Last Updated: 12/01/2022

## **ABIRATERONE**

### **Products Affected**

• Abiraterone Acetate

• Zytiga TABS 500MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Node-positive (N1), non-metastatic (M0) prostate cancer
Exclusion Criteria	N/A
Required Medical Information	The requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

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## **ACITRETIN**

### **Products Affected**

#### • Acitretin

PA Criteria	Criteria Details
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)
Exclusion Criteria	N/A
Required Medical Information	Psoriasis: The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to methotrexate or cyclosporine.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **ACTIMMUNE**

### **Products Affected**

#### • Actimmune

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

## **ADEMPAS**

### **Products Affected**

### • Adempas

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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 20 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 or equal to 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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **AIMOVIG**

### **Products Affected**

### • Aimovig

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial 3 months, Reauthorization Plan Year
Other Criteria	N/A

## **ALECENSA**

### **Products Affected**

#### • Alecensa

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

# **ALOSETRON**

### **Products Affected**

## • Alosetron Hydrochloride

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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 one conventional therapy (e.g., antispasmodics, antidepressants, antidiarrheals).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **ALPHA1-PROTEINASE INHIBITOR**

### **Products Affected**

#### • Prolastin-c

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For alpha1-proteinase inhibitor deficiency: Patient must have 1) clinically evident emphysema and 2) pretreatment serum alpha1-proteinase inhibitor level less than 11 micromol/L (80 mg/dL by radial immunodiffusion or 50 mg/dL by nephelometry).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **ALUNBRIG**

### **Products Affected**

### • Alunbrig

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

## **AMBRISENTAN**

### **Products Affected**

#### • Ambrisentan

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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 20 mmHg, 2) Pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, and 3) Pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **ARCALYST**

### **Products Affected**

### • Arcalyst

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Prevention of gout flares in patients initiating or continuing urate- lowering therapy.
Exclusion Criteria	N/A
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 (NSAID) 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 concurrently with the requested drug.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	For prevention of gout flares: 4 months. Other: Plan Year
Other Criteria	N/A

## ARMODAFINIL

## **Products Affected**

## • Armodafinil

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) The patient has a diagnosis of narcolepsy and the diagnosis is confirmed by sleep lab evaluation OR 2) The patient has a diagnosis of Shift Work Disorder (SWD) OR 3) The patient has a diagnosis of obstructive sleep apnea (OSA) and the diagnosis is confirmed by polysomnography.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **ASPARLAS**

## **Products Affected**

### • Asparlas

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Patient age 21 years or less
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **AUSTEDO**

## **Products Affected**

#### • Austedo

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

## **AVONEX**

### **Products Affected**

• Avonex Pen

• Avonex INJ 30MCG/0.5ML

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

## **A**YVAKIT

### **Products Affected**

### • Ayvakit

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Myeloid and lymphoid neoplasms with eosinophilia, gastrointestinal stromal tumor (GIST) for unresectable, recurrent, or metastatic disease without platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation
Exclusion Criteria	N/A
Required Medical Information	For myeloid and lymphoid neoplasms with eosinophilia, the patient meets all of the following criteria: 1) the disease is FIP1L1- PDGFRA rearrangement-positive, AND 2) The disease harbors a PDGFRA D842A mutation, AND 3) The disease is resistant to imatinib. For GIST, the patient meets either of the following criteria: 1) The disease harbors PDGFRA exon 18 mutation, including PDGFRA D842V mutations, OR 2) The requested drug will be used after failure on at least two Food and Drug Administration (FDA)-approved therapies in unresectable, recurrent, or metastatic disease without PDGFRA exon 18 mutation. 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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **B**ALVERSA

## **Products Affected**

#### • Balversa

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

# BANZEL

## **Products Affected**

• Banzel TABS

#### • Rufinamide

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

# BELEODAQ

### **Products Affected**

### • Beleodaq

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Adult T-cell leukemia/lymphoma, mycosis fungoides/Sezary syndrome, extranodal NK/T-cell lymphoma (nasal type), hepatosplenic gamma-delta T-cell lymphoma, and primary cutaneous anaplastic large cell lymphoma
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **BENLYSTA**

## **Products Affected**

### • Benlysta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	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 because patient tried and had an inadequate response or intolerance to a stable standard therapy regimen.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **B**ESREMI

## **Products Affected**

### • Besremi

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

## **BETASERON**

## **Products Affected**

#### • Betaseron

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

## **BEVACIZUMAB**

### **Products Affected**

#### • Zirabev

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
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, 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, uterine neoplasms, endometrial cancer, vulvar squamous cell carcinoma, 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, small bowel adenocarcinoma.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
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.
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## **BEXAROTENE**

## **Products Affected**

#### • Bexarotene CAPS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Mycosis fungoides, Sezary syndrome, CD30-positive primary cutaneous anaplastic large cell lymphoma, CD30-positive lymphomatoid papulosis.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **BLENREP**

### **Products Affected**

### • Blenrep

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

# **BOSENTAN**

### **Products Affected**

• Bosentan

#### • Tracleer TBSO

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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 20 mmHg, 2) Pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, and 3) Pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **BOSULIF**

### **Products Affected**

### • Bosulif

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL)
Exclusion Criteria	N/A
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, including patients newly diagnosed with CML and patients who have received a hematopoietic stem cell transplant: patient has experienced resistance or intolerance to imatinib or dasatinib. If patient experienced resistance to an alternative tyrosine kinase inhibitor for CML, patient is negative for all of the following mutations: T315I, G250E, V299L, and F317L.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **B**RAFTOVI

### **Products Affected**

#### • Braftovi CAPS 75MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Adjuvant systemic therapy for cutaneous melanoma
Exclusion Criteria	N/A
Required Medical Information	For colorectal cancer: The patient must meet both of the following criteria: 1) Tumor is positive for BRAF V600E mutation, 2) The requested drug will be used for either of the following: a) as subsequent therapy for advanced or metastatic disease, or b) as primary treatment for unresectable metachronous metastases. For cutaneous melanoma: The patient must meet all of the following criteria: 1) Tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K), 2) The requested drug will be used in combination with binimetinib, and 3) The requested drug will be used for either of the following: a) unresectable or metastatic disease, or b) adjuvant systemic therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **BRIVIACT**

### **Products Affected**

• Briviact ORAL SOLN

#### • Briviact TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) The patient has experienced an inadequate treatment response, intolerance, or contraindication to a generic anticonvulsant AND 2) If the patient is 4 years of age or older, the patient has experienced an inadequate treatment response, intolerance, or contraindication to any of the following: Aptiom, Vimpat, Xcopri, Spritam.
Age Restrictions	1 month of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **B**RIVIACT INJ

### **Products Affected**

#### • Briviact INJ

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) The patient has experienced an inadequate treatment response, intolerance, or contraindication to a generic anticonvulsant AND 2) If the patient is 4 years of age or older, the patient has experienced an inadequate treatment response, intolerance, or contraindication to any of the following: Aptiom, Vimpat, Xcopri, Spritam.
Age Restrictions	1 month of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **B**RUKINSA

### **Products Affected**

## • Brukinsa

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

# **BUPRENORPHINE**

### **Products Affected**

• Buprenorphine Hcl SUBL

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The requested drug is being prescribed for the treatment of opioid use disorder AND patient meets one of the following: 1) 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 2) The requested drug is being prescribed for induction therapy for transition from opioid use to treatment of opioid use disorder OR 3) 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	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

# **BUPRENORPHINE PATCH**

### **Products Affected**

### • Buprenorphine PTWK

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **CABOMETYX**

### **Products Affected**

### • Cabometyx

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Non-small cell lung cancer
Exclusion Criteria	N/A
Required Medical Information	For renal cell carcinoma: The disease is advanced, relapsed, or stage IV. For non-small cell lung cancer: 1) The disease is rearranged during transfection (RET) positive AND 2) the disease is recurrent, advanced, or metastatic. For hepatocellular carcinoma: the requested drug will be used as subsequent treatment.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **CALCIPOTRIENE**

### **Products Affected**

- Calcipotriene CREA
- Calcipotriene OINTCalcipotriene SOLN

- Calcipotriene/betamethasone Dipropionate OINT
- Calcitrene
- Calcitriol OINT
- Enstilar

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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 the patient has a contraindication to a topical steroid.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **CALQUENCE**

### **Products Affected**

### • Calquence

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma
Exclusion Criteria	N/A
Required Medical Information	For chronic lymphocytic leukemia or small lymphocytic lymphoma: the patient has experienced an intolerable adverse event with ibrutinib.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **C**APLYTA

### **Products Affected**

### • Caplyta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For treatment of schizophrenia: 1) The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following generic products: aripiprazole, asenapine, olanzapine, quetiapine, risperidone, ziprasidone, AND 2) The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following brand products: Latuda, Rexulti, Secuado, Vraylar. For treatment of depressive episodes associated with bipolar I: 1) The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following generic products: olanzapine, quetiapine, AND 2) The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following brand products: Latuda, Vraylar. For treatment of depressive episodes associated with bipolar II: The patient experienced an inadequate treatment response, intolerance, or contraindication to generic quetiapine.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **CAPRELSA**

# **Products Affected**

### • Caprelsa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Differentiated thyroid carcinoma: papillary, follicular, and Hurthle cell.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **C**ARAC

### **Products Affected**

#### • Fluorouracil CREA 0.5%

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Patients who are pregnant or may become pregnant. Patients with dihydropyrimidine dehydrogenase (DPD) enzyme deficiency.
Required Medical Information	If being used as part of a compounded product, all active ingredients in the compounded product are FDA approved for topical use.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	N/A

# **C**ARBAGLU

### **Products Affected**

• Carbaglu

### • Carglumic Acid

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

# **CAYSTON**

### **Products Affected**

### • Cayston

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **CERDELGA**

### **Products Affected**

### • Cerdelga

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

### **CHANTIX**

#### **Products Affected**

- Apo-varenicline
- Chantix TABS 0.5MG, 1MG
- Chantix Continuing Month Pak

- Chantix Starting Month Pak TBPK
- Varenicline Starting Month Box
- Varenicline Tartrate

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	This Prior Authorization requirement applies after the member has received a cumulative 24 weeks of therapy in a Plan Year.

# **CHLORDIAZEPOXIDE - 65**

### **Products Affected**

- Chlordiazepoxide Hcl CAPS 10MG, 5MG
- Chlordiazepoxide Hydrochloride CAPS 25MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For all indications: the prescriber must acknowledge the benefit of therapy with the prescribed medication outweighs the potential risks for the patient. (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.) For the management of anxiety disorders: 1) the requested drug is being used concurrently with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) until SSRI/SNRI is effective for the symptoms of anxiety, OR 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to AT LEAST TWO agents from the following classes: a) selective serotonin reuptake inhibitors (SSRIs), OR b) serotonin-norepinephrine reuptake inhibitors (SNRIs).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Short-term relief anxiety-preop apprehens and anx-1 mo, Anxiety Disorder-4 mo, Alc Withdrawal-PlanYR
Other Criteria	This Prior Authorization requirement only applies to patients 65 years of age or older.

# **CLOBAZAM**

### **Products Affected**

#### • Clobazam

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

# **CLOMIPRAMINE**

# **Products Affected**

### • Clomipramine Hcl CAPS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Depression, Panic Disorder
Exclusion Criteria	N/A
Required Medical Information	1) The requested drug is being prescribed for one of the following: 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) or a selective serotonin reuptake inhibitor (SSRI) OR 3) The requested drug is being prescribed for 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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **CLORAZEPATE**

### **Products Affected**

### • Clorazepate Dipotassium TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For all indications: the prescriber must acknowledge the benefit of therapy with the requested drug outweighs the potential risks for the patient. (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.) For the management of anxiety disorders: 1) the requested drug is being used concurrently with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) until the SSRI/SNRI becomes effective for the symptoms of anxiety OR 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to AT LEAST TWO agents from the following classes: a) selective serotonin reuptake inhibitors (SSRIs) OR b) serotonin-norepinephrine reuptake inhibitors (SNRIs).
Age Restrictions	N/A
Prescriber Restrictions	N/A
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.

# **CLOZAPINE ODT**

### **Products Affected**

• Clozapine Odt

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

# **COLY-MYCIN**

### **Products Affected**

#### • Colistimethate Sodium INJ

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Intravenous (IV) or intramuscular (IM) use only. Administration will not be via nebulizer. (Note: CMS endorsed compendia do not support inhalation/nebulization of colistimethate.). The infection is proven or strongly suspected to be caused by susceptible bacteria based on: 1) culture and susceptibility information OR 2) local epidemiology and susceptibility patterns.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist
Coverage Duration	Initial approval: 3 months, Renewal: Plan Year
Other Criteria	N/A

# **COMETRIQ**

### **Products Affected**

### • Cometriq

PA Criteria	Criteria Details
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.
Exclusion Criteria	N/A
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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **C**OPIKTRA

### **Products Affected**

### • Copiktra

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

# **C**OTELLIC

### **Products Affected**

### • Cotellic

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Central nervous system (CNS) cancer (i.e., glioma, meningioma, astrocytoma)
Exclusion Criteria	N/A
Required Medical Information	For adjuvant treatment of melanoma, and central nervous system (CNS) cancer (i.e., glioma, meningioma, astrocytoma): The patient must meet both of the following criteria: 1) The tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K), and 2) The requested drug will be used in combination with vemurafenib. For unresectable or metastatic melanoma: The patient must meet both of the following criteria: 1) The tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K), and 2) The requested drug will be used in combination with vemurafenib (with or without atezolizumab).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **CYSTAGON**

### **Products Affected**

### • Cystagon

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **CYSTARAN**

### **Products Affected**

### • Cystaran

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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) Patient has corneal cystine crystal accumulation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **D**ALFAMPRIDINE

### **Products Affected**

### • Dalfampridine Er

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **D**AURISMO

### **Products Affected**

#### • Daurismo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Post induction therapy following response to previous therapy with the same regimen for acute myeloid leukemia (AML). Relapsed/refractory AML as a component of repeating the initial successful induction regimen.
Exclusion Criteria	N/A
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-induction therapy, or relapsed or refractory disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **D**EFERASIROX

### **Products Affected**

#### • Deferasirox

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

# **DEMSER**

### **Products Affected**

### • Metyrosine

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

# **DESVENLAFAXINE**

### **Products Affected**

#### • Desvenlafaxine Er

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

# **DHE NASAL**

### **Products Affected**

• Dihydroergotamine Mesylate NASAL SOLN

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **DIACOMIT**

### **Products Affected**

#### • Diacomit

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

# **DIAZEPAM**

### **Products Affected**

- Diazepam CONC
- Diazepam INJ 5MG/ML

- Diazepam SOLN 5MG/5ML
- Diazepam TABS
  Diazepam Intensol

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For all indications: the prescriber must acknowledge the benefit of therapy with the requested drug outweighs the potential risks for the patient. (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.) For the management of anxiety disorders: 1) the requested drug is being used concurrently with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) until the SSRI/SNRI becomes effective for the symptoms of anxiety, OR 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to AT LEAST TWO agents from the following classes: a) selective serotonin reuptake inhibitors (SSRIs), b) serotonin-norepinephrine reuptake inhibitors (SNRIs).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Short-term relief anx-1 mo, skeletal muscle 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.

# DICLOFENAC GEL 1%

### **Products Affected**

• Diclofenac Sodium GEL 1%

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The patient has osteoarthritis pain in joints susceptible to topical treatment such as feet, ankles, knees, hands, wrists, or elbows.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **DICLOFENAC SOLN**

#### **Products Affected**

• Pennsaid SOLN 2%

• Diclofenac Sodium EXTERNAL SOLN 2%

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

# **DOPTELET**

# **Products Affected**

• Doptelet

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For thrombocytopenia associated with chronic liver disease: Baseline platelet count prior to a scheduled procedure is less than 50,000/mcL. For chronic immune thrombocytopenia (ITP): 1) For new starts: a) Patient has had an inadequate response or is intolerant to a prior therapy such as corticosteroids or immunoglobulins, AND b) Untransfused platelet count at any point prior to the initiation of the requested medication is less than 30,000/mcL OR 30,000 to 50,000/mcL with symptomatic bleeding or risk factor(s) for bleeding (e.g., undergoing a medical or dental procedure where blood loss is anticipated, comorbidities such as peptic ulcer disease and hypertension, anticoagulation therapy, profession or lifestyle that predisposes patient to trauma). 2) For continuation of therapy, platelet count response to the requested drug: a) Current platelet count is less than or equal to 200,000/mcL OR b) Current platelet count is greater than 200,000/mcL and less than or equal to 400,000/mcL and dosing will be adjusted to a platelet count sufficient to avoid clinically important bleeding.
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Chronic liver disease: 1 month, ITP initial: 6 months, ITP reauthorization: Plan Year
Other Criteria	N/A

# **D**RIZALMA

### **Products Affected**

### • Drizalma Sprinkle

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Cancer pain, chemotherapy-induced neuropathic pain
Exclusion Criteria	N/A
Required Medical Information	1) The patient has tried duloxetine capsules OR 2) 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	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **DRONABINOL**

### **Products Affected**

#### • Dronabinol

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For chemotherapy-induced nausea and vomiting (CINV): The patient is receiving cancer chemotherapy AND has experienced an inadequate treatment response, intolerance, or contraindication to one oral 5-HT3 receptor antagonist.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 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.

# **DUEXIS**

### **Products Affected**

• Duexis

### • Ibuprofen/famotidine

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The patient has tried two different regimens containing any combination of a nonsteroidal anti-inflammatory drug (NSAID) and an acid blocker from any of the following drug classes: H2-receptor antagonist (H2RA), proton pump inhibitor (PPI).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **EMSAM**

### **Products Affected**

#### • Emsam

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) 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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **ENBREL**

### **Products Affected**

• Enbrel

- Enbrel Mini
- Enbrel Sureclick

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Hidradenitis suppurativa
Exclusion Criteria	N/A
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 (new starts only): 1) Inadequate response to a non-steroidal anti-inflammatory drug (NSAID) trial, OR 2) Intolerance or contraindication to NSAIDs. 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 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). For hidradenitis suppurativa (new starts only): patient has severe, refractory disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **ENHERTU**

### **Products Affected**

#### • Enhertu

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Non-small cell lung cancer with human epidermal growth factor receptor 2 (HER2) mutations, HER2-amplified and RAS and BRAF wild-type colorectal cancer.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
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.

# **EPCLUSA**

### **Products Affected**

### • Epclusa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For hepatitis C virus (HCV): 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 human immunodeficiency virus (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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Criteria will be applied consistent with current AASLD-IDSA guidance.
Other Criteria	N/A

# **EPIDIOLEX**

## **Products Affected**

### • Epidiolex

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

# ЕРО

### **Products Affected**

#### • Procrit

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
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)
Exclusion Criteria	Patients receiving chemotherapy with curative intent. Patients with myeloid cancer.
Required Medical Information	Requirements regarding hemoglobin (Hgb) values exclude values due to a recent transfusion. For initial approval: 1) for all uses except anemia due to chemotherapy or myelodysplastic syndrome (MDS): patient has adequate iron stores AND 2) for all uses except surgery: pretreatment (no erythropoietin treatment in previous month) Hgb is less than 10 g/dL (less than 9 g/dL for anemia in congestive heart failure), AND 3) for MDS: pretreatment serum erythropoietin level is 500 international units/L or less. For reauthorizations (patient received erythropoietin treatment in previous month) in all uses except surgery: 1) patient has received at least 12 weeks of erythropoietin therapy, AND 2) patient responded to erythropoietin therapy, AND 3) current Hgb is less than 12 g/dL, AND 4) for all uses except anemia due to chemotherapy or MDS: patient has adequate iron stores.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	16 weeks
Other Criteria	Coverage includes use in anemia in patients whose religious beliefs forbid blood transfusions. 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).

# **ERIVEDGE**

#### **Products Affected**

### • Erivedge

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

# **ERLEADA**

#### **Products Affected**

#### • Erleada

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

# **ERLOTINIB**

#### **Products Affected**

### • Erlotinib Hydrochloride

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

# **ESBRIET**

### **Products Affected**

• Esbriet

#### • Pirfenidone

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **EVEROLIMUS**

#### **Products Affected**

- Afinitor TABS 10MG
- Afinitor Disperz

- Everolimus TABS 10MG, 2.5MG, 5MG, 7.5MG
- Everolimus TBSO

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted 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.
Exclusion Criteria	N/A
Required Medical Information	For breast cancer: 1) The disease is recurrent or metastatic hormone receptor (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 requested medication is used for subsequent treatment. For renal cell carcinoma: The disease is relapsed, advanced, or stage IV. For subependymal giant cell astrocytoma (SEGA): The requested drug is given as adjuvant treatment.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **EXKIVITY**

#### **Products Affected**

### • Exkivity

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

## **FANAPT**

### **Products Affected**

• Fanapt

### • Fanapt Titration Pack

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For treatment of schizophrenia: 1) The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following generic products: aripiprazole, asenapine, olanzapine, quetiapine, risperidone, ziprasidone AND 2) The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following brand products: Latuda, Rexulti, Secuado, Vraylar.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **FARYDAK**

#### **Products Affected**

### • Farydak

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

# **FASENRA**

## **Products Affected**

• Fasenra

#### • Fasenra Pen

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# FENTANYL PATCH

#### **Products Affected**

### • Fentanyl PT72

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **FETZIMA**

## **Products Affected**

• Fetzima

#### • Fetzima Titration Pack

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **FINTEPLA**

#### **Products Affected**

### • Fintepla

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

# FLUOROURACIL

### **Products Affected**

• Fluoroplex CREA

#### • Fluorouracil CREA 5%

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Patients who are pregnant or may become pregnant. Fluorouracil cream 5 percent only: Patients with dihydropyrimidine dehydrogenase (DPD) enzyme deficiency.
Required Medical Information	Applies to new starts only. If being used as part of a compounded product, all active ingredients in the compounded product are FDA approved for topical use.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	N/A

# FORTAMET/GLUMETZA

#### **Products Affected**

• Metformin Hydrochloride Er TB24 500MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The patient has experienced an intolerance to generic Glucophage XR.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **FORTEO**

### **Products Affected**

#### • Forteo INJ 600MCG/2.4ML

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For postmenopausal osteoporosis: patient has ONE of the following (1 or 2): 1) a history of fragility fracture, 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 or equal to -2.5, OR 3) pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment FRAX fracture probability. For glucocorticoid-induced osteoporosis: Patient has had an oral bisphosphonate trial of at least 1-year duration unless patient has a contraindication or intolerance to an oral bisphosphonate, AND patient meets ANY of the following: 1) patient has a history of fragility fracture, OR 2) a pre-treatment T-score of less than or equal to -2.5, OR 3) pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment T-score of less than or equal to -2.5, OR 3) pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment T-score of less than or equal to -2.5, OR 3) pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment T-score grea
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	24 months total unless the patient remains at high risk for fracture and benefit outweighs risk

#### **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.

# **FOTIVDA**

#### **Products Affected**

#### • Fotivda

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For advanced renal cell carcinoma: The following criteria must be met: 1) The disease is relapsed or refractory, 2) The requested medication must be used after at least two prior systemic therapies, and 3) The patient has experienced disease progression or an intolerable adverse event with a trial of cabozantinib.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **FYCOMPA**

### **Products Affected**

### • Fycompa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For treatment of partial-onset seizures: 1) The patient experienced an inadequate treatment response, intolerance, or contraindication to a generic anticonvulsant AND 2) The patient has experienced an inadequate treatment response, intolerance, or contraindication to any of the following: Aptiom, Vimpat, Xcopri, Spritam. For adjunctive treatment of primary generalized tonic-clonic seizures: 1) The patient experienced an inadequate treatment response, intolerance, or contraindication to a generic anticonvulsant AND 2) The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following: Vimpat, Spritam.
Age Restrictions	Partial-onset seizures: 4 years of age or older. Primary generalized tonic-clonic seizures: 12 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **GATTEX**

#### **Products Affected**

#### • Gattex

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For short bowel syndrome (SBS) initial therapy: Adult patients were dependent on parenteral support for at least 12 months. For SBS continuation: Requirement for parenteral support has decreased from baseline while on therapy with the requested medication.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **GAVRETO**

## **Products Affected**

#### • Gavreto

PA Criteria	Criteria Details
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
Exclusion Criteria	N/A
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	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	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **GILENYA**

### **Products Affected**

• Fingolimod

### • Gilenya CAPS 0.5MG

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

# **GILOTRIF**

#### **Products Affected**

#### • Gilotrif

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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 sensitizing EGFR mutation-positive disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **GLATIRAMER**

#### **Products Affected**

• Copaxone INJ 20MG/ML, 40MG/ML

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

# **GROWTH HORMONE**

#### **Products Affected**

• Genotropin

• Genotropin Miniquick

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Pediatric patients with closed epiphyses (except in patients with PWS).
Required Medical Information	Pediatric growth hormone deficiency (GHD): Patient (pt) meets any of the following: 1) younger than 2.5 years old (yo) with pre-treatment (pre-tx) height (ht) more than 2 standard deviations (SD) below mean and slow growth velocity OR 2) 2.5 yo or older AND one of the following: 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, AND patient meets any of the following: 1) failed 2 pre-tx growth hormone (GH) stimulation tests (peak below 10 ng/mL), OR 2) pituitary/central nervous system (CNS) disorder (e.g., genetic defects, CNS tumors, congenital structural abnormalities) and pre-tx insulin-like growth factor-1 (IGF-1) more than 2 SD below mean, OR 3) pt is a neonate or was diagnosed with GHD as a neonate. Turner syndrome: 1) Confirmed by karyotyping AND 2) pre-tx ht is less than the 5th percentile for age. Small for gestational age (GA): 1) Birth weight (wt) less than 2500g at GA greater 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.
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

Adult GHD: Pt meets any of the following: 1) failed 2 pre-tx GH stimulation tests, OR 2) pre-tx IGF-1 more than 2 SD below mean AND failed 1 pre-tx GH stimulation test. (Note: Stimulation tests include: a) insulin tolerance test [ITT] [peak GH less than or equal to 5 ng/ml], or b) Macrelin-stimulation test [peak GH level less than 2.8ng/ml], or c) glucagon-stimulation test [GST] [peak GH level less than or equal to 3 ng/ml] for pt with a body mass index [BMI] 25-30 kg/m2 and high pretest probability of GHD [e.g., acquired structural abnormalities] or BMI less than 25 kg/m2, or d) GST [peak GH level less than or equal to 1 ng/ml] in pt with BMI 25-30 kg/m2 and low pretest probability of GHD or BMI greater than 30 kg/m<sup>2</sup>), OR 3) organic hypothalamic-pituitary disease (e.g., suprasellar mass with previous surgery and cranial irradiation) with 3 or more pituitary hormone deficiencies AND pre-tx IGF-1 more than 2 SD below mean, OR 4) genetic or structural hypothalamic-pituitary defects, OR 5) childhood-onset GHD with congenital (genetic or structural) abnormality of the hypothalamus/pituitary/CNS. Renewal for pediatric GHD, TS, SGA, and adult GHD: Patient is experiencing improvement.

## HAEGARDA

#### **Products Affected**

### • Haegarda

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The requested drug is being used for the prevention 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, plasminogen, or kininogen-1 (KNG1) 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	N/A
Prescriber Restrictions	Immunologist, allergist, rheumatologist
Coverage Duration	Plan Year
Other Criteria	N/A

## **HARVONI**

#### **Products Affected**

#### • Harvoni

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For hepatitis C virus (HCV): 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 human immunodeficiency virus (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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Criteria applied consistent w/ current AASLD-IDSA guidance. Reminder for 8wk option if appropriate.
Other Criteria	N/A

# HERCEPTIN HYLECTA

#### **Products Affected**

### • Herceptin Hylecta

PA Criteria	Criteria Details
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 or advanced unresectable HER2-positive breast cancer.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
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.

# **HETLIOZ**

#### **Products Affected**

#### • Hetlioz

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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 either eye, 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 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	Non-24: 18 years of age or older. SMS: 16 years of age or older
Prescriber Restrictions	Sleep disorder specialist or neurologist
Coverage Duration	Initiation: 6 Months, Renewal: Plan Year
Other Criteria	N/A

# HETLIOZ LQ

#### **Products Affected**

### • Hetlioz Lq

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For nighttime sleep disturbances in Smith-Magenis Syndrome (SMS): 1) for initial therapy and continuation 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	3 to 15 years of age
Prescriber Restrictions	Sleep disorder specialist or neurologist
Coverage Duration	Initiation: 6 Months, Renewal: Plan Year.
Other Criteria	N/A

#### **HIGH RISK MEDICATION - 65**

#### **Products Affected**

- Chlordiazepoxide/amitriptyline
- Dicyclomine Hcl SOLN
- Dicyclomine Hydrochloride CAPS
- Dicyclomine Hydrochloride INJ
- Dicyclomine Hydrochloride TABS
- Dihydroergotamine Mesylate INJ
- Diphenhydramine Hcl INJ 50MG/ML
- Dipyridamole TABS
- Disopyramide Phosphate CAPS
- Guanfacine Er TB24 1MG, 2MG, 4MG
- Guanfacine Hcl TABS 1MG

- Guanfacine Hydrochloride TABS 2MG
- Guanfacine Hydrochloride TB24 3MG
- Ketorolac Tromethamine INJ 15MG/ML, 30MG/ML
- Ketorolac Tromethamine TABS
- Meprobamate
- Methscopolamine Bromide TABS
- Methyldopa TABS 250MG, 500MG
- Perphenazine/amitriptyline
- Thioridazine Hcl TABS 100MG, 10MG, 25MG, 50MG
- Trimethobenzamide Hydrochloride

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
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.)  Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.

# HRM - ANTICONVULSANTS - 65

#### **Products Affected**

- Phenobarbital ELIX 20MG/5ML
- Phenobarbital TABS 100MG, 15MG, 16.2MG, 30MG, 32.4MG, 60MG, 64.8MG, 97.2MG

• Phenobarbital Sodium INJ 130MG/ML, 65MG/ML

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Epilepsy
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
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.)  Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.

# HRM - HYPNOTICS - 65

### **Products Affected**

• Eszopiclone

- Zaleplon
- Zolpidem Tartrate TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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) OR 2) The non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) has been tried AND 3) 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 4) If the patient is using two or more additional central nervous system (CNS) active medications (e.g., lorazepam, quetiapine, sertraline, clonazepam, escitalopram, alprazolam) with the requested drug, the prescriber has determined that taking multiple central nervous system (CNS) active medications is medically necessary for the patient [Note: Use of multiple central nervous system (CNS) active medications in older adults is associated with an increased risk of falls.].
Age Restrictions	N/A
Prescriber Restrictions	N/A
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.) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.

## HRM - SCOPOLAMINE - 65

### **Products Affected**

• Scopolamine PT72 1MG/3DAYS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Excessive salivation
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
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.)  Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.

## HRM-ANTIPARKINSON - 65

- Benztropine Mesylate INJ
- Benztropine Mesylate TABS

- Trihexyphenidyl Hcl SOLN
- Trihexyphenidyl Hydrochloride

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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 OR 3) The patient has tried the non-HRM alternative drug amantadine AND 4) The patient experienced an inadequate treatment response OR intolerance to the non-HRM alternative drug amantadine. 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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
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.)  Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.

## HRM-CYPROHEPTADINE - 65

### **Products Affected**

• Cyproheptadine Hcl SYRP

• Cyproheptadine Hydrochloride TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Pruritus, spasticity due to spinal cord injury
Exclusion Criteria	N/A
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	N/A
Prescriber Restrictions	N/A
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.)  The prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.

## HRM-DOXEPIN - 65

#### **Products Affected**

- Doxepin Hcl CAPS 75MG
- Doxepin Hcl CONC

• Doxepin Hydrochloride CAPS 100MG, 10MG, 150MG, 25MG, 50MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For depression: 1) The patient tried two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone. 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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
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.)  Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.

### HRM-HYDROXYZINE - 65

- Hydroxyzine Hcl TABS 50MG
- Hydroxyzine Hydrochloride SYRP
- Hydroxyzine Hydrochloride TABS 10MG, 25MG
- Hydroxyzine Pamoate CAPS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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 OR 3) The patient has not tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline or venlafaxine extended-release AND 4) The patient has acute anxiety. If the patient is taking one or more additional anticholinergic medications (e.g., oxybutynin, meclizine, paroxetine, amitriptyline, dicyclomine, cyclobenzaprine) with the requested drug, the prescriber has determined that taking multiple anticholinergic medications is medically necessary for the patient [Note: Use of multiple anticholinergic medications in older adults is associated with an increased risk of cognitive decline.].
Age Restrictions	N/A
Prescriber Restrictions	N/A
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.)  Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.

## HRM-HYDROXYZINE INJ - 65

### **Products Affected**

• Hydroxyzine Hcl INJ 25MG/ML

• Hydroxyzine Hydrochloride INJ

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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 OR 3) The patient has tried one of the following alternative drugs: clorazepate or lorazepam AND 4) The patient experienced an inadequate treatment response OR intolerance to one of the following alternative drugs: clorazepate or lorazepam. 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 OR 3) The patient has not tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline or venlafaxine extended-release AND 4) The patient has acute anxiety.
Age Restrictions	N/A
Prescriber Restrictions	N/A
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.)  Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.

### **HRM-PROMETHAZINE - 65**

- Promethazine Hcl INJ
- Promethazine Hcl SUPP 12.5MG, 25MG
- Promethazine Hcl TABS 12.5MG

- Promethazine Hcl Plain
- Promethazine Hydrochloride TABS 25MG, 50MG
- Promethegan

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
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.)  Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.

### HRMS - ANTIDEPRESSANTS

- Amitriptyline Hcl TABS 100MG, 150MG, 75MG
- Amitriptyline Hydrochloride TABS 10MG, 25MG, 50MG
- Desipramine Hydrochloride

- Imipramine Hcl TABS 25MG, 50MG
- Imipramine Hydrochloride TABS 10MG
- Imipramine Pamoate

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Neuropathic pain
Exclusion Criteria	N/A
Required Medical Information	If the requested drug is being prescribed for the treatment of depression:  1) The patient tried two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone.
Age Restrictions	N/A
Prescriber Restrictions	N/A
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.)  Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.

## HRMS - CARBINOXAMINE

#### **Products Affected**

• Carbinoxamine Maleate TABS

• Carbinoxamine Maleate SOLN

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
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.)  Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.

## HRMS - CLEMASTINE- 65

### **Products Affected**

• Clemastine Fumarate TABS 2.68MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
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.)  Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.

## HRMS - MECLIZINE - 65

#### **Products Affected**

• Meclizine Hcl TABS 12.5MG

• Meclizine Hydrochloride TABS 25MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
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.)  Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.

## HRMS - TCAS

### **Products Affected**

• Protriptyline Hcl

• Trimipramine Maleate CAPS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) The patient tried two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone.
Age Restrictions	N/A
Prescriber Restrictions	N/A
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.)  Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.

## HRM-SKELETAL MUSCLE RELAXANTS - 65

#### **Products Affected**

• Chlorzoxazone TABS 500MG

• Cyclobenzaprine Hydrochloride TABS 10MG, 5MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	If the patient is using one or more additional anticholinergic medications (e.g., oxybutynin, meclizine, paroxetine, amitriptyline, dicyclomine, hydroxyzine) with the requested drug, the prescriber has determined that taking multiple anticholinergic medications is medically necessary for the patient [Note: Use of multiple anticholinergic medications in older adults is associated with an increased risk of cognitive decline.].
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
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.)  Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.

## HUMIRA

- Humira INJ 10MG/0.1ML, 20MG/0.2ML, 40MG/0.4ML, 40MG/0.8ML
- Humira Pediatric Crohns Disease Starter Pack INJ 0, 80MG/0.8ML

- Humira Pen
- Humira Pen-cd/uc/hs Starter
- Humira Pen-pediatric Uc Starter Pack
- Humira Pen-ps/uv Starter

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Axial spondyloarthritis, Behcet's syndrome
Exclusion Criteria	N/A
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): 1) Inadequate response to a non-steroidal anti-inflammatory drug (NSAID) trial OR 2) Intolerance or contraindication to NSAIDs. 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 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). 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), OR 2) Intolerance or contraindication to conventional therapy.
Age Restrictions	N/A

Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **HYPNOTIC-BENZODIAZEPINES - 65**

### **Products Affected**

• Triazolam

• Temazepam CAPS 15MG, 22.5MG, 7.5MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prescriber must acknowledge the benefit of therapy with the requested drug outweighs the potential risks for the patient. (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.) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to doxepin (3 mg or 6 mg).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization requirement only applies to patients 65 years of age or older.

## **IBRANCE**

### **Products Affected**

#### • Ibrance

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Unresectable well-differentiated/dedifferentiated liposarcoma of the retroperitoneum.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **ICATIBANT**

### **Products Affected**

• Icatibant Acetate

• Sajazir

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For hereditary angioedema (HAE): The requested drug is being used for the treatment 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, plasminogen, or kininogen-1 (KNG1) 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	Immunologist, allergist, rheumatologist
Coverage Duration	Plan Year
Other Criteria	N/A

## **ICLUSIG**

### **Products Affected**

• Iclusig

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Therapy after hematopoietic stem cell transplant (HSCT) for chronic myeloid leukemia (CML) and acute lymphoblastic leukemia (ALL) patients
Exclusion Criteria	N/A
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, including patients who have received a hematopoietic stem cell transplant: 1) patient has accelerated or blast phase CML and no other kinase inhibitor is indicated, OR 2) patient has chronic phase CML and has experienced resistance or intolerance to at least 2 prior kinase inhibitors AND at least one of those was imatinib or dasatinib, OR 3) patient is positive for the T315I mutation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **I**DHIFA

### **Products Affected**

#### • Idhifa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Newly-diagnosed acute myeloid leukemia
Exclusion Criteria	N/A
Required Medical Information	For acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation: 1) patient has a physiologic age of 60 years or older with newly-diagnosed AML and meets one of the following: a) patient is not a candidate for intensive induction therapy, or b) patient declines intensive induction chemotherapy, OR 2) patient has a physiologic age of 60 years or older and the requested drug will be used as post-induction therapy following response to induction therapy with the requested drug OR 3) patient has relapsed or refractory AML.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **IMATINIB**

### **Products Affected**

### • Imatinib Mesylate

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Desmoid tumors, pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT), recurrent chordoma, melanoma, AIDS-related Kaposi sarcoma, chronic myelomonocytic leukemia, chronic graft versus host disease (cGVHD), T-cell acute lymphoblastic leukemia, aggressive systemic mastocytosis when eosinophilia is present with FIP1L1-PDGFRA fusion gene
Exclusion Criteria	N/A
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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **IMBRUVICA**

## **Products Affected**

## • Imbruvica

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Hairy cell leukemia, lymphoplasmacytic lymphoma, follicular lymphoma, primary central nervous system lymphoma, AIDS-related B-cell lymphoma, histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma, diffuse large B-cell lymphoma, post-transplant lymphoproliferative disorders, high-grade B-cell lymphoma.
Exclusion Criteria	N/A
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 (rituximab, cyclophosphamide, vincristine, doxorubicin, and dexamethasone) regimen. For marginal zone lymphoma (including gastric mucosa-associated lymphoid tissue [MALT] lymphoma, non-gastric MALT lymphoma, nodal marginal zone lymphoma, and splenic marginal zone lymphoma): the patient has received at least one prior 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 OR 2) the requested drug is used for induction therapy as a single agent. For histologic transformation of nodal 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 as second-line or subsequent therapy. For AIDS-related B-cell lymphoma: the requested drug will be used as a single agent and as second-line or subsequent therapy for relapsed 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	N/A
Prescriber Restrictions	N/A

Coverage Duration	Plan Year
Other Criteria	N/A

## **IMLYGIC**

### **Products Affected**

## • Imlygic

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Limited resectable or incompletely resectable melanoma
Exclusion Criteria	N/A
Required Medical Information	For melanoma: The requested drug will be used for the treatment of unresectable, limited resectable, or incompletely resectable cutaneous, subcutaneous, and nodal lesions.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **INCRELEX**

### **Products Affected**

#### • Increlex

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Pediatric patients with closed epiphyses
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 (SD) below the mean for children of the same age and gender AND 2) basal IGF-1 level 3 or more SD 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. For renewal, patient is experiencing improvement.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **INLYTA**

### **Products Affected**

• Inlyta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Thyroid carcinoma (papillary, Hurthle cell, or follicular).
Exclusion Criteria	N/A
Required Medical Information	For renal cell carcinoma: the disease is advanced, relapsed, or stage IV.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# INQOVI

### **Products Affected**

• Inqovi

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

## **INREBIC**

### **Products Affected**

#### • Inrebic

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and janus kinase 2 (JAK2) rearrangement
Exclusion Criteria	N/A
Required Medical Information	For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and JAK2 rearrangement: the disease is in chronic or blast phase.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## IR BEFORE ER

- Hydrocodone Bitartrate Er T24A
- Hysingla Er
- Methadone Hcl INJ
- Methadone Hcl ORAL SOLN

- Methadone Hcl TABS
- Methadone Hydrochloride CONC
- Morphine Sulfate Er CP24
- Morphine Sulfate Er TBCR
- Tramadol Hcl Er TB24

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **IRESSA**

### **Products Affected**

#### • Iressa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Sensitizing epidermal growth factor receptor (EGFR) mutation-positive recurrent or advanced non-small cell lung cancer (NSCLC).
Exclusion Criteria	N/A
Required Medical Information	For NSCLC: 1) disease must be metastatic, advanced, or recurrent and 2) patient must have a sensitizing EGFR mutation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **ISOTRETINOIN**

- Accutane
- Amnesteem
- Claravis

- Isotretinoin CAPS
- Myorisan
- Zenatane

PA Criteria	Criteria Details
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.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **ITRACONAZOLE**

### **Products Affected**

#### • Itraconazole CAPS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Coccidioidomycosis, Coccidioidomycosis prophylaxis in HIV infection, Cryptococcosis, Histoplasmosis prophylaxis in HIV infection, invasive fungal infection prophylaxis in liver transplant patients, Microsporidiosis, Talaromycosis (formerly Penicilliosis), Pityriasis versicolor/Tinea versicolor, Sporotrichosis, Tinea corporis, Tinea cruris, Tinea capitis, Tinea manuum, Tinea pedis
Exclusion Criteria	N/A
Required Medical Information	If for the treatment of onychomycosis due to dermatophytes (Tinea unguium), the diagnosis has been confirmed by a fungal diagnostic test (e.g., potassium hydroxide [KOH] preparation, fungal culture, or nail biopsy).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Disseminated/CNS histoplasmosis, Histoplasmosis/Coccidioidomycosis ppx: 12 mths. Others: 6 mths
Other Criteria	N/A

# IVERMECTIN TAB

### **Products Affected**

### • Ivermectin TABS

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

### **IVIG**

- Bivigam INJ 10%, 5GM/50ML
- Flebogamma Dif
- Gammagard Liquid
- Gammagard S/d Iga Less Than 1mcg/ml
- Gammaked INJ 10GM/100ML, 1GM/10ML, 20GM/200ML, 5GM/50ML

- Gammaplex INJ 10GM/100ML, 10GM/200ML, 20GM/200ML, 20GM/400ML, 5GM/100ML, 5GM/50ML
- Gamunex-c
- Octagam INJ 10GM/100ML, 10GM/200ML, 2.5GM/50ML, 20GM/200ML, 25GM/500ML, 2GM/20ML, 30GM/300ML, 5GM/100ML, 5GM/50ML
- Panzyga
- Privigen

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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 (corticosteroid or immunosuppressant) 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	N/A
Prescriber Restrictions	N/A
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.

## **J**AKAFI

## **Products Affected**

#### • Jakafi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Lower-risk myelofibrosis, accelerated phase myelofibrosis, blast phase myelofibrosis/acute myeloid leukemia, acute lymphoblastic leukemia (ALL), chronic myelomonocytic leukemia (CMML)-2, BCR-ABL negative atypical chronic myeloid leukemia (aCML), essential thrombocythemia, and myeloid, lymphoid or mixed lineage neoplasms with eosinophilia and JAK2 rearrangement
Exclusion Criteria	N/A
Required Medical Information	For polycythemia vera: patient had an inadequate response or intolerance to interferon therapy or hydroxyurea. For 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. For CMML-2: the requested drug is used in combination with a hypomethylating agent. For BCR-ABL negative aCML: the requested drug is used as a single agent or in combination with a hypomethylating agent. For essential thrombocythemia: patient had an inadequate response or loss of response to hydroxyurea, interferon therapy, or anagrelide. For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and JAK2 rearrangement: the disease is in chronic or blast phase.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **KALYDECO**

### **Products Affected**

## • Kalydeco

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For cystic fibrosis (CF): The requested medication will not be used in combination with other medications containing ivacaftor.
Age Restrictions	4 months of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **KESIMPTA**

### **Products Affected**

## • Kesimpta

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

# **KETOCONAZOLE**

### **Products Affected**

#### • Ketoconazole TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Cushing's syndrome
Exclusion Criteria	Acute or chronic liver disease. Concurrent use with drugs that are contraindicated with ketoconazole tablets: dofetilide, quinidine, pimozide, cisapride, methadone, disopyramide, dronedarone, ranolazine, ergot alkaloids, irinotecan, lurasidone, oral midazolam, alprazolam, triazolam, felodipine, nisoldipine, tolvaptan, eplerenone, lovastatin, simvastatin, or colchicine.
Required Medical Information	The potential benefits outweigh the risks of treatment with oral ketoconazole. For systemic fungal infections, the patient has any of the following diagnoses: blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, or paracoccidioidomycosis. For Cushing's syndrome: the requested drug is being prescribed for a patient who cannot tolerate surgery or where surgery has not been curative.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	N/A

# KEYTRUDA

### **Products Affected**

## • Keytruda INJ 100MG/4ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# KISQALI

## **Products Affected**

- Kisqali
- Kisqali Femara 200 Dose

- Kisqali Femara 400 Dose
- Kisqali Femara 600 Dose

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
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 of the following criteria must be met: 1) the patient is pre- or peri-menopausal OR 2) the patient is postmenopausal OR male AND the patient has experienced an intolerable adverse event to Ibrance (palbociclib) AND Verzenio (abemaciclib) or has a contraindication 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 in a male, OR 2) the requested drug is being used following disease progression on endocrine therapy in a postmenopausal patient or in a male and the patient has experienced an intolerable adverse event to Ibrance (palbociclib) AND Verzenio (abemaciclib) OR has a contraindication to Ibrance (palbociclib) AND Verzenio (abemaciclib).

# **KORLYM**

### **Products Affected**

## • Korlym

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

# KRISTALOSE

## **Products Affected**

#### • Kristalose

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

# KUVAN

## **Products Affected**

• Javygtor PACK 100MG

- Javygtor TABS Sapropterin Dihydrochloride

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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 improvement (for example, reduction in blood phenylalanine levels, improvement in neuropsychiatric symptoms).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 2 months. All others: Plan Year.
Other Criteria	N/A

# **KYNMOBI**

### **Products Affected**

## • Kynmobi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For continuation treatment of off episodes in Parkinson's disease: The patient is experiencing improvement on the requested drug.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# LAPATINIB

### **Products Affected**

## • Lapatinib Ditosylate

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Brain metastases from human epidermal growth factor receptor 2 (HER2)-positive breast cancer, recurrent epidermal growth factor receptor (EGFR)-positive chordoma, HER2-amplified and RAS and BRAF wild-type colorectal cancer in combination with trastuzumab.
Exclusion Criteria	N/A
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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

### **LENVIMA**

#### **Products Affected**

- Lenvima 10 Mg Daily Dose
- Lenvima 12mg 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
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Medullary thyroid carcinoma, recurrent endometrial carcinoma, thymic carcinoma
Exclusion Criteria	N/A
Required Medical Information	For differentiated thyroid cancer (follicular, papillary, or Hurthle cell): disease is not amenable to radioactive iodine therapy and unresectable, locally recurrent, persistent, or metastatic. For hepatocellular carcinoma: disease is unresectable or inoperable, local, metastatic or with extensive liver tumor burden. For renal cell carcinoma, the disease is advanced, relapsed, or stage IV. For endometrial carcinoma, the patient meets ALL of the following: 1) The disease is advanced, recurrent, or metastatic, 2) The patient experienced disease progression following prior systemic therapy, AND 3) The patient is not a candidate for curative surgery or radiation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **LEUPROLIDE**

### **Products Affected**

• Leuprolide Acetate INJ 1MG/0.2ML

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Use in combination with growth hormone for children with growth failure and advancing puberty, recurrent androgen receptor positive salivary gland tumors.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **LIBTAYO**

### **Products Affected**

## • Libtayo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Inoperable or incompletely resected cutaneous squamous cell carcinoma
Exclusion Criteria	N/A
Required Medical Information	For cutaneous squamous cell carcinoma: patient meets both of the following: 1) disease is one of the following: a) metastatic, b) locally advanced, or c) regional and inoperable or incompletely resected, and 2) patient is not a candidate for curative surgery or curative radiation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **LIDOCAINE PATCHES**

### **Products Affected**

#### • Lidocaine PTCH 5%

PA Criteria	Criteria Details
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]).
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# LINEZOLID

### **Products Affected**

## • Linezolid

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The infection is proven or strongly suspected to be caused by susceptible bacteria. The patient will be using the requested drug orally or intravenously.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed or directed by an Infectious Disease specialist when being converted from intravenous (IV) linezolid (Zyvox)
Coverage Duration	28 days
Other Criteria	N/A

# **LONSURF**

### **Products Affected**

#### • Lonsurf

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For colorectal cancer: The disease is 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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **LORBRENA**

## **Products Affected**

#### • Lorbrena

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Anaplastic lymphoma kinase (ALK)-positive recurrent or advanced non-small cell lung cancer (NSCLC). Repressor of silencing (ROS)-1 rearrangement-positive recurrent, advanced, or metastatic NSCLC following progression on crizotinib, entrectinib, or ceritinib.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# LUMAKRAS

## **Products Affected**

#### • Lumakras

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

# LUMOXITI

### **Products Affected**

#### • Lumoxiti

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For hairy cell leukemia, the patient will not receive more than 6 cycles of treatment with the requested drug.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	N/A

# **LUPRON PED**

### **Products Affected**

• Lupron Depot-ped (1-month)

• Lupron Depot-ped (3-month)

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For central precocious puberty (CPP), patients not currently receiving therapy must meet all of the following criteria: 1) Diagnosis of CPP was confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test OR a pubertal level of a third generation luteinizing hormone (LH) assay, 2) Assessment of bone age versus chronological age supports the diagnosis of CPP, and 3) 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.
Age Restrictions	CPP: Patient must be less than 12 years old if female and less than 13 years old if male.
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **LUPRON-ENDOMETRIOSIS**

## **Products Affected**

• Lupron Depot (3-month) INJ 11.25MG

• Lupron Depot (1-month) INJ 3.75MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Breast cancer, malignant sex cord-stromal tumors, epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer
Exclusion Criteria	N/A
Required Medical Information	For uterine fibroids, patient must meet one of the following: 1) Diagnosis of anemia (e.g., 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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Fibroids: 3 months (mo), max 6 mo total. Endometriosis: 6 mo, max 12 mo total. Others: Plan Year
Other Criteria	N/A

## LYNPARZA

### **Products Affected**

## • Lynparza TABS

PA Criteria	Criteria Details
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
Exclusion Criteria	N/A
Required Medical Information	For recurrent or metastatic breast cancer: the disease is BRCA 1/2-germline mutated. For prostate cancer: The patient has progressed on prior treatment with an androgen receptor-directed therapy. For epithelial ovarian, fallopian tube, or primary peritoneal cancer: 1) The requested drug is used for maintenance therapy for stage II-IV or recurrent disease who are in complete or partial response to chemotherapy OR 2) The patient has deleterious or suspected deleterious germline BRCA-mutated advanced, recurrent, or persistent disease after two or more prior chemotherapy regimens.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# LYRICA CR

### **Products Affected**

## • Pregabalin Er

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

## **MAVYRET**

### **Products Affected**

## • Mavyret

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh [CTP] class B or C).
Required Medical Information	For hepatitis C virus (HCV): 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 [CTP class B or C]), presence or absence of human immunodeficiency virus (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 American Association for the Study of Liver Diseases (AASLD) treatment guidelines.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Criteria will be applied consistent with current AASLD-IDSA guidance
Other Criteria	N/A

# **MEKINIST**

### **Products Affected**

#### • Mekinist

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Brain metastases from melanoma, uveal melanoma, central nervous system (CNS) cancer (i.e., glioma, meningioma, astrocytoma), low grade serous ovarian cancer.
Exclusion Criteria	N/A
Required Medical Information	For brain metastasis from melanoma, adjuvant treatment of melanoma, and central nervous system (CNS) cancer (i.e., glioma, meningioma, astrocytoma): 1) The tumor is positive for a BRAF V600 activating mutation (e.g., V600E or V600K), and 2) The requested drug will be used in combination with dabrafenib. For unresectable or metastatic melanoma: 1) The tumor is positive for a BRAF V600 activating mutation (e.g., V600E or V600K), and 2) The requested drug will be used as a single agent or in combination with dabrafenib. For non-small cell lung cancer, anaplastic thyroid cancer, and solid tumors: 1) The tumor is positive for a BRAF V600E mutation, and 2) The requested drug will be used in combination with dabrafenib. For uveal melanoma, the requested drug will be used as a single agent. For low grade serous ovarian cancer: The requested drug will be used to treat persistent or recurrent disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **MEKTOVI**

### **Products Affected**

#### • Mektovi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Adjuvant systemic therapy for cutaneous melanoma
Exclusion Criteria	N/A
Required Medical Information	For cutaneous melanoma: The patient must meet all of the following criteria: 1) Tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K), 2) The requested drug will be used in combination with encorafenib, and 3) The requested drug will be used for either of the following: a) unresectable or metastatic disease, or b) adjuvant systemic therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **MEMANTINE**

#### **Products Affected**

- Memantine Hcl Titration Pak
- Memantine Hydrochloride SOLN 2MG/ML
- Memantine Hydrochloride TABSMemantine Hydrochloride Er

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

# **MEPRON**

### **Products Affected**

## • Atovaquone SUSP

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Babesiosis, Toxoplasmosis, Pneumocystis jirovecii pneumonia prophylaxis in pediatric patients, mild-to-moderate Pneumocystis jirovecii pneumonia treatment in pediatric patients.
Exclusion Criteria	N/A
Required Medical Information	For the treatment of mild-to-moderate Pneumocystis jiroveci pneumonia (PCP): the patient had an intolerance or has a contraindication to sulfamethoxazole/trimethoprim (SMX-TMP). For the prevention of PCP and primary toxoplasmosis prophylaxis indications: A) the patient had an intolerance or has a contraindication to SMX-TMP, AND B) the patient has had a CD4 cell count of less than 200 cells per cubic millimeter within the past 3 months. For secondary toxoplasmosis prophylaxis: the patient has had a CD4 cell count of less than 200 cells per cubic millimeter within the past 6 months. For babesiosis treatment: the requested drug is used concurrently with azithromycin OR clindamycin.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Secondary toxoplasmosis prophylaxis: 6 months, All other indications: 3 months
Other Criteria	N/A

# MODAFINIL

## **Products Affected**

## • Modafinil

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) The patient has a diagnosis of narcolepsy and the diagnosis is confirmed by sleep lab evaluation OR 2) The patient has a diagnosis of Shift Work Disorder (SWD) OR 3) The patient has a diagnosis of obstructive sleep apnea (OSA) and the diagnosis is confirmed by polysomnography.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# Monjuvi

## **Products Affected**

## • Monjuvi

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

# **MYLOTARG**

### **Products Affected**

## • Mylotarg

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Acute promyelocytic leukemia (APL)
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# NAPROXEN-ESOMEPRAZOLE

### **Products Affected**

• Naproxen/esomeprazole Magnesium

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The patient has tried two different regimens containing any combination of a nonsteroidal anti-inflammatory drug (NSAID) and an acid blocker from any of the following drug classes: H2-receptor antagonist (H2RA), proton pump inhibitor (PPI).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# NATPARA

### **Products Affected**

### • Natpara

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

# NAYZILAM

### **Products Affected**

## • Nayzilam

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	12 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **NERLYNX**

#### **Products Affected**

## • Nerlynx

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent human epidermal growth factor receptor 2 (HER2)-positive breast cancer, Brain metastases from HER2-positive breast cancer.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **NEXAVAR**

# **Products Affected**

• Nexavar

• Sorafenib Tosylate TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Acute myeloid leukemia, soft tissue sarcoma (angiosarcoma, desmoid tumors/aggressive fibromatosis, and solitary fibrous tumor subtypes), gastrointestinal stromal tumor, medullary thyroid carcinoma, osteosarcoma, recurrent chordoma, epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer.
Exclusion Criteria	N/A
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 azacitidine or decitabine for low-intensity treatment induction or post-induction 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 azacitidine or decitabine if the patient is FLT3-ITD mutation positive. For renal cell carcinoma, the patient meets ALL of the following: 1) The disease is advanced, AND 2) The patient has experienced disease progression or an intolerable adverse event with a trial of cabozantinib or axitinib.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **NINLARO**

## **Products Affected**

#### • Ninlaro

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Systemic light chain amyloidosis, Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma
Exclusion Criteria	N/A
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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **NITISINONE**

## **Products Affected**

#### • Nitisinone

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **NORTHERA**

#### **Products Affected**

### • Droxidopa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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 or head-up tilt test. For continuation of therapy for nOH, patient experienced benefit from therapy (e.g., a sustained decrease in dizziness, lightheadedness, or feeling faint). 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	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	N/A

# NUBEQA

### **Products Affected**

### • Nubeqa

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

# NUEDEXTA

## **Products Affected**

#### • Nuedexta

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

## NUPLAZID

#### **Products Affected**

• Nuplazid CAPS

### • Nuplazid TABS 10MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **NURTEC**

#### **Products Affected**

#### • Nurtec

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acute migraine treatment: The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to at least one triptan 5-HT1 receptor agonist. Preventive treatment of episodic migraine: 1) The patient received at least 3 months of preventive treatment with the requested drug and the patient had a reduction in migraine days per month from baseline OR 2) The patient meets either of the following: a) The patient experienced an inadequate treatment response with a 4-week trial of any one of the following: Antiepileptic drugs (AEDs), Beta-adrenergic blocking agents, Antidepressants OR b) The patient experienced an intolerance or has a contraindication that would prohibit a 4-week trial of any one of the following: Antiepileptic drugs (AEDs), Beta-adrenergic blocking agents, Antidepressants.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Preventive treatment of migraine - initial: 3 months, All other indications: Plan Year
Other Criteria	N/A

## **O**CTREOTIDE

### **Products Affected**

• Octreotide Acetate INJ 1000MCG/ML, 100MCG/ML, 200MCG/ML, 500MCG/ML

<b>D.</b> C. A.	
PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Tumor control of thymomas and thymic carcinomas.
Exclusion Criteria	N/A
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. For acromegaly (continuation of therapy): patient's IGF-1 level has decreased or normalized since initiation of therapy. For tumor control of thymomas and thymic carcinomas, the requested drug will be used as second-line systemic therapy in patients with unresectable or extrathoracic metastatic disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **O**DOMZO

#### **Products Affected**

#### • Odomzo

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

# **OFEV**

#### **Products Affected**

• Ofev

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

## **O**NCASPAR

#### **Products Affected**

#### • Oncaspar

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Extranodal natural killer/T-cell lymphoma (nasal type), hepatosplenic gamma-delta T-cell lymphoma
Exclusion Criteria	N/A
Required Medical Information	For extranodal natural killer/T-cell lymphoma (nasal type), acute lymphoblastic leukemia, and hepatosplenic gamma-delta T-cell lymphoma: the requested drug must be used in conjunction with multiagent chemotherapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **O**NUREG

#### **Products Affected**

#### • Onureg

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

# **O**PSUMIT

### **Products Affected**

### • Opsumit

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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 20 mmHg, 2) Pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, and 3) Pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **O**RACEA

### **Products Affected**

• Oracea

• Doxycycline CPDR

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Patient must have experienced an inadequate treatment response, intolerance, or has a contraindication to formulary generic topical metronidazole.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **ORAL-INTRANASAL FENTANYL**

#### **Products Affected**

• Fentanyl Citrate Oral Transmucosal

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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 with underlying CANCER pain 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.] AND 3) The patient is currently receiving, and will continue to receive, around-the-clock opioid therapy for underlying CANCER pain AND 4) The requested drug is intended only for use in opioid tolerant patients. The patient can safely take the requested dose based on their current opioid use history. [Note: 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 of oral hydrocodone per day, at least 8 mg of oral hydromorphone per day, at least 25 mg of oral oxymorphone per day, or an equianalgesic dose of another opioid medication daily for one week or longer.].
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **O**RGOVYX

#### **Products Affected**

## • Orgovyx

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

## **O**RKAMBI

## **Products Affected**

#### • Orkambi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For cystic fibrosis (CF): The requested medication will not be used in combination with other medications containing ivacaftor.
Age Restrictions	1 year of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **O**TEZLA

#### **Products Affected**

#### • Otezla

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For plaque psoriasis (new starts only): Patient meets either of the following: 1) Inadequate response or intolerance to ANY of the following: a) a topical therapy (e.g., a topical corticosteroid, calcineurin inhibitor, vitamin D analog), b) phototherapy (e.g., UVB, PUVA), or c) pharmacologic treatment with methotrexate, cyclosporine, or acitretin OR 2) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **O**XANDROLONE

#### **Products Affected**

#### • Oxandrolone TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Cachexia associated with AIDS (HIV wasting), To enhance growth in patients with Turners Syndrome
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Turners Syndrome: Plan Year, All other diagnoses: 6 months
Other Criteria	Coverage will be denied if request is for an indication excluded from Medicare Part D.

# OXAZEPAM - 65

#### **Products Affected**

#### • Oxazepam

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For all indications: the prescriber must acknowledge the benefit of therapy with the requested drug outweighs the potential risks for the patient. (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.) For the management of anxiety disorders, anxiety associated with depression, and the management of anxiety, tension, agitation and irritability in older patients: 1) the requested drug is being used concurrently with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) until the SSRI/SNRI becomes effective for the symptoms of anxiety, OR 2) the patient has experienced an inadequate treatment response, intolerance, or a has a contraindication to AT LEAST TWO agents from the following classes: a) selective serotonin reuptake inhibitors (SSRIs), b) serotonin-norepinephrine reuptake inhibitors (SNRIs).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Short-term relief anxiety-1 month, Anxiety Disorders-4 months, Alcohol Withdrawal-Plan Year
Other Criteria	This Prior Authorization requirement only applies to patients 65 years of age or older.

# **PADCEV**

#### **Products Affected**

#### • Padcev

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent primary carcinoma of the urethra, recurrent or persistent urothelial carcinoma of the bladder.
Exclusion Criteria	N/A
Required Medical Information	For urothelial carcinoma, the requested drug will be used as subsequent therapy for any of the following: a) locally advanced or metastatic urothelial carcinoma, b) urothelial carcinoma of the bladder with muscle invasive local recurrence or persistent disease in a preserved bladder, c) urothelial carcinoma of the bladder with metastatic or local recurrence post cystectomy, or d) recurrent primary carcinoma of the urethra.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **PEGASYS**

#### **Products Affected**

## • Pegasys

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Myeloproliferative neoplasm (essential thrombocythemia, polycythemia vera, symptomatic low risk myelofibrosis), systemic mastocytosis, adult T-cell leukemia/lymphoma, mycosis fungoides/Sezary syndrome, primary cutaneous CD30+ T-cell lymphoproliferative disorders.
Exclusion Criteria	N/A
Required Medical Information	For chronic hepatitis C: Hepatitis C virus (HCV) confirmed by presence of hepatitis C virus HCV RNA in serum prior to starting treatment and the planned treatment regimen.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	HCV: 12-48 weeks depending on regimen. HBV: 48 weeks. All Other: Plan Year.
Other Criteria	N/A

# **PEMAZYRE**

#### **Products Affected**

### • Pemazyre

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

# **PEPAXTO**

#### **Products Affected**

### • Pepaxto

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

## **PHENYLBUTYRATE**

#### **Products Affected**

• Sodium Phenylbutyrate POWD 3GM/TSP

• Sodium Phenylbutyrate TABS

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

# **PHESGO**

#### **Products Affected**

### • Phesgo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent human epidermal growth factor receptor 2 (HER2)-positive breast cancer
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Neoadjuvant therapy for breast cancer: 6 months. Other: Plan Year
Other Criteria	N/A

# **PIQRAY**

### **Products Affected**

• Piqray 200mg Daily Dose

- Piqray 250mg Daily Dose
- Piqray 300mg Daily Dose

PA Criteria	Criteria Details
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.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **POLIVY**

#### **Products Affected**

## • Polivy

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	High-grade B-cell lymphomas, histologic transformation of follicular to diffuse large B-cell lymphoma without translocations of MYC and BCL2 and/or BCL6, monomorphic post-transplant lymphoproliferative disorders (B-cell type), acquired immunodeficiency syndrome (AIDS)-related B-cell lymphomas (AIDS-related diffuse large B-cell lymphoma, primary effusion lymphoma, and human herpesvirus-8 (HHV8)-positive diffuse large B-cell lymphoma), histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma, follicular lymphoma.
Exclusion Criteria	N/A
Required Medical Information	For diffuse large B-cell lymphomas and high-grade B-cell lymphomas: 1) The requested drug is used as a single agent or in combination with bendamustine with or without a rituximab product, AND 2) Patient has received at least two prior therapies.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **POMALYST**

#### **Products Affected**

### • Pomalyst

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Systemic light chain amyloidosis, primary central nervous system (CNS) lymphoma, POEMS syndrome.
Exclusion Criteria	N/A
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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **POTELIGEO**

## **Products Affected**

### • Poteligeo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Adult T-cell leukemia/lymphoma
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **PRALUENT**

## **Products Affected**

#### • Praluent

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

## **PREGABALIN**

## **Products Affected**

• Pregabalin CAPS

### • Pregabalin SOLN

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Cancer-Related Neuropathic Pain, Cancer Treatment-Related Neuropathic Pain
Exclusion Criteria	N/A
Required Medical Information	1) The requested drug is being prescribed for the management of postherpetic neuralgia, the management of neuropathic pain associated with diabetic peripheral neuropathy, cancer-related neuropathic pain, or cancer treatment-related neuropathic pain AND 2) The patient has experienced an inadequate treatment response, intolerance, or contraindication to gabapentin OR 3) The requested drug is being prescribed as adjunctive therapy for the treatment of partial onset seizures OR 4) The requested drug is being prescribed for the management of fibromyalgia or the management of neuropathic pain associated with spinal cord injury.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **PRETOMANID**

## **Products Affected**

#### • Pretomanid

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

# **PROMACTA**

## **Products Affected**

#### • Promacta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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 a prior therapy such as corticosteroids or immunoglobulins, 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 (e.g., undergoing a medical or dental procedure where blood loss is anticipated, comorbidities such as peptic ulcer disease and hypertension, anticoagulation therapy, profession or lifestyle that predisposes patient to trauma) AND c) For chronic ITP only: patient has had an inadequate response or intolerance to avatrombopag. 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 to less than or equal to 400,000/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 is transfusion-independent, OR 4) Current plt count is greater than 200,000/mcL to less than or equal to 400,000/mcL and dosing will be adjusted to achieve and maintain an appropriate target plt count.
Age Restrictions	N/A
Prescriber Restrictions	N/A

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).

# **PULMOZYME**

## **Products Affected**

• Pulmozyme SOLN 2.5MG/2.5ML

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For cystic fibrosis: Diagnosis of cystic fibrosis was confirmed by appropriate diagnostic or genetic testing.
Age Restrictions	N/A
Prescriber Restrictions	N/A
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.

# **Q**INLOCK

## **Products Affected**

• Qinlock

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

# QUETIAPINE XR

## **Products Affected**

• Quetiapine Fumarate Er

PA Criteria	Criteria Details
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
Exclusion Criteria	N/A
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 experienced an inadequate treatment response, intolerance, or contraindication to one of the following generic products: A) aripiprazole, B) asenapine, C) olanzapine, D) quetiapine immediate-release, E) risperidone, F) ziprasidone. For all indications: If the patient is 65 years of age or older AND is using two or more additional central nervous system (CNS) active medications (e.g., lorazepam, sertraline, clonazepam, escitalopram, alprazolam, zolpidem) with the requested drug, the prescriber determined that taking multiple central nervous system (CNS) active medications is medically necessary. [Note: Use of multiple central nervous system (CNS) active medications in older adults is associated with an increased risk of falls.].
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# QUININE SULFATE

## **Products Affected**

• Quinine Sulfate CAPS 324MG

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

## **REGRANEX**

## **Products Affected**

## • Regranex

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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	N/A
Prescriber Restrictions	N/A
Coverage Duration	20 weeks
Other Criteria	N/A

## **RETEVMO**

## **Products Affected**

#### • Retevmo

PA Criteria	Criteria Details
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
Exclusion Criteria	N/A
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	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## REVLIMID

## **Products Affected**

• Lenalidomide

• Revlimid

PA Criteria	Criteria Details
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 non-germinal center 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, 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 T-cell lymphoma, high-grade B-cell lymphomas, histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma, histologic transformation of follicular lymphoma to diffuse large B-cell lymphoma, AIDS-related Kaposi sarcoma, smoldering myeloma
Exclusion Criteria	N/A
Required Medical Information	For myelodysplastic syndrome (MDS): Lower risk MDS with symptomatic anemia per the Revised International Prognostic Scoring System (IPSS-R), International Prognostic Scoring System (IPSS), or World Health organization (WHO) classification-based Prognostic Scoring System (WPSS).
Age Restrictions	N/A
Prescriber Restrictions	N/A

Coverage Duration	Plan Year
Other Criteria	N/A

## **REZUROCK**

## **Products Affected**

#### • Rezurock

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	12 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# RINVOQ

## **Products Affected**

## • Rinvoq

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For moderately to severely active rheumatoid arthritis (new starts only): patient has experienced an inadequate treatment response or intolerance to at least one tumor necrosis factor (TNF) inhibitor.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# RITUXAN HYCELA

## **Products Affected**

## • Rituxan Hycela

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Castleman's disease (CD), high-grade B-cell lymphoma, histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma, marginal zone lymphomas (nodal marginal zone lymphoma, gastric mucosa-associated lymphoid tissue (MALT) lymphoma, nongastric MALT lymphoma, and splenic marginal zone lymphoma), mantle cell lymphoma, post-transplant lymphoproliferative disorder (PTLD), primary cutaneous B-cell lymphoma (e.g., cutaneous marginal zone lymphoma or cutaneous follicle center lymphomas), hairy cell leukemia, small lymphocytic lymphoma (SLL).
Exclusion Criteria	N/A
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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **RITUXIMAB**

## **Products Affected**

• Rituxan

• Ruxience

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
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, histological transformation from follicular lymphoma to diffuse large B-cell lymphoma, histological transformation from nodal marginal zone lymphoma to diffuse large B-cell lymphoma, Castleman's disease, acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma, hairy cell leukemia, post-transplant lymphoproliferative disorder (PTLD), B-cell lymphoblastic lymphoma], 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
Exclusion Criteria	N/A

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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Immune checkpoint inhibitor-related toxicities: 3 months, All other: Plan Year
Other Criteria	N/A

# ROZLYTREK

## **Products Affected**

# • Rozlytrek

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent or advanced ROS1-positive non-small cell lung cancer (NSCLC), advanced, recurrent, or persistent neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors, first-line treatment of NTRK gene fusion-positive solid tumors.
Exclusion Criteria	N/A
Required Medical Information	For all neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors, the disease is without a known acquired resistance mutation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# RUBRACA

## **Products Affected**

#### • Rubraca

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For metastatic castration-resistant prostate cancer with a deleterious breast cancer susceptibility gene (BRCA) mutation (germline and/or somatic): 1) patient has been treated with androgen receptor-directed therapy, 2) patient has been treated with a taxane-based chemotherapy or the patient is not fit for chemotherapy, 3) the requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy, and 4) patient experienced an unacceptable toxicity with a trial of Lynparza (olaparib). For maintenance treatment of patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy, patient experienced an unacceptable toxicity with a trial of Lynparza (olaparib). For treatment of patients with a deleterious breast cancer susceptibility gene (BRCA) mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies: if prescribed for deleterious germline BRCA-mutated advanced ovarian cancer treated with two or more prior chemotherapies, the patient experienced an unacceptable toxicity with a trial of Lynparza (olaparib).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# RYDAPT

## **Products Affected**

## • Rydapt

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Relapsed or refractory acute myeloid leukemia (AML), myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FGFR1 or FLT3 rearrangements, post-remission maintenance therapy for acute myeloid leukemia (AML), re-induction in residual disease for acute myeloid leukemia (AML)
Exclusion Criteria	N/A
Required Medical Information	For acute myeloid leukemia (AML): AML must be FLT3 mutation-positive. For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FGFR1 or FLT3 rearrangements: the disease is in chronic or blast phase.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# SANDOSTATIN LAR

## **Products Affected**

• Sandostatin Lar Depot

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Tumor control of thymomas and thymic carcinomas, neuroendocrine tumors (NETs) of the gastrointestinal (GI) tract, lung, thymus (carcinoid tumors), unresected primary gastrinoma, NETs of the pancreas, and pheochromocytoma/paraganglioma.
Exclusion Criteria	N/A
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. For acromegaly (continuation of therapy): patient's IGF-1 level has decreased or normalized since initiation of therapy. For tumor control, the requested drug will be used for any of the following: 1) neuroendocrine tumors of the gastrointestinal tract or pancreas in patients with locoregional advanced disease and/or distant metastatic disease, OR 2) neuroendocrine tumors of the thymus or lung in patients with locoregional unresectable disease and/or distant metastatic disease, OR 3) unresected primary gastrinoma, OR 4) thymomas and thymic carcinomas as second-line systemic therapy in patients with unresectable or extrathoracic metastatic disease, OR 5) pheochromocytomas and paragangliomas, used for either of the following: a) symptomatic locally unresectable disease with somatostatin receptor positive imaging, OR b) secreting tumors in metastatic disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **SARCLISA**

## **Products Affected**

## • Sarclisa

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

## **SCEMBLIX**

## **Products Affected**

#### • Scemblix

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For chronic myeloid leukemia (CML) in the chronic phase: 1) the diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene AND the patient meets either of the following: A) the patient has previously been treated with 2 or more tyrosine kinase inhibitors (TKIs) AND at least one of those was imatinib or dasatinib, OR B) the patient is positive for the T315I mutation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **SIGNIFOR**

## **Products Affected**

## • Signifor

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

## **SILDENAFIL**

## **Products Affected**

• Sildenafil INJ

#### • Sildenafil Citrate TABS 20MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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 20 mmHg, 2) Pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, and 3) Pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **SIRTURO**

## **Products Affected**

#### • Sirturo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist.
Coverage Duration	Plan Year
Other Criteria	N/A

## **SKYRIZI**

## **Products Affected**

• Skyrizi

• Skyrizi Pen

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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 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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# SOMATULINE DEPOT

## **Products Affected**

## • Somatuline Depot

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Tumor control of neuroendocrine tumors (NETs) of the lung, thymus (carcinoid tumors) or unresected primary gastrinoma, and pheochromocytoma/paraganglioma.
Exclusion Criteria	N/A
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. For acromegaly continuation of therapy: patient's IGF-1 level has decreased or normalized since initiation of therapy. For tumor control, the requested drug will be used for any of the following: 1) neuroendocrine tumor of the thymus or lung in patients with locoregional unresectable disease and/or distant metastatic disease, OR 2) unresected primary carcinoma, OR 3) pheochromocytomas and paragangliomas, used for either of the following: a) symptomatic locally unresectable disease with somatostatin receptor positive imaging OR b) secreting tumor in metastatic disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **SOMAVERT**

## **Products Affected**

#### • Somavert

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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. For acromegaly continuation of therapy: patient's IGF-1 level has decreased or normalized since initiation of therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **SPRITAM**

## **Products Affected**

## • Spritam

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Partial-Onset Seizures: 4 years of age or older. Myoclonic Seizures: 12 years of age or older. Primary Generalized Tonic-Clonic Seizures: 6 years of age or older.
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **SPRYCEL**

## **Products Affected**

• Sprycel

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Gastrointestinal stromal tumor (GIST), metastatic chondrosarcoma, recurrent chordoma, T-cell acute lymphoblastic leukemia (ALL), Philadelphia (Ph)-like B-ALL
Exclusion Criteria	N/A
Required Medical Information	For chronic myeloid leukemia (CML), including patients who have received a hematopoietic stem cell transplant: diagnosis was confirmed by detection of the Philadelphia (Ph) chromosome or BCR-ABL gene. If patient experienced resistance to an alternative tyrosine kinase inhibitor for CML, patient is negative for T315I/A, F317L/V/I/C, and V299L mutations. For acute lymphoblastic leukemia (ALL), the patient has a diagnosis of one of the following: 1) Philadelphia chromosome positive ALL that has been confirmed by detection of the Ph chromosome or BCR-ABL gene, OR 2) Ph-like B-ALL with ABL-class kinase fusion, OR 3) relapsed or refractory T-cell ALL with ABL-class translocation. For GIST, patient must have progressed on imatinib, sunitinib, and regorafenib.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **STELARA**

## **Products Affected**

• Stelara INJ 45MG/0.5ML, 90MG/ML

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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 had an inadequate response, intolerance, or contraindication to two of the following products: Enbrel (etanercept), Humira (adalimumab), Otezla (apremilast), Skyrizi (risankizumab-rzaa). For active psoriatic arthritis (PsA) (new starts only): patient had an inadequate response, intolerance, or contraindication to two of the following products: Enbrel (etanercept), Humira (adalimumab), Otezla (apremilast), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For moderately to severely active Crohn's disease (new starts only): patient had an inadequate response, intolerance, or contraindication to one of the following products: Humira (adalimumab) or Skyrizi (risankizumab-rzaa). For moderately to severely active ulcerative colitis (new starts): patient had an inadequate response, intolerance, or contraindication to Humira (adalimumab).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **STIVARGA**

## **Products Affected**

## • Stivarga

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

## **SUTENT**

## **Products Affected**

Sutent

• Sunitinib Malate

PA Criteria	Criteria Details
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 alveolar soft part sarcoma subtypes), recurrent chordoma, thymic carcinoma.
Exclusion Criteria	N/A
Required Medical Information	For renal cell carcinoma, the disease is relapsed, advanced, or stage IV.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **SYMLIN**

## **Products Affected**

• Symlinpen 120

## • Symlinpen 60

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

## **SYMPAZAN**

## **Products Affected**

## • Sympazan

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

## **SYNRIBO**

## **Products Affected**

## • Synribo

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

# **TABRECTA**

## **Products Affected**

#### • Tabrecta

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

# TADALAFIL (PAH)

## **Products Affected**

• Alyq

#### • Tadalafil TABS 20MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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 20 mmHg, 2) Pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, and 3) Pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **TAFINLAR**

## **Products Affected**

#### • Tafinlar

PA Criteria	Criteria Details
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), central nervous system (CNS) cancer (i.e., glioma, meningioma, astrocytoma)
Exclusion Criteria	N/A
Required Medical Information	For brain metastases from melanoma, adjuvant treatment of melanoma, and central nervous system (CNS) cancer (i.e., glioma, meningioma, astrocytoma): 1) The tumor is positive for a BRAF V600 activating mutation (e.g., V600E or V600K), and 2) The requested drug will be used in combination with trametinib. For unresectable or metastatic melanoma: 1) The tumor is positive for a BRAF V600 activating mutation (e.g., V600E or V600K), and 2) The requested drug will be used as a single agent or in combination with trametinib. For non-small cell lung cancer and solid tumors: 1) The tumor is positive for a BRAF V600E mutation, and 2) The requested drug will be used in combination with trametinib. For thyroid carcinoma with papillary, follicular, or Hurthle histology: The tumor is positive for BRAF activating mutation (e.g., V600E or V600K).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **TAGRISSO**

### **Products Affected**

### • Tagrisso

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Sensitizing epidermal growth factor receptor (EGFR) mutation-positive recurrent or advanced non-small cell lung cancer (NSCLC), brain metastases from sensitizing EGFR mutation-positive NSCLC, leptomeningeal metastases from EGFR mutation-positive NSCLC
Exclusion Criteria	N/A
Required Medical Information	For NSCLC, the requested drug is used in any of the following settings:  1) The patient meets both of the following: a) patient has metastatic, advanced, or recurrent NSCLC (including brain and/or leptomeningeal metastases from NSCLC) and b) patient has a sensitizing EGFR mutation OR 2) Patient meets both of the following: a) request is for adjuvant treatment of NSCLC following tumor resection and b) patient has EGFR mutation-positive disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **TALTZ**

#### **Products Affected**

• Taltz

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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) The patient had an inadequate response, intolerance, or contraindication to one of the following products: Enbrel (etanercept), Humira (adalimumab), Otezla (apremilast), Skyrizi (risankizumab-rzaa). For active ankylosing spondylitis (new starts only): the patient had an inadequate response, intolerance, or contraindication to one of the following products: Enbrel (etanercept), Humira (adalimumab), Rinvoq, (upadacitinib), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). 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), Otezla (apremilast), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For active axial spondyloarthritis (new starts only): Patient meets any of the following: 1) has had an inadequate response to a non-steroidal anti-inflammatory drug (NSAID) trial or 2) has an intolerance or contraindication to NSAIDs.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **TALZENNA**

#### **Products Affected**

#### • Talzenna

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent germline breast cancer susceptibility gene (BRCA)-mutated breast cancer
Exclusion Criteria	N/A
Required Medical Information	For germline BRCA-mutated (gBRCAm) metastatic or recurrent breast cancer, the patient experienced an unacceptable toxicity with a trial of Lynparza (olaparib).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# TARGRETIN TOPICAL

#### **Products Affected**

• Bexarotene GEL

• Targretin GEL

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Mycosis fungoides, chronic or smoldering adult T-cell leukemia/lymphoma, primary cutaneous marginal zone lymphoma, primary cutaneous follicle center lymphoma.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **TASIGNA**

#### **Products Affected**

### • Tasigna

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL), gastrointestinal stromal tumor (GIST)
Exclusion Criteria	N/A
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, including patients newly diagnosed with CML and patients who have received a hematopoietic stem cell transplant: patient has experienced resistance or intolerance to imatinib or dasatinib. If patient experienced resistance to an alternative tyrosine kinase inhibitor for CML, patient is negative for T315I, Y253H, E255K/V, and F359V/C/I mutations. For GIST, patient must have progressed on imatinib, sunitinib, and regorafenib.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **TAZAROTENE**

#### **Products Affected**

• Tazarotene CREA

- Tazarotene GEL
- Tazorac CREA 0.05%

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For plaque psoriasis: 1) The requested drug is being prescribed to treat less than 20 percent of the patient's body surface area AND 2) The patient experienced an inadequate treatment response or intolerance to at least one topical corticosteroid OR has a contraindication that would prohibit a trial of topical corticosteroids.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **TAZVERIK**

### **Products Affected**

## • Tazverik

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

# **TECENTRIQ**

### **Products Affected**

• Tecentriq

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent or advanced non-small cell lung cancer, PD-L1 positive triple negative recurrent breast cancer in combination with paclitaxel protein-bound
Exclusion Criteria	N/A
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 (defined as PD-L1 stained tumor-infiltrating immune cells [IC] covering greater than or equal to 5 percent of the tumor area) OR 2) Patient is ineligible for any platinum containing chemotherapy. For non-small cell lung cancer (NSCLC): 1) the patient has recurrent, advanced or metastatic disease AND the requested drug will be used as any of the following: a) first-line treatment of tumors with high PD-L1 expression (defined as PD-L1 stained greater than or equal to 50 percent of tumor cells or PD-L1 stained tumor-infiltrating immune cells [IC] covering greater than or equal to 10 percent of the tumor area) and no EGFR or ALK genomic tumor aberrations, b) used in combination with carboplatin, paclitaxel, and bevacizumab, or in combination with carboplatin and albumin-bound paclitaxel for nonsquamous NSCLC, or c) the requested drug will be used as subsequent therapy or continuation maintenance therapy, OR 2) the patient has stage II to IIIA disease AND the requested drug will be used as adjuvant treatment following resection and platinum-based chemotherapy for tumors with PD-L1 expression on greater than or equal to 1 percent of tumor cells. For hepatocellular carcinoma, the requested drug will be used as initial treatment in combination with bevacizumab.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **TECFIDERA**

### **Products Affected**

• Tecfidera

#### • Tecfidera Starter Pack

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

# **TEMAZEPAM 30MG - 65**

#### **Products Affected**

### • Temazepam CAPS 30MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prescriber must acknowledge that the benefit of therapy with the requested drug outweighs the potential risks for the patient. (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.) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to doxepin (3 mg or 6 mg).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization requirement only applies to patients 65 years of age or older.

## Терметко

#### **Products Affected**

### • Tepmetko

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

# **TESTOSTERONE CYPIONATE INJ**

#### **Products Affected**

• Testosterone Cypionate INJ 100MG/ML, 200MG/ML

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

# **TESTOSTERONE ENANTHATE INJ**

#### **Products Affected**

• Testosterone Enanthate INJ

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

## **TETRABENAZINE**

#### **Products Affected**

### • Tetrabenazine

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Tic disorders, tardive dyskinesia, hemiballismus, chorea not associated with Huntington's disease.
Exclusion Criteria	N/A
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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **THALOMID**

## **Products Affected**

#### • Thalomid

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

# **TIBSOVO**

#### **Products Affected**

#### • Tibsovo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Conventional (grades 1-3) or dedifferentiated chondrosarcoma
Exclusion Criteria	N/A
Required Medical Information	Patient has disease with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation. For acute myeloid leukemia (AML): 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 physiologic years of age or older and declines intensive induction chemotherapy, OR 2) patient is 60 physiologic years of age or older and the requested drug will be used as post-induction therapy following response to induction therapy with the requested drug, OR 3) patient has relapsed or refractory AML. For unresectable or metastatic cholangiocarcinoma: the requested drug will be used as subsequent treatment for progression on or after systemic treatment.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **TOBRAMYCIN**

#### **Products Affected**

• Tobramycin NEBU 300MG/5ML

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Non-cystic fibrosis bronchiectasis
Exclusion Criteria	N/A
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	N/A
Prescriber Restrictions	N/A
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.

# TOPICAL DOXEPIN

#### **Products Affected**

### • Doxepin Hydrochloride CREA

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The patient has experienced an inadequate response to a topical corticosteroid or a topical calcineurin inhibitor (e.g., tacrolimus).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 month
Other Criteria	N/A

# TOPICAL LIDOCAINE

#### **Products Affected**

• Lidocaine OINT 5%

- Lidocaine Hcl EXTERNAL SOLN 4%
- Lidocaine/prilocaine CREA

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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	N/A
Prescriber Restrictions	N/A
Coverage Duration	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.

## **TOPICAL TESTOSTERONES**

#### **Products Affected**

- Androderm PT24 2MG/24HR, 4MG/24HR
- Testosterone GEL 10MG/ACT, 25MG/2.5GM, 50MG/5GM

- Testosterone Pump GEL 1%
- Testosterone Topical Solution

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

# TOPICAL TRETINOIN

#### **Products Affected**

- Tretinoin CREA
- Tretinoin GEL

- Tretinoin Microsphere
- Tretinoin Microsphere Pump

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

# **TOREMIFENE**

### **Products Affected**

#### • Toremifene Citrate

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Congenital/acquired QT prolongation (long QT syndrome), uncorrected hypokalemia, or uncorrected hypomagnesemia.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **TRELSTAR**

#### **Products Affected**

• Trelstar Mixject INJ 11.25MG, 3.75MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Gender dysphoria
Exclusion Criteria	N/A
Required Medical Information	For gender dysphoria, patient meets either of the following (1 or 2): 1) the requested drug is used to suppress puberty and the patient is at Tanner stage 2 or greater, OR 2) patient is undergoing gender transition, and the patient will receive the requested drug concomitantly with genderaffirming hormones.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# TREPROSTINIL INJ

#### **Products Affected**

### • Treprostinil

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For pulmonary arterial hypertension (World Health Organization [WHO] Group 1), the diagnosis was confirmed by right heart catheterization. For new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units.
Age Restrictions	N/A
Prescriber Restrictions	N/A
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.

# **TRIENTINE**

## **Products Affected**

### • Trientine Hydrochloride

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

# TRIKAFTA

### **Products Affected**

#### • Trikafta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The requested medication will not be used in combination with other medications containing ivacaftor.
Age Restrictions	6 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **TRODELVY**

#### **Products Affected**

### • Trodelvy

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent triple-negative breast cancer
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **TRUSELTIQ**

#### **Products Affected**

### • Truseltiq

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

# **TUKYSA**

#### **Products Affected**

• Tukysa

PA Criteria	Criteria Details
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 metastases, who have received one or more lines of prior HER2-targeted therapy in the metastatic setting.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **TURALIO**

## **Products Affected**

#### • Turalio

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

# **UBRELVY**

#### **Products Affected**

### • Ubrelvy

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

# UKONIQ

#### **Products Affected**

• Ukoniq

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

## **VALCHLOR**

#### **Products Affected**

#### • Valchlor

PA Criteria	Criteria Details
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.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **VALTOCO**

#### **Products Affected**

#### • Valtoco

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	6 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **VELCADE**

## **Products Affected**

• Velcade

• Bortezomib INJ 1MG, 2.5MG, 3.5MG

PA Criteria	Criteria Details
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, acute lymphoblastic leukemia, AIDS-related Kaposi's sarcoma, Hodgkin lymphoma, POEMS syndrome
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
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.

## **VELTASSA**

### **Products Affected**

#### • Veltassa

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

## VENCLEXTA

## **Products Affected**

• Venclexta

• Venclexta Starting Pack

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Mantle cell lymphoma, blastic plasmacytoid dendritic cell neoplasm (BPDCN), multiple myeloma, relapsed or refractory acute myeloid leukemia (AML), AML in patients 60 physiologic years of age or older.
Exclusion Criteria	N/A
Required Medical Information	For acute myeloid leukemia (AML), any of the following criteria must be met: 1) the patient's physiologic age 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. For blastic plasmacytoid dendritic cell neoplasm (BPDCN), any of the following criteria must be met: 1) patient has systemic disease treated with palliative intent OR 2) patient has relapsed or refractory disease. For multiple myeloma, all of the following must be met: 1) the disease is relapsed or progressive AND 2) the requested drug will be used in combination with dexamethasone AND 3) patient has t(11:14) translocation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **VENTAVIS**

### **Products Affected**

### • Ventavis

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For pulmonary arterial hypertension (World Health Organization [WHO] Group 1), the diagnosis was confirmed by right heart catheterization. For new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units.
Age Restrictions	N/A
Prescriber Restrictions	N/A
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.

## VERSACLOZ

## **Products Affected**

### • Versacloz

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For the treatment of a severely ill patient with schizophrenia who failed to respond adequately to standard antipsychotic treatment (i.e., treatment-resistant schizophrenia), 1) the patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following generic products: A) aripiprazole, B) asenapine, C) olanzapine, D) quetiapine, E) risperidone, F) ziprasidone AND 2) The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following brand products: A) Latuda, B) Rexulti, C) Secuado, D) Vraylar.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **VERZENIO**

### **Products Affected**

### • Verzenio

PA Criteria	Criteria Details
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.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **VIGABATRIN**

### **Products Affected**

• Vigabatrin

## • Vigadrone

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

## VITRAKVI

### **Products Affected**

### • Vitrakvi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Advanced, recurrent, or persistent neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors, first-line treatment of NTRK gene fusion-positive solid tumors.
Exclusion Criteria	N/A
Required Medical Information	For all neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors, the disease is without a known acquired resistance mutation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **VIZIMPRO**

### **Products Affected**

## • Vizimpro

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

## Vonjo

## **Products Affected**

• Vonjo

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

## VORICONAZOLE

### **Products Affected**

• Voriconazole INJ

### • Voriconazole SUSR

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

## Vosevi

### **Products Affected**

### • Vosevi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh class B or C)
Required Medical Information	For 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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Criteria will be applied consistent with current AASLD-IDSA guidance.
Other Criteria	N/A

## **VOTRIENT**

### **Products Affected**

### • Votrient

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Thyroid carcinoma (follicular, papillary, Hurthle cell, or medullary), uterine sarcoma.
Exclusion Criteria	N/A
Required Medical Information	For renal cell carcinoma: The disease is advanced, relapsed, or stage IV. For soft tissue sarcoma (STS): The patient does not have an adipocytic soft tissue sarcoma. For uterine sarcoma: The disease is recurrent or metastatic.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## WELIREG

### **Products Affected**

• Welireg

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

## XALKORI

### **Products Affected**

### • Xalkori

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

## **XELJANZ**

## **Products Affected**

• Xeljanz

• Xeljanz Xr

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For moderately to severely active rheumatoid arthritis (new starts only): patient has experienced an inadequate treatment response or intolerance to at least one tumor necrosis factor (TNF) inhibitor. For active psoriatic arthritis (new starts only): 1) Patient has experienced an inadequate treatment response or intolerance to at least one TNF inhibitor AND 2) 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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **XERMELO**

### **Products Affected**

### • Xermelo

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

# **XGEVA**

### **Products Affected**

## • Xgeva

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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	N/A
Prescriber Restrictions	N/A
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.

## **XIFAXAN**

### **Products Affected**

### • Xifaxan TABS 550MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Reduction in risk of overt HE recurrence: 6 months, IBS-D: 14 days
Other Criteria	N/A

# XOLAIR

## **Products Affected**

• Xolair

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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	N/A
Coverage Duration	Allergic asthma and nasal polyps: Plan Year. CIU initial: 6 months. CIU continuation: Plan Year
Other Criteria	N/A

# XOSPATA

### **Products Affected**

## • Xospata

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FLT3 rearrangement
Exclusion Criteria	N/A
Required Medical Information	For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FLT3 rearrangement: the disease is in chronic or blast phase.
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **XPOVIO**

### **Products Affected**

- Xpovio
- 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
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **XTANDI**

### **Products Affected**

### • Xtandi

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

## **XYREM**

### **Products Affected**

• Xyrem

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
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) [Note: Coverage of amphetamines 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 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	Prescribed by or in consultation with a sleep disorder specialist or neurologist.
Coverage Duration	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.

# YERVOY

### **Products Affected**

• Yervoy

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **Z**ARXIO

### **Products Affected**

### • Zarxio

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Neutropenia in myelodysplastic syndromes (MDS), agranulocytosis, neutropenia in aplastic anemia, human immunodeficiency virus (HIV)-related neutropenia, neutropenia related to renal transplant.
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) patient 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	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	N/A

# ZEJULA

## **Products Affected**

• Zejula

PA Criteria	Criteria Details
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 platinumsensitive disease.
Exclusion Criteria	N/A
Required Medical Information	For ovarian, fallopian tube, or primary peritoneal cancer, the requested drug is used in any of the following settings: 1) as maintenance treatment of stage II-IV epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients who are in a complete or partial response to first-line platinum-based chemotherapy AND if it is known that the patient has breast cancer susceptibility gene (BRCA)-mutated disease, the patient experienced an unacceptable toxicity with a trial of Lynparza (olaparib), 2) as maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients who are in a complete or partial response to chemotherapy AND the patient experienced an unacceptable toxicity with a trial of Lynparza (olaparib), 3) as treatment of advanced, persistent, or recurrent ovarian, fallopian tube, or primary peritoneal cancer in patients treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either a) a deleterious or suspected deleterious BRCA mutation AND if prescribed for advanced, persistent, or recurrent ovarian cancer with deleterious or suspected deleterious germline BRCA mutation, the patient experienced an unacceptable toxicity with a trial of Lynparza (olaparib), or b) genomic instability and progression more than six months after response to the last platinum-based chemotherapy, or 4) in combination with bevacizumab for platinum-sensitive persistent or recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.
Age Restrictions	N/A
Prescriber Restrictions	N/A

Coverage Duration	Plan Year
Other Criteria	N/A

## **Z**ELBORAF

### **Products Affected**

### • Zelboraf

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Non-small cell lung cancer, hairy cell leukemia, thyroid carcinoma (i.e., papillary carcinoma, follicular carcinoma, and Hurthle cell carcinoma), central nervous system cancer (i.e., glioma, meningioma, astrocytoma), adjuvant systemic therapy for cutaneous melanoma.
Exclusion Criteria	N/A
Required Medical Information	For adjuvant treatment of melanoma, and central nervous system (CNS) cancer (i.e., glioma, meningioma, astrocytoma): 1) The tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K) and 2) The requested drug will be used in combination with cobimetinib. For unresectable or metastatic melanoma: 1) The tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K) and 2) the requested drug will be used as a single agent, or in combination with cobimetinib (with or without atezolizumab). For Erdheim-Chester Disease: Tumor is positive for BRAF V600 mutation. For non-small cell lung cancer: 1) Tumor is positive for the BRAF V600E mutation, and 2) The patient has recurrent, advanced, or metastatic disease. For thyroid carcinoma: 1) Tumor is positive for BRAF mutation, and 2) Patient has radioiodine refractory follicular, Hurthle cell, or papillary thyroid carcinoma. For hairy cell leukemia: The requested drug will be used for subsequent therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## ZEPZELCA

## **Products Affected**

## • Zepzelca

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Relapsed small cell lung cancer, primary progressive small cell lung cancer.
Exclusion Criteria	N/A
Required Medical Information	For small cell lung cancer: the requested medication will be used as a single agent in one of the following settings: 1) the disease has relapsed following complete or partial response or stable disease with initial treatment, 2) the patient has primary progressive disease, or 3) the patient has metastatic disease following disease progression on or after platinum-based chemotherapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## ZOLINZA

### **Products Affected**

### • Zolinza

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

## **ZONISADE**

### **Products Affected**

### • Zonisade

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For adjunctive treatment of partial-onset seizures (i.e., focal-onset seizures): 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to any of the following: Aptiom, Xcopri, Spritam OR 2) The patient has difficulty swallowing solid oral dosage forms (e.g., tablets, capsules).
Age Restrictions	16 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## **Z**TALMY

### **Products Affected**

## • Ztalmy

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

## **Z**YDELIG

### **Products Affected**

## • Zydelig

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Relapsed or refractory chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), relapsed or 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].
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## ZYKADIA

### **Products Affected**

## • Zykadia TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent or advanced ALK-positive non-small cell lung cancer (NSCLC), recurrent, advanced, or metastatic ROS1-positive NSCLC, inflammatory myofibroblastic tumor (IMT), brain metastases from NSCLC.
Exclusion Criteria	N/A
Required Medical Information	For NSCLC: the patient 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 patient has ALK-positive NSCLC.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

## ZYPREXA RELPREVV

### **Products Affected**

## • Zyprexa Relprevv

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

### PART B VERSUS PART D

#### **Products Affected**

- Abelcet
- Acetylcysteine INHALATION SOLN
- Acyclovir Sodium INJ 50MG/ML
- Albuterol Sulfate NEBU 0.083%, 0.63MG/3ML, 1.25MG/3ML, 2.5MG/0.5ML
- Ambisome
- Aminosyn-pf 7% INJ 32.5MEQ/L; 490MG/100ML; 861MG/100ML; 370MG/100ML; 576MG/100ML; 270MG/100ML; 220MG/100ML; 534MG/100ML; 831MG/100ML; 475MG/100ML; 125MG/100ML; 10.69GM/L; 300MG/100ML; 570MG/100ML; 70GM/L; 347MG/100ML; 50MG/100ML; 360MG/100ML; 452MG/100ML
- Amphotericin B INJ
- Amphotericin B Liposome
- Aprepitant CAPS
- Azathioprine INJ
- Azathioprine TABS 50MG
- Bleomycin Sulfate INJ
- Budesonide SUSP
- Cladribine
- Clinimix 4.25%/dextrose 10%
- Clinimix 4.25%/dextrose 5%
- Clinimix 5%/dextrose 15%
- Clinimix 5%/dextrose 20%
- Clinimix 6/5
- Clinimix 8/10
- Clinimix 8/14
- Clinisol Sf 15%
- Clinolipid
- Cromolyn Sodium NEBU
- Cyclophosphamide CAPS
- Cyclophosphamide TABS
- Cyclosporine CAPS
- Cyclosporine INJ
- Cyclosporine Modified

- Cytarabine INJ 100MG/ML
- Cytarabine Aqueous
- Dextrose 50%
- Dextrose 70%
- Diphtheria/tetanus Toxoids Adsorbed Pediatric
- Emend SUSR
- Engerix-b
- Epoprostenol Sodium
- Everolimus TABS 0.25MG, 0.5MG, 0.75MG, 1MG
- Fluorouracil INJ 1GM/20ML, 2.5GM/50ML, 500MG/10ML, 5GM/100ML
- Freamine Hbc 6.9%
- Freamine III INJ 89MEQ/L; 710MG/100ML; 950MG/100ML; 3MEQ/L; 24MG/100ML; 1400MG/100ML; 280MG/100ML; 690MG/100ML; 910MG/100ML; 730MG/100ML; 530MG/100ML; 560MG/100ML; 10MMOLE/L; 120MG/100ML; 1120MG/100ML; 590MG/100ML; 10MEQ/L; 400MG/100ML; 150MG/100ML; 660MG/100ML
- Gamastan
- Ganciclovir INJ 500MG, 500MG/10ML
- Gengraf CAPS 100MG, 25MG
- Gengraf SOLN
- Granisetron Hydrochloride TABS
- Hepatamine INJ 62MEQ/L;
  770MG/100ML; 600MG/100ML;
  3MEQ/L; 20MG/100ML;
  900MG/100ML; 240MG/100ML;
  900MG/100ML; 1100MG/100ML;
  610MG/100ML; 100MG/100ML;
  100MG/100ML; 115MG/100ML;
  800MG/100ML; 500MG/100ML;
  450MG/100ML; 66MG/100ML;
  840MG/100ML
- Humulin R U-500 (concentrated)

- Hydromorphone Hcl INJ 10MG/ML, 1MG/ML, 4MG/ML
- Hydromorphone Hydrochloride INJ 1MG/ML, 2MG/ML, 4MG/ML, 50MG/5ML
- Hyperlyte-cr
- Imovax Rabies (h.d.c.v.)
- Ipratropium Bromide INHALATION SOLN 0.02%
- Ipratropium Bromide/albuterol Sulfate
- Isolyte-s INJ 27MEQ/L; 98MEQ/L; 23MEQ/L; 3MEQ/L; 5MEQ/L; 140MEQ/L
- Isolyte-s Ph 7.4
- Khapzory
- Levalbuterol NEBU
- Levalbuterol Hcl NEBU
- Melphalan
- Methylprednisolone TABS
- Methylprednisolone Acetate INJ 40MG/ML, 80MG/ML
- Methylprednisolone Sodium Succinate
- Methylprednisolone Sodiumsuccinate INJ 125MG, 40MG
- Morphine Sulfate INJ 0.5MG/ML, 10MG/ML, 1MG/ML, 2MG/ML, 4MG/ML, 50MG/ML, 5MG/ML, 8MG/ML
- Morphine Sulfate/sodium Chloride INJ 1MG/ML
- Mycophenolate Mofetil CAPS
- Mycophenolate Mofetil INJ
- Mycophenolate Mofetil SUSR
- Mycophenolate Mofetil TABS
- Mycophenolic Acid Dr
- Nephramine
- Nulojix
- Nutrilipid
- Ondansetron Hcl SOLN
- Ondansetron Hcl TABS 24MG
- Ondansetron Hydrochloride TABS
- Ondansetron Odt
- Pentamidine Isethionate INHALATION SOLR

- Plenamine INJ 147.4MEQ/L; 2.17GM/100ML; 1.47GM/100ML; 434MG/100ML; 749MG/100ML; 1.04GM/100ML; 894MG/100ML; 749MG/100ML; 1.04GM/100ML; 1.18GM/100ML; 749MG/100ML; 1.04GM/100ML; 894MG/100ML; 592MG/100ML; 749MG/100ML; 250MG/100ML; 39MG/100ML; 960MG/100ML
- Prednisolone SOLN
- Prednisolone Sodium Phosphate ORAL SOLN 10MG/5ML, 15MG/5ML, 20MG/5ML, 25MG/5ML, 5MG/5ML
- Prednisone SOLN
- Prednisone TABS 10MG, 1MG, 2.5MG, 20MG, 50MG, 5MG
- Prednisone Intensol
- Prehevbrio
- Premasol INJ 52MEQ/L; 1760MG/100ML; 880MG/100ML; 34MEQ/L; 1760MG/100ML; 372MG/100ML; 406MG/100ML; 526MG/100ML; 492MG/100ML; 492MG/100ML; 526MG/100ML; 356MG/100ML; 356MG/100ML; 390MG/100ML; 34MG/100ML; 152MG/100ML
- Procalamine
- Prograf PACK
- Prosol
- Rabavert
- Recombivax Hb
- Sandimmune SOLN
- Sirolimus SOLN
- Sirolimus TABS
- Tacrolimus CAPS
- Tdvax
- Tenivac
- Tpn Electrolytes INJ 29.5MEQ/20ML;
   4.5MEQ/20ML; 35MEQ/20ML;
   5MEQ/20ML; 20MEQ/20ML;
   35MEQ/20ML

- Travasol INJ 52MEQ/L; 1760MG/100ML; 880MG/100ML; 34MEQ/L; 1760MG/100ML; 372MG/100ML; 406MG/100ML; 526MG/100ML; 492MG/100ML; 492MG/100ML; 526MG/100ML; 356MG/100ML; 390MG/100ML; 356MG/100ML; 152MG/100ML
- Trophamine INJ 97MEQ/L;
  0.54GM/100ML; 1.2GM/100ML;
  0.32GM/100ML; 0; 0; 0.5GM/100ML;
  0.36GM/100ML; 0.48GM/100ML;
  0.82GM/100ML; 1.4GM/100ML;
  1.2GM/100ML; 0.34GM/100ML;
  0.48GM/100ML; 0.68GM/100ML;
  0.38GM/100ML; 5MEQ/L;
  0.025GM/100ML; 0.42GM/100ML;
  0.2GM/100ML; 0.24GM/100ML;
  0.78GM/100ML
- Vinblastine Sulfate INJ 1MG/ML
- Vincasar Pfs
- Vincristine Sulfate INJ
- Zortress TABS 1MG

#### **Details**

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.

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