specified, Castleman's disease, acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma, hairy cell leukemia, post-transplant lymphoproliferative disorder (PTLD)], refractory immune or idiopathic thrombocytopenic purpura (ITP), autoimmune hemolytic anemia, Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma, chronic graft-versus-host disease (GVHD), Sjogren syndrome, thrombotic thrombocytopenic purpura, refractory myasthenia gravis, Hodgkin's lymphoma (nodular lymphocyte-predominant), primary central nervous system (CNS) lymphoma, leptomeningeal metastases from lymphomas, acute lymphoblastic leukemia, prevention of Epstein-Barr virus (EBV)-related PTLD, multiple sclerosis, immune checkpoint inhibitor-related toxicities, and pemphigus vulgaris

## **RYDAPT**

### **Products Affected**

• Rydapt

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For acute myeloid leukemia (AML), AML must be FLT3 mutation-positive.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Relapsed or refractory acute myeloid leukemia

## SAVELLA

### **Products Affected**

- Savella
- Savella Titration Pack

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to duloxetine or pregabalin
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## SIGNIFOR

### **Products Affected**

• Signifor

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# SILDENAFIL

### **Products Affected**

• Sildenafil Citrate Oral Tablet 20 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): Diagnosis was confirmed by right heart catheterization. For PAH new starts only: 1) Pretreatment mean pulmonary arterial pressure is greater than or equal to 25 mmHg, 2) Pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, and 3) Pretreatment pulmonary vascular resistance is greater than 3 Wood units.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## **SIRTURO**

#### **Products Affected**

• Sirturo

PA Criteria	Criteria Details
Exclusion Criteria	The requested drug is being prescribed for the treatment of latent infection due to Mycobacterium tuberculosis, drug-sensitive tuberculosis, extra-pulmonary tuberculosis, or infection caused by the non-tuberculous mycobacteria
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **SKYRIZI**

### **Products Affected**

- SkyriziSkyrizi (150 MG Dose)Skyrizi Pen

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) patient meets any of the following: a) patient has experienced an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, or b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, or c) patient has severe psoriasis that warrants a biologic disease-modifying antirheumatic drug (DMARD) as first-line therapy (i.e. at least 10% of the body surface area (BSA) or crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected).
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **SOMATULINE DEPOT**

#### **Products Affected**

• Somatuline Depot Subcutaneous Solution 120 MG/0.5ML, 60 MG/0.2ML, 90 MG/0.3ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For acromegaly (initial): 1) Patient has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range, and 2) Patient had an inadequate or partial response to surgery or radiotherapy OR there is a clinical reason for why the patient has not had surgery or radiotherapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	For acromegaly continuation of therapy: patient's IGF-1 level has decreased or normalized since initiation of therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Neuroendocrine tumors (NETs) of the gastrointestinal (GI) tract, lung, thymus (carcinoid tumors) or unresected primary gastrinoma, NETs of the pancreas, and pheochromocytoma/paraganglioma.

## **SOMAVERT**

#### **Products Affected**

• Somavert

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For acromegaly (initial): 1) Patient has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range, and 2) Patient had an inadequate or partial response to surgery or radiotherapy OR there is a clinical reason for why the patient has not had surgery or radiotherapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	For acromegaly continuation of therapy: patient's IGF-1 level has decreased or normalized since initiation of therapy.
Indications	All FDA-approved Indications.
Off Label Uses	

## **SPRYCEL**

### **Products Affected**

• Sprycel

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For chronic myeloid leukemia (CML) or acute lymphoblastic leukemia (ALL), diagnosis was confirmed by detection of the Philadelphia chromosome or BCR- ABL gene. For CML, patient meets one of the following: 1) patient received a hematopoietic stem cell transplant, OR 2) patient has accelerated or blast phase CML, OR 3) for chronic phase CML (includes newly diagnosed), the patient has one of the following a) patient is 21 years of age or younger, or b) high or intermediate risk for disease progression, or c) low risk for disease progression and has experienced resistance, intolerance or toxicity to imatinib or an alternative tyrosine kinase inhibitor. If patient experienced resistance to imatinib or an alternative tyrosine kinase inhibitor for CML, patient is negative for T315I mutation. For gastrointestinal stromal tumor (GIST), patient must have progressed on imatinib, sunitinib, or regorafenib.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Gastrointestinal stromal tumor (GIST), metastatic chondrosarcoma, recurrent chordoma

## **STELARA**

### **Products Affected**

- Stelara Subcutaneous Solution 45 MG/0.5ML
- Stelara Subcutaneous Solution Prefilled Syringe

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For moderate to severe plaque psoriasis (new starts only): at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	For moderate to severe plaque psoriasis (new starts): the patient had an inadequate response, intolerance, or contraindication to two of the following products: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab-rzaa). For active psoriatic arthritis (PsA) (new starts): the patient had an inadequate response, intolerance, or contraindication to two of the following products: Enbrel (etanercept), Humira (adalimumab), Xeljanz (tolfacitinib)/Xeljanz XR (tofacitinib extended-release). For moderately to severely active Crohn's disease (new starts): patient had an inadequate response, intolerance, or contraindication to Humira (adalimumab). For moderately to severely active ulcerative colitis (new starts): patient had an inadequate response, intolerance, or contraindication to both Humira (adalimumab) and Xeljanz (tolfacitinib)/Xeljanz XR (tofacitinib extended-release).
Indications	All FDA-approved Indications.
Off Label Uses	

## **STIVARGA**

### **Products Affected**

• Stivarga

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For gastrointestinal stromal tumors: The disease is progressive, locally advanced, unresectable, or metastatic.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Progressive gastrointestinal stromal tumors (GIST), retroperitoneal/intra- abdominal soft tissue sarcoma, rhabdomyosarcoma, and soft tissue sarcomas of the extremities, superficial trunk, head and neck, unresectable or advanced colorectal cancer.

# **SUTENT**

### **Products Affected**

- SUNItinib Malate
- Sutent

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For renal cell carcinoma, any of the following criteria must be met: 1) The disease is relapsed or metastatic, OR 2) The patient is at high risk of disease recurrence following nephrectomy.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Thyroid carcinoma (follicular, medullary, papillary, and Hurthle cell), soft tissue sarcoma (angiosarcoma, solitary fibrous tumor, and hemangiopericytoma subtypes), gastrointestinal stromal tumor, recurrent chordoma, thymic carcinoma.

## **SYMDEKO**

#### **Products Affected**

• Symdeko

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For cystic fibrosis (CF): The patient is positive for the F508del mutation on both alleles of the cystic fibrosis transmembrane conductance regulator (CFTR) gene OR the patient has a mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor potentiation based on clinical and/or in vitro assay data.
Age Restrictions	6 years of age or older
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	The requested medication will not be used in combination with other medications containing ivacaftor.
Indications	All FDA-approved Indications.
Off Label Uses	

### **SYMPAZAN**

#### **Products Affected**

• Sympazan

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	2 years of age or older
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## **SYNRIBO**

### **Products Affected**

• Synribo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Follow-up therapy for CML patients after hematopoietic stem cell transplant (HSCT).

## **TABRECTA**

#### **Products Affected**

• Tabrecta

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	For recurrent, advanced, or metastatic NSCLC: Tumor is positive for mesenchymal-epithelial transition (MET) exon 14 skipping mutation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Treatment of recurrent or advanced non-small cell lung cancer (NSCLC).

### TAFINLAR

#### **Products Affected**

• Tafinlar

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For brain metastases from melanoma or for adjuvant treatment of melanoma, the tumor is positive for a BRAF V600 activating mutation and the requested drug will be used in combination with trametinib. For unresectable or metastatic melanoma, the tumor is positive for a BRAF V600 activating mutation and the requested drug will be used as a single agent or in combination with trametinib. For non-small cell lung cancer, the tumor is positive for a BRAF V600E mutation and the requested drug will be used as a single agent or in combination with trametinib. For thyroid carcinoma, the tumor is positive for BRAF activating mutation with papillary, follicular, or Hurthle histology. For unresectable advanced or metastatic colorectal cancer, the tumor is positive for a BRAF V600E activating mutation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Brain metastases from melanoma, thyroid carcinoma (papillary carcinoma, follicular carcinoma, and Hurthle cell carcinoma), colorectal cancer

# **TAGRISSO**

### **Products Affected**

• Tagrisso

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For recurrent, advanced or metastatic NSCLC (including brain metastases from NSCLC), patient must have a sensitizing EGFR mutation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Recurrent or advanced non-small cell lung cancer (NSCLC), brain metastases from sensitizing EGFR mutation-positive NSCLC, brain metastases from EGFR T790M mutation-positive NSCLC.

### **Products Affected**

• Taltz

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For moderate to severe plaque psoriasis (new starts only): At least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis.
Age Restrictions	For plaque psoriasis: 6 years of age or older. Other: 18 years of age or older
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	For moderate to severe plaque psoriasis (new starts only): the patient had an inadequate response, intolerance, or contraindication to one of the following products: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab-rzaa). For active ankylosing spondylitis (new starts only): the patient had an inadequate response, intolerance, or contraindication to either Enbrel (etanercept) or Humira (adalimumab). For active psoriatic arthritis (PsA) (new starts only): the patient had an inadequate response, intolerance, or contraindication to one of the following products: Enbrel (etanercept), Humira (adalimumab). Keljanz (adalimumab). For active psoriatic arthritis (PsA) (new starts only): the patient had an inadequate response, intolerance, or contraindication to one of the following products: Enbrel (etanercept), Humira (adalimumab), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For active axial spondyloarthritis (new starts only): Patient meets any of the following: 1) has an inadequate response to a non-steroidal anti-inflammatory drug (NSAID) trial or 2) has an intolerance or contraindication to NSAIDs.
Indications	All FDA-approved Indications.
Off Label Uses	

### TALZENNA

#### **Products Affected**

• Talzenna

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Recurrent, BRCA 1/2-germline mutated breast cancer

## TASIGNA

### **Products Affected**

• Tasigna

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For chronic myeloid leukemia (CML) or acute lymphoblastic leukemia (ALL), diagnosis was confirmed by detection of the Philadelphia chromosome or BCR- ABL gene. For CML, patient meets one of the following: 1) patient received a hematopoietic stem cell transplant, OR 2) patient has accelerated or blast phase CML, OR 3) for chronic phase CML (includes newly diagnosed), the patient has one of the following: a) patient is 18 years of age or younger, b) high or intermediate risk for disease progression, or c) low risk for disease progression and has experienced resistance, intolerance or toxicity to imatinib or an alternative tyrosine kinase inhibitor. If patient experienced resistance to imatinib or an alternative tyrosine kinase inhibitor for CML, patient is negative for T315I mutation. For GIST, patient must have progressed on imatinib, sunitinib or regorafenib.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), gastrointestinal stromal tumor (GIST).

# TAZAROTENE

#### **Products Affected**

- Tazarotene External Cream
- Tazorac External Cream 0.05 %

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For plaque psoriasis, the requested drug is being prescribed to treat less than 20 percent of the patient's body surface area.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## TAZVERIK

#### **Products Affected**

• Tazverik

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Epithelioid sarcoma: 16 years of age or older, Follicular lymphoma: 18 years of age or older
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## **TECENTRIQ**

### **Products Affected**

• Tecentriq

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For urothelial carcinoma, patient meets one of the following criteria: 1) Patient is ineligible for cisplatin therapy and tumors express PD-L1, OR 2) Patient is ineligible for any platinum containing chemotherapy, OR 3) The requested medication will be used as subsequent therapy following platinum-containing chemotherapy. For non-small cell lung cancer (NSCLC), patient meets one of the following criteria: 1) The requested medication will be used as treatment for NSCLC AND patients with EGFR or ALK positive disease must have received previous EGFR or ALK therapy, OR 2) The requested medication will be used as continuation maintenance therapy when tumor response or stable disease is achieved following initial systemic therapy, OR 3) The requested medication will be used as subsequent therapy for recurrent, advanced, or metastatic NSCLC.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## **TECFIDERA**

#### **Products Affected**

• Tecfidera

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## **TEMAZEPAM 30MG**

### **Products Affected**

• Temazepam Oral Capsule 30 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	<ol> <li>The non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) has been tried AND 2) The patient experienced an inadequate treatment response OR intolerance to the non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) AND 3) The benefit of therapy with this prescribed medication outweighs the potential risk in a patient 65 years of age or older. OR</li> <li>The patient has a contraindication to the non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) AND 5) The benefit of therapy with this prescribed medication outweighs the potential risk in a patient 65 years of age or older. OR</li> </ol>
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization requirement only applies to patients 65 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
Indications	All FDA-approved Indications.
Off Label Uses	

### **TEPMETKO**

#### **Products Affected**

• Tepmetko

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## TETRABENAZINE

### **Products Affected**

• Tetrabenazine

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For treatment of chorea associated with Huntington's disease: The patient must have a prior inadequate response or intolerable adverse event with deutetrabenazine therapy. For treatment of tardive dyskinesia: The patient must have a prior inadequate response or intolerable adverse event with deutetrabenazine or valbenazine therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Tic disorders, tardive dyskinesia, hemiballismus, chorea not associated with Huntington's disease.

# TETRACYCLINE

### **Products Affected**

• Tetracycline HCI Oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	The patient will use the requested drug orally.
Indications	All FDA-approved Indications.
Off Label Uses	

## THALOMID

#### **Products Affected**

• Thalomid

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For cachexia: Cachexia must be due to cancer or human immunodeficiency virus (HIV) infection. For Kaposi's sarcoma: The patient has human immunodeficiency virus (HIV) infection.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Myelofibrosis-related anemia, recurrent aphthous stomatitis, recurrent HIV- associated aphthous ulcers, cachexia, human immunodeficiency virus (HIV)- associated diarrhea, Kaposi's sarcoma, Behcet's syndrome, chronic graft- versus-host disease, Crohn's disease, multicentric Castleman's disease.

# **TIBSOVO**

### **Products Affected**

Tibsovo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation, 1) patient has newly-diagnosed AML and meets one of the following: a) 75 years of age or older, b) patient has comorbidities that preclude use of intensive induction chemotherapy, or c) patient is 60 years of age or older and declines intensive induction chemotherapy, OR 2) patient is 60 years of age or older and the requested drug will be used as post-remission therapy following response to previous lower intensity therapy with the same regimen, OR 3) patient has relapsed or refractory AML.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# TOBRAMYCIN

### **Products Affected**

 Tobramycin Inhalation Nebulization Solution 300 MG/5ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For cystic fibrosis and non-cystic fibrosis bronchiectasis, the patient must meet one of the following: 1) Pseudomonas aeruginosa is present in the patient's airway cultures, OR 2) the patient has a history of Pseudomonas aeruginosa infection or colonization in the airways.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Non-cystic fibrosis bronchiectasis

# **TOPICAL LIDOCAINE**

#### **Products Affected**

- Glydo External Prefilled SyringeLidocaine External Ointment 5 %
- Lidocaine HCI External Solution
- Lidocaine HCI Urethral/Mucosal External Gel ٠

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1) The requested drug is being used for topical anesthesia, AND 2) If the requested drug will be used as part of a compounded product, then all the active ingredients in the compounded product are Food and Drug Administration (FDA) approved for topical use.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	3 months
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
Indications	All FDA-approved Indications.
Off Label Uses	

• Lidocaine-Prilocaine External Cream

# **TOPICAL TESTOSTERONES**

- Androderm Transdermal Patch 24 Hour
- Testosterone Transdermal Gel 12.5 MG/ACT (1%), 25 MG/2.5GM (1%), 50 MG/5GM (1%)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	1) Request is for continuation of testosterone therapy and requested drug is being prescribed for primary or hypogonadotropic hypogonadism [Note: Safety and efficacy of testosterone products in patients with age-related hypogonadism (also referred to as late-onset hypogonadism) have not been established.] and the patient had a confirmed low morning testosterone level according to current practice guidelines or your standard lab reference values before starting testosterone therapy OR 2) Request is not for continuation of testosterone therapy and requested drug is being prescribed for primary or hypogonadotropic hypogonadism [Note: Safety and efficacy of testosterone products in patients with age-related hypogonadism (also referred to as late-onset hypogonadism) have not been established.] and the patient has at least two confirmed low morning testosterone levels according to current practice guidelines or your standard lab reference values OR 3) Requested drug is being prescribed for gender dysphoria in a patient who is able to make an informed decision to engage in hormone therapy.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Gender Dysphoria

# **TOPICAL TRETINOIN**

- Avita
- Tretinoin External Cream
- Tretinoin External Gel 0.01 %, 0.025 %

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## TRAZIMERA

### **Products Affected**

• Trazimera

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Neoadjuvant therapy for breast cancer: 6 months. Other: Plan Year.
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Neoadjuvant treatment for human epidermal growth factor receptor 2 (HER2)- positive breast cancer, recurrent HER2-positive breast cancer, leptomeningeal metastases from breast cancer, HER2-positive esophageal and esophagogastric junction cancer, HER2-positive advanced and recurrent uterine serous carcinoma, HER2-amplified colorectal cancer in combination with pertuzumab or lapatinib.

# TRELSTAR

### **Products Affected**

 Trelstar Mixject Intramuscular Suspension Reconstituted 11.25 MG, 3.75 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **TREPROSTINIL INJ**

### **Products Affected**

• Treprostinil

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For pulmonary arterial hypertension (WHO Group 1), the diagnosis was confirmed by right heart catheterization. For new starts only, the patient must meet all of the following: 1) pretreatment mean pulmonary arterial pressure is greater than or equal to 25 mmHg, 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) pretreatment pulmonary vascular resistance is greater than 3 Wood units.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
Indications	All FDA-approved Indications.
Off Label Uses	

## TRIENTINE

### **Products Affected**

• Trientine HCI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## TRIKAFTA

#### **Products Affected**

• Trikafta

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For cystic fibrosis (CF): The patient has at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene OR the patient has a mutation in the CFTR gene that is responsive to elexacaftor/tezacaftor/ivacaftor potentiation based on in vitro assay data.
Age Restrictions	6 years of age or older
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	The requested medication will not be used in combination with other medications containing ivacaftor.
Indications	All FDA-approved Indications.
Off Label Uses	

# TRUSELTIQ

- Truseltiq (100MG Daily Dose)Truseltiq (125MG Daily Dose)
- Truseltiq (50MG Daily Dose)
  Truseltiq (75MG Daily Dose)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## TRUXIMA

#### **Products Affected**

• Truxima

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For moderately to severely active rheumatoid arthritis (new starts only): 1) patient meets ANY of the following: a) requested drug will be used in combination with methotrexate (MTX) OR b) patient has intolerance or contraindication to MTX, AND 2) patient meets ANY of the following: a) inadequate response, intolerance, or contraindication to MTX OR b) inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. Hematologic malignancies must be CD20-positive. For multiple sclerosis: 1) patient has a diagnosis of relapsing remitting multiple sclerosis and 2) patient has had an inadequate response to two or more disease-modifying drugs indicated for multiple sclerosis despite adequate duration of treatment.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Immune checkpoint inhibitor-related toxicities: 3 months, All other: Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	Non-Hodgkin's lymphoma subtypes [small lymphocytic lymphoma (SLL), mantle cell lymphoma, marginal zone lymphomas (nodal, splenic, gastric mucosa- associated lymphoid tissue [MALT], nongastric MALT), Burkitt lymphoma, primary cutaneous B-cell lymphoma, high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 (double/triple hit lymphoma), high-grade B-cell lymphoma not otherwise specified, Castleman's disease, acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma, hairy cell leukemia, post-transplant lymphoproliferative disorder (PTLD)], refractory immune or idiopathic thrombocytopenic purpura (ITP), autoimmune hemolytic anemia, Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma, chronic graft-versus-host disease (GVHD), Sjogren syndrome, thrombotic thrombocytopenic purpura, refractory myasthenia gravis, Hodgkin's lymphoma (nodular lymphocyte-predominant), primary central nervous system (CNS) lymphoma, leptomeningeal metastases from lymphomas, acute lymphoblastic leukemia, prevention of Epstein-Barr virus (EBV)-related PTLD, multiple sclerosis, immune checkpoint inhibitor-related toxicities, and pemphigus vulgaris

# TUKYSA

### **Products Affected**

• Tukysa

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Recurrent human epidermal growth factor receptor 2 (HER2)-positive breast cancer, including patients with brain metastasis, who have received one or more lines of prior HER2-targeted therapy in the metastatic setting.

# **TURALIO**

### **Products Affected**

• Turalio

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **TYKERB**

### **Products Affected**

• Lapatinib Ditosylate

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For HER2-positive breast cancer, the requested drug will be used in combination with any of the following: 1) aromatase inhibitor, 2) capecitabine, OR 3) trastuzumab.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Metastatic CNS lesions from HER2-positive breast cancer, recurrent EGFR- positive chordoma, HER2-amplified colorectal cancer in combination with trastuzumab.

# **TYMLOS**

### **Products Affected**

• Tymlos

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	For postmenopausal osteoporosis: patient has ONE of the following: 1) a history of fragility fractures, OR 2) a pre-treatment T-score of less than or equal to -2.5 or pre-treatment T-score greater than -2.5 and less than -1 with a high pre- treatment Fracture Risk Assessment Tool (FRAX) fracture probability AND patient has ANY of the following: a) indicators for higher fracture risk (e.g., advanced age, frailty, glucocorticoid therapy, very low T-scores, or increased fall risk), OR b) patient has failed prior treatment with or is intolerant to a previous injectable osteoporosis therapy, OR c) patient has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	24 months lifetime total for parathyroid hormone analogs (e.g., abaloparatide or teriparatide)
Other Criteria	Patient has high Fracture Risk Assessment Tool (FRAX) fracture probability if the 10 year probability is either greater than or equal to 20 percent for any major osteoporotic fracture or greater than or equal to 3 percent for hip fracture. If glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day, the estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture and 1.2 for hip fracture.
Indications	All FDA-approved Indications.
Off Label Uses	

## UBRELVY

### **Products Affected**

• Ubrelvy

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1) The patient has experienced an inadequate treatment response to one triptan 5-HT1 receptor agonist, OR 2) The patient has experienced an intolerance to one triptan 5-HT1 receptor agonist, OR 3) The patient has a contraindication that would prohibit a trial of triptan 5-HT1 receptor agonists.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# UKONIQ

### **Products Affected**

• Ukoniq

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## VALCHLOR

#### **Products Affected**

• Valchlor

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Chronic or smoldering adult T-cell leukemia/lymphoma, Stage 2 or higher mycosis fungoides/Sezary syndrome, primary cutaneous marginal zone lymphoma, primary cutaneous follicle center lymphoma, lymphomatoid papulosis.

# VELCADE

- Bortezomib
- Velcade Injection

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Systemic light chain amyloidosis, Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma, multicentric Castleman's disease, adult T-cell leukemia/lymphoma, pediatric acute lymphoblastic leukemia.

## **VELTASSA**

### **Products Affected**

• Veltassa

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1) The patient has experienced an inadequate treatment response or intolerance to Lokelma OR 2) The patient has a contraindication that would prohibit a trial of Lokelma.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

### VEMLIDY

### **Products Affected**

• Vemlidy

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	For chronic hepatitis B virus infection, the requested drug will be used in a patient who meets either of the following (new starts only): 1) inadequate virologic response, resistance, or intolerable adverse event to tenofovir disoproxil fumarate, OR 2) bone loss and mineralization defects or is at risk for bone loss and mineralization defects (for example, history of fragility fractures, advanced age, frailty, chronic glucocorticoid use, low T-scores, or increased fall risk).
Indications	All FDA-approved Indications.
Off Label Uses	

# VENCLEXTA

- Venclexta
- Venclexta Starting Pack

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For AML, any of the following criteria must be met: 1) the patient is 60 years of age or older OR 2) the requested drug will be used as a component of repeating the initial successful induction regimen if late relapse OR 3) the patient has comorbidities that preclude use of intensive induction chemotherapy OR 4) the requested drug will be used for relapsed or refractory disease.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Mantle cell lymphoma, blastic plasmacytoid dendritic cell neoplasm (BPDCN).

## **VENTAVIS**

#### **Products Affected**

• Ventavis

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For pulmonary arterial hypertension (WHO Group 1), the diagnosis was confirmed by right heart catheterization. For new starts only, the patient must meet all of the following: 1) pretreatment mean pulmonary arterial pressure is greater than or equal to 25 mmHg, 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) pretreatment pulmonary vascular resistance is greater than 3 Wood units.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
Indications	All FDA-approved Indications.
Off Label Uses	

## VERSACLOZ

### **Products Affected**

• Versacloz

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## **VERZENIO**

### **Products Affected**

• Verzenio

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Recurrent hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer in combination with fulvestrant or an aromatase inhibitor, or as a single agent if progression on prior endocrine therapy and prior chemotherapy in the metastatic setting.

# V-GO

- V-Go 20
- V-Go 30
- V-Go 40

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	1) The patient has diabetes requiring insulin management with multiple daily injections AND 2) The patient is self-testing glucose levels 4 or more times per day AND 3) The patient has experienced any of the following with the current diabetes regimen: inadequate glycemic control, recurrent hypoglycemia, wide fluctuations in blood glucose, dawn phenomenon with persistent severe early morning hyperglycemia, severe glycemic excursions.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	For continuation of therapy with an insulin pump, the patient has stable or improved glycemic control.
Indications	All FDA-approved Indications.
Off Label Uses	

# VIGABATRIN

- VigabatrinVigadrone

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For complex partial seizures (CPS): patient had an inadequate response to at least 2 antiepileptic drugs for CPS.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## VITRAKVI

#### **Products Affected**

• Vitrakvi

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## **VIZIMPRO**

### **Products Affected**

• Vizimpro

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-small cell lung cancer (NSCLC), the patient meets all of the following: 1) the disease is recurrent, advanced or metastatic, and 2) the member has sensitizing EGFR mutation-positive disease.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Recurrent or advanced non-small cell lung cancer (NSCLC)

# VORICONAZOLE

- Voriconazole Intravenous
- Voriconazole Oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	The patient will be using the requested drug orally or intravenously.
Indications	All FDA-approved Indications.
Off Label Uses	

## VOSEVI

#### **Products Affected**

• Vosevi

PA Criteria	Criteria Details
Exclusion Criteria	Decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh class B or C).
Required Medical Information	For chronic hepatitis C: Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [Child Turcotte Pugh class B or C]), presence or absence of HIV coinfection, presence or absence of resistance-associated substitutions where applicable, liver and kidney transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current AASLD treatment guidelines.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Criteria will be applied consistent with current AASLD-IDSA guidance.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

### VOTRIENT

#### **Products Affected**

• Votrient

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For renal cell carcinoma: The disease is relapsed, metastatic, or unresectable. For soft tissue sarcoma (STS): 1) The patient does not have an adipocytic soft tissue sarcoma, AND 2) The patient has one of the following subtypes of STS: a) gastrointestinal stromal tumor (GIST), b) angiosarcoma, c) pleomorphic rhabdomyosarcoma, d) retroperitoneal/intra-abdominal sarcoma, e) extremity/superficial trunk, head/neck sarcoma, f) solitary fibrous tumor or hemangiopericytoma, or g) alveolar soft part sarcoma (ASPS)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Thyroid carcinoma (follicular, papillary, Hurthle cell, or medullary), uterine sarcoma.

### VRAYLAR

### **Products Affected**

• Vraylar

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following: aripiprazole, lurasidone, olanzapine, paliperidone, quetiapine, risperidone, or ziprasidone.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

### **VUMERITY**

### **Products Affected**

- VumerityVumerity (Starter)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

### **VYVANSE**

### **Products Affected**

• Vyvanse

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

### WELIREG

#### **Products Affected**

• Welireg

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# XALKORI

### **Products Affected**

• Xalkori

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	For NSCLC, the requested drug is used in any of the following settings: 1) the member has recurrent, advanced or metastatic ALK-positive NSCLC (including brain metastases from NSCLC), 2) the member has recurrent, advanced or metastatic ROS-1 positive NSCLC (including brain metastases from NSCLC), or 3) the member has NSCLC with high-level MET amplification or MET exon 14 skipping mutation. For IMT and ALCL: the disease is ALK-positive.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Recurrent or advanced anaplastic lymphoma kinase (ALK)-positive or ROS1- positive non-small cell lung cancer (NSCLC), NSCLC with high-level MET amplification or MET exon 14 skipping mutation, brain metastases from NSCLC, inflammatory myofibroblastic tumors (IMT), anaplastic large cell lymphoma (ALCL)

### **XELJANZ**

### **Products Affected**

- XeljanzXeljanz XR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For moderately to severely active rheumatoid arthritis (new starts only): Patient meets at least one of the following criteria: 1) Inadequate response, intolerance or contraindication to methotrexate (MTX), OR 2) Inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD). For active psoriatic arthritis (new starts only): The requested drug is used in combination with a nonbiologic DMARD. For moderately to severely active ulcerative colitis (new starts only): Inadequate response, intolerance or contraindication to a tumor necrosis factor (TNF) blocker.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# XGEVA

### **Products Affected**

• Xgeva

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	For hypercalcemia of malignancy: condition is refractory to intravenous (IV) bisphosphonate therapy or there is a clinical reason to avoid IV bisphosphonate therapy.
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Systemic mastocytosis related osteopenia or osteoporosis

## XIFAXAN

### **Products Affected**

• Xifaxan Oral Tablet 550 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1) The requested drug is being prescribed to reduce the risk of overt hepatic encephalopathy (HE) recurrence OR 2) The patient has the diagnosis of irritable bowel syndrome with diarrhea (IBS-D) AND 3) If the patient has previously received treatment with the requested drug, the patient has experienced a recurrence of symptoms AND 4) The patient has not already received an initial 14-day course of treatment and two additional 14-day courses of treatment with the requested drug OR 5) The patient has not previously received treatment with the requested drug.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Reduction in risk of overt HE recurrence: 6 months, IBS-D: 14 days
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# XOLAIR

### **Products Affected**

• Xolair

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For allergic asthma initial therapy: 1) Patient has positive skin test (or blood test) to at least 1 perennial aeroallergen, 2) Patient has baseline IgE level greater than or equal to 30 IU/mL, and 3) Patient has inadequate asthma control despite current treatment with both of the following medications at optimized doses: a) Inhaled corticosteroid, and b) Additional controller (long acting beta2-agonist, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies. For allergic asthma continuation therapy only: Patient's asthma control has improved on treatment with the requested drug since initiation of therapy. For chronic idiopathic urticaria (CIU) initial therapy: 1) Patient has been evaluated for other causes of urticaria, including bradykinin-related angioedema and IL-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis), and 2) Patient has experienced a spontaneous onset of wheals, angioedema, or both, for at least 6 weeks. For CIU continuation therapy: Patient has experienced a response (e.g., improved symptoms) since initiation of therapy.
Age Restrictions	For CIU: 12 years of age or older. For allergic asthma: 6 years of age or older. For nasal polyps: 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	Allergic asthma and nasal polyps: Plan Year. CIU initial: 6 months. CIU continuation: Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# XOSPATA

### **Products Affected**

• Xospata

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **XPOVIO**

#### **Products Affected**

- Xpovio (100 MG Once Weekly)
- Xpovio (40 MG Once Weekly)
- Xpovio (40 MG Twice Weekly)
- Xpovio (60 MG Once Weekly)

- Xpovio (60 MG Twice Weekly)
- Xpovio (80 MG Once Weekly)
- Xpovio (80 MG Twice Weekly)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

# **XTANDI**

### **Products Affected**

• Xtandi

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

## **XYREM**

### **Products Affected**

• Xyrem

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	1) The requested drug is being prescribed for the treatment of excessive daytime sleepiness in a patient 7 years of age or older with narcolepsy and 2) The diagnosis has been confirmed by sleep lab evaluation AND 3)The patient experienced an inadequate treatment response or intolerance to at least one central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, or methylphenidate) OR has a contraindication that would prohibit a trial of central nervous system (CNS) stimulant drugs (e.g., amphetamine, dextroamphetamine, or methylphenidate) INote: Coverage of amphetamines and methylphenidates may require prior authorization.] AND 4) If the patient is 18 years of age or older, the patient experienced an inadequate treatment response or intolerance to at least one central nervous system (CNS) wakefulness promoting drug (e.g., armodafinil) OR has a contraindication that would prohibit a trial of central nervous system (CNS) wakefulness promoting drug (e.g., armodafinil) OR has a contraindication that would prohibit a trial of central nervous system (CNS) wakefulness promoting drug (e.g., armodafinil) OR has a contraindication that would prohibit a trial of central nervous system (CNS) wakefulness promoting drug (e.g., armodafinil) OR has a contraindication that would prohibit a trial of central nervous system (CNS) wakefulness promoting drugs (e.g., armodafinil) [Note: coverage of armodafinil may require prior authorization.] OR 5) The requested drug is being prescribed for the treatment of cataplexy in a patient 7 years of age or older with narcolepsy AND 6) The diagnosis has been confirmed by sleep lab evaluation.
Age Restrictions	7 years of age or older
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	If the request is for a continuation of therapy, then the patient experienced a decrease in daytime sleepiness with narcolepsy or a decrease in cataplexy episodes with narcolepsy.
Indications	All FDA-approved Indications.
Off Label Uses	

# **ZARXIO**

#### **Products Affected**

• Zarxio

PA Criteria	Criteria Details
Exclusion Criteria	Use of the requested product within 24 hours prior to or following chemotherapy.
Required Medical Information	For prophylaxis or treatment of myelosuppressive chemotherapy-induced febrile neutropenia (FN) patients must meet both of the following: 1) Patient has a solid tumor or non-myeloid cancer, and 2) Patient has received, is currently receiving, or will be receiving treatment with myelosuppressive anti-cancer therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Following chemotherapy for acute lymphocytic leukemia (ALL), stem cell transplantation related indications, neutropenia in myelodysplastic syndromes (MDS), agranulocytosis, neutropenia in aplastic anemia, HIV-related neutropenia, neutropenia related to renal transplant.

# ZEJULA

### **Products Affected**

• Zejula

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
<b>Coverage Duration</b>	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	In combination with bevacizumab for persistent or recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer for platinum-sensitive disease.

### ZELBORAF

#### **Products Affected**

• Zelboraf

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For cutaneous melanoma, all of the following criteria must be met: 1) tumor is positive for BRAF V600E or V600K mutation, and 2) disease is unresectable or metastatic. For Erdheim-Chester Disease, tumor is positive for BRAF V600E or BRAF V600K mutation. For non-small cell lung cancer all of the following criteria must be met: 1) tumor is positive for the BRAF V600E mutation, and 2) patient has recurrent, advanced, or metastatic NSCLC. For thyroid carcinoma, all the following criteria must be met: 1) tumor is positive for spositive for BRAF V600E or V600K mutation, and 2) patient has recurrent, advanced, or metastatic NSCLC. For thyroid carcinoma, all the following criteria must be met: 1) tumor is positive for BRAF V600E or V600K mutation, and 2) patient has radioiodine refractory follicular, Hurthle cell, or papillary thyroid carcinoma. For colorectal cancer, all of the following criteria must be met: 1) tumor is BRAF V600E mutation positive, 2) disease is unresectable or metastatic. For hairy cell leukemia: the requested drug will be used for subsequent therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Non-small cell lung cancer, hairy cell leukemia, thyroid carcinoma (papillary carcinoma, follicular carcinoma, and Hurthle cell carcinoma), and colorectal cancer.

### ZIRABEV

#### **Products Affected**

• Zirabev

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	Breast cancer, central nervous system (CNS) tumor types: adult low-grade (WHO Grade II) infiltrative supratentorial astrocytoma/oligodendroglioma, adult intracranial and spinal ependymoma, anaplastic gliomas, adult medulloblastoma, primary central nervous system lymphoma, meningiomas, limited and extensive brain metastases, leptomeningeal metastases and metastatic spine tumors, malignant pleural mesothelioma, epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer, including the following cancer types: carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma, mucinous carcinoma, grade 1 endometrioid carcinoma, low-grade serous carcinoma, ovarian borderline epithelial tumors (low malignant potential) with invasive implants, and malignant sex cord-stromal tumors, soft tissue sarcoma types: angiosarcoma and solitary fibrous tumor/hemangiopericytoma, AIDS-related Kaposi sarcoma, uterine cancer, endometrial cancer, vulvar cancer, and ophthalmic-related disorders: diabetic macular edema, neovascular (wet) age-related macular degeneration including polypoidal choroidopathy and retinal angiomatous proliferation subtypes, macular edema following retinal vein occlusion, proliferative diabetic retinopathy, choroidal neovascularization, neovascular glaucoma and retinopathy of prematurity, hepatocellular carcinoma.

## ZOLINZA

### **Products Affected**

• Zolinza

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Mycosis fungoides, Sezary syndrome.

# ZYDELIG

### **Products Affected**

• Zydelig

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Refractory chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), refractory follicular lymphoma, and marginal zone lymphomas [nodal marginal zone lymphoma, gastric mucosa associated lymphoid tissue (MALT) lymphoma, non-gastric MALT lymphoma, and splenic marginal zone lymphoma].

# ZYKADIA

### **Products Affected**

• Zykadia Oral Tablet

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
Required Medical Information	For NSCLC: the member has recurrent, advanced, or metastatic ALK-positive or ROS1-positive disease. For inflammatory myofibroblastic tumor: the disease is ALK-positive. For brain metastases from NSCLC: the member has ALK-positive NSCLC
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Recurrent or advanced anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC), recurrent, advanced, or metastatic repressor of silencing(ROS-1)-positive non-small cell lung cancer (NSCLC), inflammatory myofibroblastic tumor (IMT), brain metastases from NSCLC.

# ZYPREXA RELPREVV

### **Products Affected**

• ZyPREXA Relprevv

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Tolerability with oral olanzapine has been established.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	