

# 2026 Employer Group Prior Authorization Medical Necessity Guidelines

Effective: January 1, 2026

Updated: September 23, 2025

These guidelines were updated on September 23, 2025. For more recent information or other questions, please contact Mass General Brigham Health Plan Member Services. Visit **MassGeneralBrighamAdvantage.org/Rx-information** for the most up-to-date information on Medicare Part D drug coverage.

You can reach Member Services by calling: **855-833-3668** (TTY: 711)

October 1 – March 31 8:00 AM to 8:00 PM EST, Monday through Sunday

April 1 – September 30 8:00 AM to 8:00 PM EST, Monday through Friday

Mass General Brigham Advantage Group (HMO-POS) Mass General Brigham Advantage Group (PPO)

Mass General Brigham Health Plan is a Medicare Advantage organization with a Medicare contract offering Employer Group plans. Enrollment in Mass General Brigham Health Plan depends on contract renewal.

## **A**BIRATERONE

### **Products Affected**

• Abiraterone Acetate

### Abirtega

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Node-positive (N1), non-metastatic (M0) prostate cancer, very-high-risk prostate cancer, non-metastatic high-risk prostate cancer, non-metastatic prostate cancer with prostate-specific antigen (PSA) persistence/recurrence after radical prostatectomy
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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **A**CTIMMUNE

#### **Products Affected**

• Actimmune INJ 100MCG/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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **A**DBRY

### **Products Affected**

• Adbry

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **A**DEMPAS

# **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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **A**DLARITY

### **Products Affected**

### • Adlarity

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Vascular dementia
Exclusion Criteria	N/A
Required Medical Information	Patient is unable to take oral dosage forms (e.g., difficulty swallowing tablets or capsules). For dementia of the Alzheimer's type: the patient has experienced an inadequate response, intolerance, or the patient has a contraindication to rivastigmine transdermal patch.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **A**GAMREE

### **Products Affected**

### • Agamree

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 Duchenne muscular dystrophy (DMD): 1.) The diagnosis was confirmed by genetic testing identifying a disease-causing mutation of the DMD gene AND 2) The patient has tried prednisone and experienced any of the following a) unmanageable and/or clinically significant weight gain/obesity, b) unmanageable and/or clinically significant psychiatric/behavioral issues such as abnormal behavior, aggression, or irritability, or c) clinically significant growth stunting.
Age Restrictions	2 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **A**IMOVIG

### **Products Affected**

### • Aimovig

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For preventive treatment of migraine, continuation: The patient received at least 3 months of treatment with the requested drug and had a reduction in migraine days per month from baseline.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 3 months, Continuation: Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **A**KEEGA

### **Products Affected**

### • Akeega

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **A**LECENSA

### **Products Affected**

#### Alecensa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC), brain metastases from ALK-positive NSCLC, ALK-positive anaplastic large-cell lymphoma (ALCL), Erdheim-Chester Disease (ECD) with ALK-fusion, inflammatory myofibroblastic tumors (IMT) with ALK translocation, ALK-positive large B-cell lymphoma
Exclusion Criteria	N/A
Required Medical Information	For non-small cell lung cancer (NSCLC): 1) the disease is recurrent, advanced, or metastatic OR 2) the requested drug will be used as adjuvant treatment following tumor resection.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **ALPHA1-PROTEINASE INHIBITOR**

### **Products Affected**

Prolastin-c INJ 1000MG/20ML

• Aralast Np INJ 1000MG, 500MG

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 milligrams per deciliter [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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **A**LUNBRIG

### **Products Affected**

### • Alunbrig

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC), brain metastases from ALK-positive NSCLC, inflammatory myofibroblastic tumors (IMT) with ALK translocation, Erdheim-Chester disease (ECD) with ALK-fusion
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 disease is anaplastic lymphoma kinase (ALK)-positive.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **A**LVAIZ

### **Products Affected**

#### Alvaiz

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

# **A**LYFTREK

### **Products Affected**

## • Alyftrek

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For cystic fibrosis: the requested drug will not be used in combination with other CFTR (cystic fibrosis transmembrane conductance regulator) potentiating agents (e.g., ivacaftor, deutivacaftor).
Age Restrictions	6 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **A**MBRISENTAN

### **Products Affected**

#### Ambrisentan

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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **A**QNEURSA

# **Products Affected**

### • Aqneursa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For Niemann-Pick disease type C (NPC), initial: 1) The diagnosis was confirmed by genetic testing demonstrating a variant of either the NPC1 or NPC2 gene, 2) The patient has neurological manifestations of disease (e.g., loss of fine motor skills, swallowing, speech, ambulation), AND 3) The requested medication will not be used in combination with Miplyffa (arimoclomol). For Niemann-Pick disease type C, continuation: The patient is experiencing benefit from therapy (e.g., stabilization or improvement in fine motor skills, swallowing, speech, ambulation).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **A**RCALYST

### **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. For recurrent pericarditis: patient must have had an inadequate response, intolerance, or contraindication to maximum tolerated doses of a NSAID and colchicine.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **A**RIKAYCE

### **Products Affected**

### • Arikayce

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **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	For excessive sleepiness associated with narcolepsy: The diagnosis has been confirmed by sleep lab evaluation. For excessive sleepiness associated with obstructive sleep apnea (OSA): The diagnosis has been confirmed by polysomnography.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **A**TTRUBY

### **Products Affected**

Attruby

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For cardiomyopathy of variant or wild-type transthyretin-mediated amyloidosis (ATTR-CM), initial therapy: 1) patient exhibits clinical manifestation of disease (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema), AND 2) cardiac involvement was confirmed by one of the following: a) imaging via echocardiography or cardiac magnetic resonance imaging (e.g., end-diastolic interventricular septal wall thickness exceeding 12 millimeters), or b) myocardial technetium-labeled scintigraphy, AND 3) patient meets one of the following: a) if the request is for variant ATTR-CM the patient is positive for a mutation of the transthyretin (TTR) gene, b) if the request is for wild-type ATTR-CM the patient has transthyretin precursor proteins confirmed by testing. For ATTR-CM, continuation: patient demonstrates a beneficial response to therapy (e.g., slowing of clinical decline).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **A**UGTYRO

### **Products Affected**

## Augtyro

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **A**USTEDO

# **Products Affected**

Austedo

- Austedo Xr
- Austedo Xr Patient Titration Kit

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# AVMAPKI FAKZYNJA

#### **Products Affected**

Avmapki Fakzynja Co-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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **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 residual, unresectable, tumor rupture, or recurrent/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 D842V 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 a PDGFRA D842V mutation, OR 2) The requested drug will be used after failure on at least two Food and Drug Administration (FDA)-approved therapies in residual, unresectable, tumor rupture, or recurrent/metastatic disease without PDGFRA exon 18 mutation. For systemic mastocytosis: 1) The patient has a diagnosis of indolent systemic mastocytosis or 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/microliter (mcL).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.
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# **B**AFIERTAM

# **Products Affected**

#### • Bafiertam

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **BALVERSA**

### **Products Affected**

#### Balversa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For urothelial carcinoma: 1) disease has susceptible fibroblast growth factor receptor 3 (FGFR3) genetic alterations, AND 2) the requested drug will be used as subsequent therapy for any of the following: a) locally advanced, recurrent, or metastatic urothelial carcinoma, OR b) stage II-IV, recurrent, or persistent urothelial carcinoma of the bladder.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **BANZEL**

### **Products Affected**

#### • 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **B**AXDELA

### **Products Affected**

#### • Baxdela TABS

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 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	14 days
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **BENLYSTA**

#### **Products Affected**

• Benlysta INJ 200MG/ML

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 for SLE (for example, corticosteroid, antimalarial, or NSAIDs), OR 2) patient has experienced an intolerance or has a contraindication to standard therapy regimen for SLE. For lupus nephritis: 1) patient is currently receiving a stable standard therapy regimen for lupus nephritis (for example, corticosteroid, cyclophosphamide, mycophenolate mofetil, or azathioprine) OR 2) patient has experienced an intolerance or has a contraindication to standard therapy regimen for lupus nephritis.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **BESREMI**

### **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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **BOSENTAN**

### **Products Affected**

Bosentan TABS

#### • 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): 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) if the request is for an adult patient, the patient meets both of the following: a) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units, and b) the patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to ambrisentan (Letairis).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **Bosulif**

### **Products Affected**

#### • Bosulif

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Philadelphia chromosome positive B-cell acute lymphoblastic leukemia (Ph+ B-ALL), myeloid and/or lymphoid neoplasms with eosinophilia and ABL1 rearrangement in the chronic phase or blast phase.
Exclusion Criteria	N/A
Required Medical Information	For chronic myeloid leukemia (CML), including patients newly diagnosed with CML and patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) If patient experienced resistance to an alternative tyrosine kinase inhibitor, patient is negative for all of the following mutations: T315I, G250E, V299L, and F317L, AND 3) Patient has experienced resistance or intolerance to imatinib, dasatinib, or nilotinib. For B-ALL including patients who have received hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) If patient experienced resistance to an alternative tyrosine kinase inhibitor, 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

Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.
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# **BRAFTOVI**

#### **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, appendiceal adenocarcinoma, recurrent NSCLC
Exclusion Criteria	N/A
Required Medical Information	For colorectal cancer (including appendiceal adenocarcinoma): 1) Tumor is positive for BRAF V600E mutation, AND 2) The patient has either of the following: a) advanced or metastatic disease, b) unresectable metachronous metastases. For melanoma: 1) 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 binimetinib, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, b) adjuvant systemic therapy. For non-small cell lung cancer (NSCLC): 1) Tumor is positive for BRAF V600E mutation, AND 2) Disease is advanced, recurrent, or metastatic, AND 3) The requested drug will be used in combination with binimetinib.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **BRIVIACT**

### **Products Affected**

Briviact SOLN

### Briviact TABS

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 (i.e., focal-onset seizures):  1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to any of the following: Aptiom (if 4 years of age or older), Xcopri (if 18 years of age or older), Spritam (if 4 years of age or older).
Age Restrictions	1 month of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **BRUKINSA**

### **Products Affected**

### • Brukinsa CAPS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For mantle cell lymphoma and chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL): the patient has experienced an intolerable adverse event or has a contraindication to Calquence (acalabrutinib).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **BYLVAY**

# **Products Affected**

• Bylvay

• Bylvay (pellets)

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

# **C**ABLIVI

## **Products Affected**

### • Cablivi

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **C**ABOMETYX

### **Products Affected**

• Cabometyx

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Non-small cell lung cancer, Ewing sarcoma, osteosarcoma, gastrointestinal stromal tumor, endometrial carcinoma
Exclusion Criteria	N/A
Required Medical Information	For renal cell carcinoma: The disease is advanced, relapsed, or stage IV (including brain metastases). 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 therapy. For gastrointestinal stromal tumor (GIST): 1) the disease is residual, unresectable, recurrent, or metastatic/tumor rupture, AND 2) the disease has progressed after at least two FDA-approved therapies (e.g., imatinib, sunitinib, regorafenib, ripretinib). For Ewing sarcoma and osteosarcoma: the requested drug will be used as subsequent therapy. For differentiated thyroid cancer (DTC) (follicular, papillary, oncocytic): 1) the disease is locally advanced or metastatic, AND 2) the disease has progressed after a vascular endothelial growth factor receptor (VEGFR)- targeted therapy, AND 3) the patient is refractory to radioactive iodine therapy (RAI) or ineligible for RAI. For endometrial carcinoma: 1) the disease is recurrent, AND 2) the requested drug will be used as subsequent therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.
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# **CALQUENCE**

### **Products Affected**

## • Calquence TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Waldenstrom macroglobulinemia (lymphoplasmacytic lymphoma), marginal zone lymphoma (including extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of nongastric sites, nodal marginal zone lymphoma, splenic marginal zone lymphoma)
Exclusion Criteria	N/A
Required Medical Information	For marginal zone lymphoma (including extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of nongastric sites, nodal marginal zone lymphoma, and splenic marginal zone lymphoma): the requested drug is being used for the treatment of relapsed, refractory, or progressive disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **C**AMZYOS

## **Products Affected**

## • Camzyos

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For obstructive hypertrophic cardiomyopathy: 1) before initiating therapy, patient has left ventricular ejection fraction (LVEF) of 55 percent or greater, AND 2) patient has New York Heart Association (NYHA) class II-III symptoms.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **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	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **C**APRELSA

### **Products Affected**

## • Caprelsa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Thyroid carcinomas (follicular, oncocytic, papillary).
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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **C**ARBAGLU

### **Products Affected**

## • 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, biochemical, or genetic testing.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **C**ERDELGA

# **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 type 1 Gaucher disease (GD1): 1) Diagnosis was confirmed by an enzyme assay demonstrating a deficiency of beta-glucocerebrosidase enzyme activity or by genetic testing, and 2) Patient's CYP2D6 metabolizer status has been established using an FDA-cleared test, and 3) 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **C**EREZYME

### **Products Affected**

## • Cerezyme

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Type 2 Gaucher disease, Type 3 Gaucher disease.
Exclusion Criteria	N/A
Required Medical Information	For Gaucher disease: Diagnosis was confirmed by an enzyme assay demonstrating a deficiency of beta-glucocerebrosidase enzyme activity or by genetic testing.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **C**HOLBAM

## **Products Affected**

### • Cholbam

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For bile acid synthesis disorders due to single enzyme defects (SEDs) and adjunctive treatment of peroxisomal disorders (PDs): Diagnosis was confirmed by mass spectrometry or other biochemical or genetic testing. For bile acid synthesis disorders due to SEDs and adjunctive treatment of PDs, continuation of therapy: Patient has achieved and maintained improvement in liver function.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months, Continuation: Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **CIBINQO**

## **Products Affected**

• Cibinqo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For atopic dermatitis (AD) (continuation of therapy): Patient achieved or maintained positive clinical response.
Age Restrictions	12 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Initial: 4 months, Continuation: Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **CINRYZE**

## **Products Affected**

## • Cinryze

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For the prophylaxis of angioedema attacks due to hereditary angioedema (HAE): 1) the patient has HAE with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing, OR 2) the patient has HAE with normal C1 inhibitor confirmed by laboratory testing and one of the following: a) the patient tested positive for an F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation, b) the patient has a family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy for at least one month.
Age Restrictions	6 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **CLOBAZAM**

### **Products Affected**

• Clobazam SUSP 2.5MG/ML

Clobazam TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Seizures associated with Dravet syndrome
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Seizures associated with Lennox-Gastaut syndrome (LGS): 2 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **C**OBENFY

# **Products Affected**

• Cobenfy

Cobenfy Starter 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 has a contraindication to one of the following generic products: aripiprazole, asenapine, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, AND 2) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following brand products: Caplyta, Lybalvi, Rexulti, Secuado, Vraylar.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# 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), thyroid carcinomas (follicular, oncocytic, papillary).
Exclusion Criteria	N/A
Required Medical Information	For non-small cell lung cancer (NSCLC): Disease is positive for rearranged during transfection (RET) rearrangements.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **C**OPIKTRA

## **Products Affected**

## • Copiktra

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Hepatosplenic T-Cell lymphoma, breast implant-associated anaplastic large cell lymphoma (ALCL), peripheral T-Cell lymphoma
Exclusion Criteria	N/A
Required Medical Information	For chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), breast implant-associated anaplastic large cell lymphoma (ALCL), and peripheral T-Cell lymphoma: the patient has relapsed or refractory disease. For hepatosplenic T-Cell lymphoma: the patient has refractory disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **CORTROPHIN**

### **Products Affected**

## • Cortrophin

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For the following diagnoses, patient has experienced an inadequate treatment response to a parenteral or an oral glucocorticoid (for ophthalmic diseases only, inadequate response to a trial of a topical ophthalmic glucocorticoid is also acceptable):  1) For rheumatic disorders (e.g., psoriatic arthritis, rheumatoid arthritis, ankylosing spondylitis, acute gouty arthritis): The requested drug must be used as adjunctive treatment, 2) For nephrotic syndrome: the requested drug must be requested for induction of diuresis or for remission of proteinuria, 3) For multiple sclerosis (MS): patient has an acute exacerbation of MS, 4) Collagen diseases (e.g., systemic lupus erythematosus, dermatomyositis, or polymyositis), 5) Dermatologic diseases (e.g., severe erythema multiforme, Stevens-Johnson syndrome, severe psoriasis), 6) Ophthalmic diseases, acute or chronic (e.g., iritis, keratitis, optic neuritis), 7) Symptomatic sarcoidosis, 8) Allergic states (e.g., serum sickness, atopic dermatitis).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	MS exacerbation: 3 weeks, Allergic states: 1 month, All other diagnoses: 3 months
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **COSENTYX**

### **Products Affected**

Cosentyx Unoready

- Cosentyx INJ 150MG/ML, 75MG/0.5ML
- Cosentyx Sensoready Pen

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

#### Required Medical Information

Member must have a documented diagnosis of moderate to severe plaque psoriasis (PsO), active psoriatic arthritis (PsA), active ankylosing spondylitis (AS), active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation, active enthesitis-related arthritis (ERA), or moderate to severe hidradenitis suppurativa (HS) and meet the following requirements:

For plaque psoriasis member must have tried a minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, or calcineurin inhibitors (eg, tacrolimus, pimecrolimus) and meet one of the following: 1) at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR 2)palmoplantar (ie, palms, soles), facial, or genital involvement.

For psoriatic arthritis member must have actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement.

For ankylosing apondylitis (AS) member must have tried a minimum duration of a one-month trial and failure, contraindication, or intolerance to one nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses.

For non-radiographic axial spondyloarthritis (nr-axSpA) objective signs of inflammation are defined as C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.

For enthesitis-related arthritis (ERA) member must have tried a minimum duration of a one-month TF/C/I to two non-steroidal anti-inflammatory drugs (NSAIDs) (eg, ibuprofen, naproxen) at maximally tolerated doses.

#### Age Restrictions

For plaque psoriasis (PsO) patient must be 6 years of age and older: For psoriatic arthritis (PsA) patients must be 2 years of age and older. For ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation, and moderate to severe hidradenitis suppurativa (HS) patients must be 18 years of age and older. For enthesitis-related arthritis (ERA) patients must be 4 years of age and older.

Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **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, glioblastoma), adjuvant systemic therapy for cutaneous melanoma.
Exclusion Criteria	N/A
Required Medical Information	For central nervous system (CNS) cancer (i.e., glioma, glioblastoma): 1) The tumor is positive for BRAF V600E activating mutation, AND 2) The requested drug will be used in combination with vemurafenib. For melanoma: 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, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, b) adjuvant systemic therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **CRENESSITY**

## **Products Affected**

## • Crenessity

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For congenital adrenal hyperplasia (CAH), initial: 1) Patient has a confirmed diagnosis of CAH by any of the following: a) genetic testing to confirm the presence of pathogenic variants in CYP21A1, b) confirmed 21-hydroxylase deficiency (e.g., cosyntropin [ACTH] stimulation test, baseline morning serum 17-hydroxyprogesterone [17-OHP] measurement by liquid chromatography-tandem mass spectrometry), AND 2) Patient is currently on supraphysiological glucocorticoid therapy.
Age Restrictions	4 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **CRINONE**

## **Products Affected**

### • Crinone

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Prophylaxis for premature birth in women with a short cervix
Exclusion Criteria	Prescribed to promote fertility
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **CTEXLI**

### **Products Affected**

Ctexli

Chenodal

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Patient must have a documented diagnosis of cerebrotendinous xanthomatosis (CTX).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **C**UVRIOR

## **Products Affected**

### • Cuvrior

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **CYSTADROPS**

# **Products Affected**

## • Cystadrops

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 was confirmed by ANY of the following: a) the presence of increased cystine concentration in leukocytes, OR b) genetic testing, OR c) demonstration of corneal cystine crystals by slit lamp examination, AND 2) the patient has corneal cystine crystal accumulation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **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 was confirmed by ANY of the following: 1) the presence of increased cystine concentration in leukocytes, OR 2) genetic testing, OR 3) demonstration of corneal cystine crystals by slit lamp examination.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **C**YSTARAN

### **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 was confirmed by ANY of the following: a) the presence of increased cystine concentration in leukocytes, OR b) genetic testing, OR c) demonstration of corneal cystine crystals by slit lamp examination, AND 2) the patient has corneal cystine crystal accumulation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **DALFAMPRIDINE**

### **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 demonstrates sustained walking impairment. For multiple sclerosis (continuation): 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **DANZITEN**

### **Products Affected**

### Danziten

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), pigmented villonodular synovitis/tenosynovial giant cell tumor
Exclusion Criteria	N/A
Required Medical Information	For chronic myeloid leukemia (CML), including patients newly diagnosed with CML and patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) 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 acute lymphoblastic leukemia (ALL), including patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) If the patient has experienced resistance to an alternative tyrosine kinase inhibitor for ALL, patient is negative for T315I, Y253H, E255K/V, F359V/C/I and G250E mutations.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **D**AURISMO

# **Products Affected**

#### Daurismo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Post-induction therapy/consolidation 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 (AML): 1) the requested drug 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 drug will be used as treatment for induction therapy, post-induction/consolidation therapy, or relapsed or refractory disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **D**AYBUE

## **Products Affected**

• Daybue

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **DEFERASIROX**

#### **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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **DEFERIPRONE**

#### **Products Affected**

## • Deferiprone

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **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	6 months of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **DICLOFENAC EPOLAMINE PATCH**

#### **Products Affected**

Diclofenac Epolamine

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Must have a documented diagnosis of acute pain due to one of the following: minor strain, sprain, or contusion.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **DOPTELET**

## **Products Affected**

## • Doptelet

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

## **DUPIXENT**

#### **Products Affected**

• Dupixent INJ 200MG/1.14ML, 300MG/2ML

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

# **EBGLYSS**

## **Products Affected**

• Ebglyss

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For atopic dermatitis, initial therapy: 1) Patient has moderate-to-severe disease, AND 2) Patient has experienced an inadequate treatment response to either a topical corticosteroid or a topical calcineurin inhibitor OR topical corticosteroids and topical calcineurin inhibitors are not advisable for the patient. For atopic dermatitis, continuation of therapy: The patient achieved or maintained positive clinical response.
Age Restrictions	12 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Initial: 4 months, Continuation: Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **EGRIFTA**

## **Products Affected**

• Egrifta Sv

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

# **ELIGARD**

## **Products Affected**

## • Eligard

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **EMFLAZA**

#### **Products Affected**

Deflazacort

• Jaythari

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 Duchenne muscular dystrophy (DMD): 1) The diagnosis was confirmed by genetic testing identifying a disease-causing mutation of the DMD gene AND 2) The patient has tried prednisone and experienced unmanageable and clinically significant weight gain/obesity or psychiatric/behavioral issues such as abnormal behavior, aggression, or irritability.
Age Restrictions	2 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **EMGALITY**

## **Products Affected**

## • Emgality

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For preventive treatment of migraine, continuation: The patient received at least 3 months of treatment with the requested drug and had a reduction in migraine days per month from baseline. For episodic cluster headache, initial: The patient experienced an inadequate treatment response, intolerance, or contraindication to a triptan 5-HT1 receptor agonist. For episodic cluster headache, continuation: The patient received the requested drug for at least 3 weeks of treatment and had a reduction in weekly cluster headache attack frequency from baseline.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 3 months, Continuation: Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **ENBREL**

#### **Products Affected**

- Enbrel INJ 25MG/0.5ML, 50MG/ML
- Enbrel Mini

• Enbrel Sureclick

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

## **ENSPRYNG**

## **Products Affected**

## • Enspryng

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For neuromyelitis optica spectrum disorder (continuation): 1) there is no evidence of unacceptable toxicity or disease progression while on the current regimen, AND 2) the patient has demonstrated a positive response to therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **E**OHILIA

## **Products Affected**

#### • Eohilia

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For eosinophilic esophagitis (EoE): 1) Diagnosis has been confirmed by esophageal biopsy characterized by greater than or equal to 15 intraepithelial esophageal eosinophils per high power field, AND 2) The patient is exhibiting clinical manifestations of the disease (for example, dysphagia).
Age Restrictions	11 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, allergist, or immunologist
Coverage Duration	6 months
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **E**PCLUSA

## **Products Affected**

#### • Sofosbuvir/velpatasvir

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, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **E**PIDIOLEX

## **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	1 year of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **EPRONTIA**

#### **Products Affected**

## • Topiramate SOLN

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 (i.e., focal-onset seizures):  1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to any of the following: Aptiom (if 4 years of age or older), Xcopri (if 18 years of age or older), Spritam (if 4 years of age or older). For monotherapy treatment of primary generalized tonic-clonic seizures: 1) The patient has experienced an inadequate treatment response or intolerance to a generic topiramate immediate release product, OR 2) The patient has difficulty swallowing solid oral dosage forms (e.g., tablets, capsules). For adjunctive treatment of primary generalized tonic-clonic seizures: 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) If the patient is 6 years of age or older, the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Spritam. For the preventative treatment of migraines: 1) The patient has experienced an inadequate treatment response or intolerance to a generic topiramate immediate release product, OR 2) The patient has difficulty swallowing solid oral dosage forms (e.g., tablets, capsules).
Age Restrictions	Epilepsy: 2 years of age or older, Migraine: 12 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year

Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **ERGOTAMINE**

#### **Products Affected**

## • Ergotamine Tartrate/caffeine

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Coverage will be denied when used in conjunction with potent CYP3A4 inhibitors (e.g., ritonavir, nelfinavir, indinavir, erythromycin, clarithromycin).
Required Medical Information	The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least ONE triptan 5-HT1 agonist.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **E**RIVEDGE

## **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 prior systemic therapy 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
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **E**RLEADA

## **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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **E**RLOTINIB

#### **Products Affected**

• Erlotinib Hydrochloride TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent non-small cell lung cancer (NSCLC), recurrent chordoma, relapsed or stage IV renal cell carcinoma (RCC), brain metastases from non-small cell lung cancer (NSCLC), recurrent pancreatic cancer
Exclusion Criteria	N/A
Required Medical Information	For non-small cell lung cancer (NSCLC) (including brain metastases from NSCLC): 1) the disease is recurrent, advanced, or metastatic, AND 2) the patient has sensitizing epidermal growth factor receptor (EGFR) mutation-positive disease. For pancreatic cancer: the disease is locally advanced, unresectable, recurrent, or metastatic.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **E**SBRIET

## **Products Affected**

#### • 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 (new starts 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **EUCRISA**

## **Products Affected**

#### • Eucrisa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For mild to moderate atopic dermatitis, the patient meets either of the following criteria: 1) If the patient is 2 years of age or older and the requested drug will be used on sensitive skin areas (e.g., face, genitals, or skin folds), the patient has experienced an inadequate treatment response, intolerance, or contraindication to a topical calcineurin inhibitor OR 2) If the patient is 2 years of age or older and the requested drug is being prescribed for use on nonsensitive (or remaining) skin areas, the patient has experienced an inadequate treatment response, intolerance, or contraindication to a medium or higher potency topical corticosteroid or a topical calcineurin inhibitor.
Age Restrictions	3 months of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **EVENITY**

## **Products Affected**

## • Evenity

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

## **EVEROLIMUS**

## **Products Affected**

- Torpenz
- 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, previously treated Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma, soft tissue sarcoma (perivascular epithelioid cell tumors (PEComa) and lymphangioleiomyomatosis subtypes), gastrointestinal stromal tumors, neuroendocrine tumors of the thymus, well differentiated grade 3 neuroendocrine tumors, thyroid carcinoma (papillary, oncocytic, and follicular), endometrial carcinoma, uterine sarcoma, breast cancer (in combination with fulvestrant or tamoxifen), histiocytic neoplasms (Rosai-Dorfman Disease, Erdheim-Chester Disease, Langerhans Cell Histiocytosis), meningiomas.
Exclusion Criteria	N/A
Required Medical Information	For breast cancer: 1) The disease is recurrent unresectable, advanced, or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, AND 2) The requested drug is prescribed in combination with exemestane, fulvestrant, or tamoxifen, AND 3) The requested drug 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. For gastrointestinal stromal tumor: 1) The disease is residual, recurrent, unresectable, or metastatic/tumor rupture, AND 2) The disease has progressed after use of at least two FDA-approved therapies (e.g., imatinib, sunitinib, regorafenib, ripretinib). For Erdheim-Chester Disease (ECD), Rosai-Dorfman Disease, and Langerhans Cell Histiocytosis (LCH): the patient must have a phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha (PIK3CA) mutation.

Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **EVRYSDI**

## **Products Affected**

• Evrysdi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

# **FABHALTA**

## **Products Affected**

#### • Fabhalta

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

## **FABRAZYME**

#### **Products Affected**

## • Fabrazyme

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For Fabry disease, the patient meets ANY of the following: 1) diagnosis of Fabry disease was confirmed by an enzyme assay demonstrating a deficiency of alpha-galactosidase enzyme activity or by genetic testing, OR 2) the patient is a symptomatic obligate carrier.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **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, 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: a) medium-to-high-dose inhaled corticosteroid AND b) additional controller (i.e., long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies. For severe asthma, 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. For eosinophilic granulomatosis with polyangiitis (EGPA), initial therapy: patient has a history or the presence of an eosinophil count of more than 1000 cells per microliter or a blood eosinophil level of greater than 10 percent. For EGPA, continuation of therapy: patient has a beneficial response to treatment with the requested drug, as demonstrated by any of the following: 1) a reduction in the frequency of relapses, 2) a reduction in the daily oral corticosteroid dose, OR 3) no active vasculitis.
Age Restrictions	Asthma: 6 years of age or older, EGPA: 18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year

Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **FENTANYL PATCH**

#### **Products Affected**

 Fentanyl PT72 100MCG/HR, 12MCG/HR, 25MCG/HR, 50MCG/HR, 75MCG/HR

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

# **FILSPARI**

## **Products Affected**

• Filspari

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For patients with primary immunoglobulin A nephropathy (IgAN) at risk of disease progression: 1) The patient had an inadequate response to therapy with a maximally tolerated dose of a reninangiotensin system (RAS) inhibitor (e.g., angiotensin-converting enzyme [ACE] inhibitor or angiotensin-receptor blocker [ARB]), OR 2) The patient experienced an intolerance or has a contraindication to RAS inhibitors.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **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	2 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **FIRMAGON**

#### **Products Affected**

• Firmagon INJ 120MG/VIAL, 80MG

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **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 renal cell carcinoma: 1) The disease is advanced, relapsed, refractory or Stage IV, AND 2) The patient has received two or more prior systemic therapies.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **FRUZAQLA**

## **Products Affected**

## • Fruzaqla

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **FULPHILA**

### **Products Affected**

## • Fulphila

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Stem cell transplantation-related indications
Exclusion Criteria	N/A
Required Medical Information	If receiving chemotherapy, the requested drug will be administered at least 24 hours after chemotherapy. For prophylaxis of myelosuppressive chemotherapy-induced febrile neutropenia: the patient must meet both of the following: 1) Patient has a solid tumor or non-myeloid cancer, AND 2) Patient 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **FYCOMPA**

### **Products Affected**

• Fycompa SUSP

## • Perampanel

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 (i.e., focal-onset seizures):  1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to any of the following: Aptiom, Xcopri, Spritam. For adjunctive treatment of primary generalized tonic-clonic seizures: 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Spritam.
Age Restrictions	Partial-onset seizures (i.e., focal-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
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **G**AMASTAN

### **Products Affected**

#### Gamastan

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **GATTEX**

## **Products Affected**

#### Gattex

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

# **G**AVRETO

## **Products Affected**

#### Gavreto

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent rearranged during transfection (RET) rearrangement- positive non-small cell lung cancer, RET mutation-positive medullary carcinoma
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, Thyroid cancer: 12 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **GILENYA**

### **Products Affected**

## • Fingolimod 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **G**ILOTRIF

## **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) has sensitizing epidermal growth factor receptor (EGFR) mutation-positive disease AND a) has experienced an intolerable adverse event or contraindication to erlotinib, gefitinib or osimertinib, OR 2) has metastatic squamous NSCLC that progressed after platinum-based chemotherapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **GLATIRAMER**

#### **Products Affected**

#### • Glatiramer Acetate

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **GLP-1 AGONISTS**

#### **Products Affected**

- Liraglutide INJ 6MG/ML
- Mounjaro

- Ozempic INJ 2MG/3ML, 4MG/3ML, 8MG/3ML
- Rybelsus TABS 14MG, 3MG, 7MG
- Trulicity

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Excluded if used for weight loss only.
Required Medical Information	The patient must have a documented diagnosis with supporting medical records confirming diagnosis of Type 2 Diabetes Mellitus and must meet the additional requirements stated below for the requested drug. For liraglutide: Must meet one of the following requirements: 1) to be used as an adjunct to diet and exercise to improve glycemic control or 2) to reduce the risk of major adverse cardiovascular events in patients with established cardiovascular disease. For MOUNJARO: To be used as an adjunct to diet and exercise to improve glycemic control. For OZEMPIC: Must meet one of the following requirements: 1) to be used as an adjunct to diet and exercise to improve glycemic control 2) to reduce the risk of major adverse cardiovascular events in patients with established cardiovascular disease or 3) to reduce the risk of sustained eGFR decline, end-stage kidney disease and cardiovascular death in patients with chronic kidney disease. For RYBELSUS: To be used as an adjunct to diet and exercise to improve glycemic control. For TRULICITY: Must meet one of the following requirements: 1) to be used as an adjunct to diet and exercise to improve glycemic control or 2) to reduce the risk of major adverse cardiovascular events in patients who have established cardiovascular disease or multiple cardiovascular risk factors.
Age Restrictions	Adjunct to improve glycemic control (liraglutide and Trulicity only): 10 years of age or older
Prescriber Restrictions	N/A

Coverage Duration	Plan Year
Other Criteria	Type 2 Diabetes Mellitus (Reauthorization): Patient demonstrates positive clinical response to therapy.
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **G**OMEKLI

## **Products Affected**

#### • Gomekli

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **GRALISE**

#### **Products Affected**

• Gralise TABS 450MG, 750MG, 900MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For postherpetic neuralgia: The patient has experienced an inadequate treatment response or intolerance to gabapentin immediate-release.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **GROWTH HORMONE**

#### **Products Affected**

- Genotropin
- Genotropin Miniquick
- Humatrope INJ 12MG, 24MG, 6MG
- Norditropin Flexpro

- Nutropin Aq Nuspin 10
- Nutropin Aq Nuspin 20
- Nutropin Aq Nuspin 5
- Omnitrope
- Zomacton

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Pediatric patients with closed epiphyses
Required Medical Information	Pediatric growth hormone deficiency (GHD): Patient (pt) is a neonate or was diagnosed with GHD as a neonate OR meets any of the following: 1) younger than 2.5 years old (yo) with pretreatment (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, acquired structural abnormalities, congenital structural abnormalities) and pre-tx insulin-like growth factor-1 (IGF-1) more than 2 SD below mean. Turner syndrome (TS): 1) Confirmed by karyotyping AND 2) pre-tx ht is less than the 5th percentile for age. Small for gestational age (SGA): 1) Birth weight (wt) less than 2500g at gestational age (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	Prescribed by or in consultation with an endocrinologist, nephrologist, infectious disease specialist, gastroenterologist/nutritional support specialist, or 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, 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. For pediatric GHD, TS, SGA, and adult GHD, continuation of therapy: Patient is experiencing improvement.
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **HARLIKU**

## **Products Affected**

#### Harliku

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **HARVONI**

### **Products Affected**

• Ledipasvir/sofosbuvir

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, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **HERCEPTIN**

### **Products Affected**

• Herceptin INJ 150MG

• 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, leptomeningeal metastases from HER2-positive breast cancer, brain metastases from HER2-positive breast cancer, HER2-positive esophageal and esophagogastric junction adenocarcinoma, HER2-positive advanced, recurrent, or metastatic uterine serous carcinoma, HER2-amplified and RAS and BRAF wild-type colorectal cancer (including appendiceal adenocarcinoma), HER2-positive recurrent salivary gland tumor, HER2-positive unresectable or metastatic hepatobiliary carcinoma (gallbladder cancer, intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma), HER2 overexpression positive locally advanced, unresectable, or recurrent gastric adenocarcinoma, HER2-positive endometrial cancer.
Exclusion Criteria	N/A
Required Medical Information	All indications: the patient had an intolerable adverse event to Trazimera and that adverse event was NOT attributed to the active ingredient as described in the prescribing information. For colorectal cancer (including appendiceal adenocarcinoma): 1) the disease is HER2-amplified and RAS and BRAF wild-type and 2) the requested drug is used in combination with pertuzumab, tucatinib or lapatinib and 3) the patient has not had previous treatment with a HER2 inhibitor. For hepatobiliary carcinoma: 1) the disease is HER2-positive AND 2) the requested drug is used in combination with pertuzumab. For endometrial cancer: 1) the disease is HER2-positive AND 2) the requested drug is used in combination with paclitaxel and continued as a single agent for maintenance 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.
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **HERNEXEOS**

## **Products Affected**

#### Hernexeos

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

# **HERZUMA**

### **Products Affected**

#### Herzuma

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, leptomeningeal metastases from HER2-positive breast cancer, brain metastases from HER2-positive breast cancer, HER2-positive esophageal and esophagogastric junction adenocarcinoma, HER2-positive advanced, recurrent, or metastatic uterine serous carcinoma, HER2-amplified and RAS and BRAF wild-type colorectal cancer (including appendiceal adenocarcinoma), HER2-positive recurrent salivary gland tumor, HER2-positive unresectable or metastatic hepatobiliary carcinoma (gallbladder cancer, intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma), HER2 overexpression positive locally advanced, unresectable, or recurrent gastric adenocarcinoma, HER2-positive endometrial cancer.
Exclusion Criteria	N/A
Required Medical Information	All indications: the patient had an intolerable adverse event to Trazimera and that adverse event was NOT attributed to the active ingredient as described in the prescribing information. For colorectal cancer (including appendiceal adenocarcinoma): 1) the disease is HER2-amplified and RAS and BRAF wild-type and 2) the requested drug is used in combination with pertuzumab, tucatinib or lapatinib and 3) the patient has not had previous treatment with a HER2 inhibitor. For hepatobiliary carcinoma: 1) the disease is HER2-positive AND 2) the requested drug is used in combination with pertuzumab. For endometrial cancer: 1) the disease is HER2-positive AND 2) the requested drug is used in combination with paclitaxel and continued as a single agent for maintenance 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.
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **HETLIOZ**

## **Products Affected**

#### • Tasimelteon

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 the patient must meet both of the following: 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 experienced 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	Prescribed by or in consultation with a sleep disorder specialist, neurologist, or psychiatrist
Coverage Duration	Initiation: 6 months, Renewal: Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# 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 experienced improvement in the quality of sleep since starting therapy.
Age Restrictions	3 to 15 years of age
Prescriber Restrictions	Prescribed by or in consultation with a sleep disorder specialist, neurologist, or psychiatrist
Coverage Duration	Initiation: 6 months, Renewal: Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

### HUMIRA

#### **Products Affected**

- Adalimumab-aaty 1-pen Kit
- Adalimumab-aaty 2-pen Kit
- Adalimumab-aaty 2-syringe Kit
- Adalimumab-aaty Cd/uc/hs Starter
- Cyltezo
- Cyltezo Starter Package For Crohns Disease/uc/hs
- Cyltezo Starter Package For Psoriasis
- Cyltezo Starter Package For Psoriasis/uveitis

- Humira INJ 10MG/0.1ML, 20MG/0.2ML, 40MG/0.4ML, 40MG/0.8ML
- Humira Pen
- Humira Pen-cd/uc/hs Starter INJ 80MG/0.8ML
- Humira Pen-ps/uv Starter INJ 0
- Yuflyma 1-pen Kit
- Yuflyma 2-syringe Kit
- Yuflyma Cd/uc/hs Starter

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A

Required Medical Information	For moderately to severely active rheumatoid arthritis (new starts only): 1) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to methotrexate (MTX) OR 2) patient has experienced an inadequate treatment response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis and non-radiographic axial spondyloarthritis (new starts only): patient has experienced an inadequate treatment response or intolerance to a non-steroidal anti-inflammatory drug (NSAID) OR the patient has a contraindication that would prohibit a trial of 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, scalp, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) the patient meets any of the following: a) the patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) the patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	For non-infectious intermediate, posterior and panuveitis (new starts only): 1) patient has experienced an inadequate treatment response or intolerance to a corticosteroid OR 2) the patient has a contraindication that would prohibit a trial of corticosteroids.
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **IBRANCE**

## **Products Affected**

• Ibrance

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

# **I**BTROZI

## **Products Affected**

• Ibtrozi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

## **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 the treatment of acute angioedema attacks due to hereditary angioedema (HAE): 1) the patient has HAE with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing OR 2) the patient has HAE with normal C1 inhibitor confirmed by laboratory testing and one of the following: a) the patient tested positive for an F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation, b) the patient has a family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy for at least one month.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **I**CLUSIG

## **Products Affected**

• Iclusig

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Myeloid and/or lymphoid neoplasms with eosinophilia and FGFR1 or ABL1 rearrangement in the chronic phase or blast phase, Gastrointestinal Stromal Tumors
Exclusion Criteria	N/A
Required Medical Information	For chronic myeloid leukemia (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, dasatinib, or nilotinib, OR 3) Patient is positive for the T315I mutation. For acute lymphoblastic leukemia (ALL), including patients who have received a hematopoietic stem cell transplant: Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene. For gastrointestinal stromal tumors (GIST): 1) Disease meets any of the following: A) residual, B) unresectable, C) recurrent, D) metastatic/tumor rupture, AND 2) Disease has progressed after use of at least two Food and Drug Administration (FDA) approved therapies (e.g., imatinib, sunitinib, regorafenib, ripretinib).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.
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# **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 newly-diagnosed AML and is not a candidate for intensive induction therapy, OR 2) 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
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **IMATINIB**

#### **Products Affected**

• Imatinib Mesylate TABS

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, cutaneous melanoma, Kaposi sarcoma, chronic graft versus host disease (cGVHD), T-cell acute lymphoblastic leukemia with ABL-class translocation, aggressive systemic mastocytosis for well-differentiated systemic mastocytosis (WDSM) or when eosinophilia is present with FIP1L1-PDGFRA fusion gene, myeloid and/or lymphoid neoplasms with eosinophilia and ABL1, FIP1L1-PDGFRA, or PDGFRB rearrangement in the chronic phase or blast phase.
Exclusion Criteria	N/A
Required Medical Information	For chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), including patients who have received a hematopoietic stem cell transplant: 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 cutaneous melanoma: 1) Disease is metastatic or unresectable AND 2) Disease is positive for c-KIT activating mutations AND 3) Requested medication will be used as subsequent therapy AND 4) Patient has had disease progression, intolerance, or risk of progression with BRAF-targeted therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year

Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **I**MBRUVICA

#### **Products Affected**

- Imbruvica CAPS
- Imbruvica SUSP

• Imbruvica TABS 140MG, 280MG, 420MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Hairy cell leukemia, lymphoplasmacytic lymphoma, primary central nervous system (CNS) lymphoma, human immunodeficiency virus (HIV)-related B-cell lymphoma, diffuse large B-cell lymphoma, post-transplant lymphoproliferative disorders, high-grade B-cell lymphoma, mantle cell lymphoma, marginal zone lymphoma (including extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of nongastric sites, nodal marginal zone lymphoma, splenic marginal zone lymphoma)
Exclusion Criteria	N/A

Required Medical Information	For mantle cell lymphoma: 1) the requested drug will be used as subsequent therapy AND the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Calquence (acalabrutinib), 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, OR 3) the requested drug will be used as aggressive induction therapy. For marginal zone lymphoma (including extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of nongastric sites, nodal marginal zone lymphoma, and splenic marginal zone lymphoma): the requested drug will be used as second-line or subsequent therapy. For hairy cell leukemia: the requested drug will be used as a single agent for disease progression. For primary CNS lymphoma: 1) the disease is relapsed or refractory OR 2) the requested drug is used for induction therapy as a single agent. For diffuse large B-cell lymphoma, high-grade B-cell lymphoma, human immunodeficiency virus (HIV)-related B-cell lymphoma: The requested drug will be used as a single agent and as second-line or subsequent therapy for relapsed or refractory disease. For post-transplant lymphoproliferative disorders: the requested drug will be used in patients who have received prior chemoimmunotherapy. For chronic lymphocytic leukemia/small lymphocytic lymphoma: the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Calquence (acalabrutinib).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **I**MKELDI

## **Products Affected**

#### • Imkeldi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent chordoma, cutaneous melanoma, Kaposi sarcoma
Exclusion Criteria	N/A
Required Medical Information	For all indications: The patient is unable to use imatinib tablets. For chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), including patients who have received a hematopoietic stem cell transplant: 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 cutaneous melanoma: 1) Disease is metastatic or unresectable AND 2) Disease is positive for c-KIT activating mutations AND 3) Requested medication will be used as subsequent therapy AND 4) Patient has had disease progression, intolerance, or risk of progression with BRAF-targeted therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **IMVEXXY**

### **Products Affected**

• Imvexxy Maintenance Pack

• Imvexxy 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **I**NBRIJA

## **Products Affected**

• Inbrija

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **I**NCRELEX

## **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 (GH) gene deletion in patients who have developed neutralizing antibodies to GH, patient meets 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 growth failure due to severe primary IGF-1 deficiency or GH gene deletion in patients who have developed neutralizing antibodies to GH, continuation of therapy: patient is experiencing improvement.
Age Restrictions	2 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **I**NLYTA

## **Products Affected**

• Inlyta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Thyroid carcinoma (papillary, oncocytic, or follicular), alveolar soft part sarcoma
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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **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, accelerated or blast phase myeloproliferative neoplasms
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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **INSULIN SUPPLIES**

#### **Products Affected**

- Alcohol Prep Pads PADS 70%
- Bd Insulin Syringe Safetyglide/1ml/29g X 1/2"
- B-d Insulin Syringe Ultrafine li/0.3ml/31g X 5/16"
- Bd Insulin Syringe Ultrafine/0.5ml/30g X 12.7mm

- Bd Insulin Syringe Ultrafine/1ml/31g X 8mm
- Bd Pen Needle/original/ultrafine/29g X 12.7mm
- Curity Gauze Pads 2"x2" 12 Ply

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The requested product is being used with insulin.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## IR BEFORE ER

#### **Products Affected**

- Methadone Hcl SOLN
- Methadone Hcl TABS
- Morphine Sulfate Er TBCR

- Tramadol Hcl Er CP24 100MG, 200MG, 300MG
- Tramadol Hcl Er TB24
- Tramadol Hydrochloride Er

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

## **I**RESSA

## **Products Affected**

#### • Gefitinib

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 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 must have a sensitizing epidermal growth factor receptor (EGFR) mutation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **I**STURISA

#### **Products Affected**

• Isturisa TABS 1MG, 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	Prescribed by or in consultation with an endocrinologist
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **I**TOVEBI

## **Products Affected**

#### • Itovebi

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **IVERMECTIN TAB**

#### **Products Affected**

• Ivermectin TABS 3MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Ascariasis, Cutaneous Iarva 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **WILFIN**

## **Products Affected**

Iwilfin

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **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 or blast phase myeloproliferative neoplasms, acute lymphoblastic leukemia (ALL), chronic myelomonocytic leukemia (CMML)-2, myelodysplastic syndrome/myeloproliferative neoplasm (MDS/MPN) with neutrophilia, essential thrombocythemia, myeloid, lymphoid or mixed lineage neoplasms with eosinophilia and JAK2 rearrangement, T-cell prolymphocytic leukemia
Exclusion Criteria	N/A
Required Medical Information	For polycythemia vera: 1) patient had an inadequate response or intolerance to hydroxyurea and Besremi (ropeginterferon alfa-2b-njft), OR 2) patient has high risk disease. 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 myelodysplastic syndrome/myeloproliferative neoplasm (MDS/MPN) with neutrophilia: 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
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **JAYPIRCA**

## **Products Affected**

## • Jaypirca

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **J**OENJA

## **Products Affected**

• Joenja

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For activated phosphoinositide 3-kinase delta syndrome (APDS): the diagnosis was confirmed by genetic testing demonstrating variant in either PIK3CD or PIK3R1.
Age Restrictions	12 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **J**OURNAVX

## **Products Affected**

#### Journavx

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

## **JUXTAPID**

### **Products Affected**

 Juxtapid CAPS 10MG, 20MG, 30MG, 5MG

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

Required Medical Information	For initiation of therapy to treat homozygous familial hypercholesterolemia (HoFH), patient (pt) must meet ALL of the following: A) Diagnosis of HoFH confirmed by one of the following: 1) Genetic testing to confirm two mutant alleles at low-density lipoprotein receptor (LDLR), apolipoprotein B (ApoB), proprotein convertase subtilisin/kexin type 9 (PCSK9), or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1) gene locus OR 2) History of an untreated low-density lipoprotein-cholesterol (LDL-C) of greater than 400 mg/dL and either of the following: a) Presence of cutaneous or tendinous xanthomas before the age of 10 years, or b) An untreated LDL-C level of greater than or equal to 190 mg/dL in both parents, which is consistent with heterozygous familial hypercholesterolemia (HeFH), AND B) Prior to initiation of treatment, the pt is currently receiving treatment with a high-intensity statin at a maximally tolerated dose or at the maximum dose approved by the Food and Drug Administration (FDA) unless the pt is statin intolerant or has a contraindication to statin therapy, AND C) Prior to initiation of treatment with the requested drug, the pt is currently receiving treatment with a PCSK9-directed therapy at a maximally tolerated dose or at the maximum dose approved by the FDA unless the patient has experienced an intolerance or has a contraindication to all PCSK9-directed therapies, AND D) Prior to initiation of treatment, pt is/was experiencing an inadequate response to lipid-lowering therapy as indicated by a treated LDL-C greater than 100 mg/dL (or greater than 70 mg/dL with clinical atherosclerotic cardiovascular disease), AND E) The pt will continue to receive concomitant lipid lowering therapy. For renewal of therapy to treat HoFH: A) Pt meets all initial criteria, AND B) Has responded to therapy as demonstrated by a reduction in LDL-C from baseline, AND C) Is receiving concomitant lipid lowering therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.
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# **JYLAMVO**

## **Products Affected**

## Jylamvo

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **K**ALYDECO

## **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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **K**ANJINTI

## **Products Affected**

Kanjinti

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, leptomeningeal metastases from HER2-positive breast cancer, brain metastases from HER2-positive breast cancer, HER2-positive esophageal and esophagogastric junction adenocarcinoma, HER2-positive advanced, recurrent, or metastatic uterine serous carcinoma, HER2-amplified and RAS and BRAF wild-type colorectal cancer (including appendiceal adenocarcinoma), HER2-positive recurrent salivary gland tumor, HER2-positive unresectable or metastatic hepatobiliary carcinoma (gallbladder cancer, intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma), HER2 overexpression positive locally advanced, unresectable, or recurrent gastric adenocarcinoma, HER2-positive endometrial cancer.
Exclusion Criteria	N/A
Required Medical Information	All indications: the patient had an intolerable adverse event to Trazimera and that adverse event was NOT attributed to the active ingredient as described in the prescribing information. For colorectal cancer (including appendiceal adenocarcinoma): 1) the disease is HER2-amplified and RAS and BRAF wild-type and 2) the requested drug is used in combination with pertuzumab, tucatinib or lapatinib and 3) the patient has not had previous treatment with a HER2 inhibitor. For hepatobiliary carcinoma: 1) the disease is HER2-positive AND 2) the requested drug is used in combination with pertuzumab. For endometrial cancer: 1) the disease is HER2-positive AND 2) the requested drug is used in combination with paclitaxel and continued as a single agent for maintenance 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.
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **K**ERENDIA

### **Products Affected**

#### Kerendia

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **K**ESIMPTA

## **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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **K**EVEYIS

### **Products Affected**

• Dichlorphenamide

- Keveyis
- Ormalvi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For primary HYPOkalemic periodic paralysis: 1) The diagnosis was supported by genetic test results, OR 2) Patient has a family history of primary hypokalemic periodic paralysis, OR 3) Patient's attacks are associated with hypokalemia AND both Andersen-Tawil syndrome and thyrotoxic periodic paralysis have been ruled out. For primary HYPERkalemic periodic paralysis: 1) The diagnosis was supported by genetic test results, OR 2) Patient has a family history of primary hyperkalemic periodic paralysis, OR 3) Patient's attacks are associated with hyperkalemia AND Andersen-Tawil syndrome has been ruled out. For continuation of therapy for primary HYPOkalemic and primary HYPERkalemic periodic paralysis: Patient is demonstrating a response to therapy with the requested drug as demonstrated by a decrease in the number or severity of attacks.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 2 months. Continuation: Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **K**EVZARA

### **Products Affected**

#### Kevzara

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, intolerance, or has a contraindication to two of the following products: Cyltezo (adalimumab-adbm), Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release), Yuflyma (adalimumab-aaty). For polymyalgia rheumatica (PMR) (new starts only): 1) Patient has experienced an inadequate treatment response to corticosteroids OR 2) Patient has experienced a disease flare while attempting to taper corticosteroids OR 3) Patient has a contraindication that would prohibit a trial of corticosteroids. For active polyarticular juvenile idiopathic arthritis (new starts only): Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: Cyltezo (adalimumab-adbm), Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib)/Rinvoq LQ (upadacitinib), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release), Yuflyma (adalimumab-aaty).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.
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## **K**INERET

## **Products Affected**

#### Kineret

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Systemic juvenile idiopathic arthritis, adult-onset Still's disease, multicentric Castleman's disease, Schnitzler syndrome, Erdheim-Chester disease.
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid Arthritis (RA) (new starts only): The patient must have a documented diagnosis of moderately to severely active RA. The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: Cyltezo (adalimumab-adbm), Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Tyenne (tocilizumab-aazg), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib-extended release), Yuflyma (adalimumab-aaty). Systemic Juvenile Idiopathic Arthritis (SJIA) (new starts only): The patient must have a documented diagnosis of active SJIA. The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Tyenne (tocilizumab-aazg).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **K**ISQALI

### **Products Affected**

• Kisqali

- Kisqali Femara 400 Dose
- Kisqali Femara 600 Dose

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer, in combination with an aromatase inhibitor, or fulvestrant. Endometrial cancer, in combination with letrozole, for estrogen receptor positive 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **K**LISYRI

## **Products Affected**

• Klisyri

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 ONE of the following: A) imiquimod 5 percent cream, B) fluorouracil cream or solution.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **K**ORLYM

#### **Products Affected**

• Mifepristone TABS 300MG

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 endocrinologist
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **K**oselugo

## **Products Affected**

## • Koselugo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	BRAF fusion or BRAF V600E activating mutation-positive recurrent or progressive circumscribed glioma, Langerhans cell histiocytosis.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	For neurofibromatosis type 1: 2 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **K**RAZATI

#### **Products Affected**

#### Krazati

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent KRAS G12C-positive non-small cell lung cancer (NSCLC), Central nervous system (CNS) brain metastases from KRAS G12C-positive NSCLC, KRAS G12C-positive pancreatic adenocarcinoma
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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **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 HER2-positive breast cancer, recurrent epidermal growth factor receptor (EGFR)-positive chordoma, HER2-amplified and RAS and BRAF wild-type colorectal cancer (including appendiceal adenocarcinoma).
Exclusion Criteria	N/A
Required Medical Information	For breast cancer, the patient meets all the following: a) the disease is recurrent, advanced, or metastatic (including brain metastases), b) the disease is human epidermal growth factor receptor 2 (HER2)-positive, c) the requested drug will be used in combination with any of the following: 1) aromatase inhibitor, 2) capecitabine, OR 3) trastuzumab. For colorectal cancer: 1) requested drug will be used in combination with trastuzumab and 2) patient has not had previous treatment with a HER2 inhibitor.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **LAZCLUZE**

## **Products Affected**

#### • Lazcluze

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

#### 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 DoseLenvima 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, unresectable or metastatic cutaneous melanoma.
Exclusion Criteria	N/A
Required Medical Information	For differentiated thyroid cancer (follicular, papillary, or oncocytic): disease is not amenable to radioactive iodine therapy and unresectable, locally recurrent, persistent, or metastatic. For hepatocellular carcinoma (HCC): disease is unresectable or inoperable, local, metastatic or with extensive liver tumor burden. For renal cell carcinoma (RCC): the disease is advanced, relapsed, or stage IV. For endometrial carcinoma (EC), the patient meets ALL of the following: 1) The disease is advanced, recurrent, or metastatic, 2) The requested drug will be used in combination with pembrolizumab, 3) The patient experienced disease progression following prior systemic therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.
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## **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, central precocious puberty
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, 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **LIDOCAINE**

#### **Products Affected**

- Lidocaine OINT 5%
- Lidocaine PTCH 5%

- Lidocaine Hydrochloride SOLN
- Lidocaine/prilocaine CREA
- Lidocan

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## LIVDELZI

## **Products Affected**

• Livdelzi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For primary biliary cholangitis (PBC): For initial therapy: 1) Diagnosis of PBC is confirmed by at least two of the following: a) Biochemical evidence of cholestasis with elevation of alkaline phosphatase (ALP) level for at least 6 months duration, b) Presence of antimitochondrial antibodies (AMA) (titer greater than 1:40 by immunofluorescence or immunoenzymatic reactivity) or PBC-specific antinuclear antibodies ANA (e.g., anti-gp210, anti-sp100), c) Histologic evidence of PBC on liver biopsy (e.g., non-suppurative inflammation and destruction of interlobular and septal bile ducts), AND 2) Patient has an elevated serum ALP level prior to initiation of therapy with the requested drug and meets one of the following requirements: a) Has experienced an inadequate response to at least 12 months of prior therapy with ursodeoxycholic acid (UDCA)/ursodiol and the patient will continue concomitant therapy with UDCA/ursodiol, b) Is intolerant to prior therapy with UDCA/ursodiol. For PBC (continuation): Patient achieved or maintained a clinical benefit from Livdelzi therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months, Continuation: Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## LIVMARLI

## **Products Affected**

#### • Livmarli

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

## **LIVTENCITY**

## **Products Affected**

• Livtencity

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	Prescribed by or in consultation with an infectious disease specialist, transplant specialist, hematologist, or oncologist.
Coverage Duration	3 months
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **LONSURF**

## **Products Affected**

#### • Lonsurf

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Unresectable locally advanced, recurrent, or metastatic esophageal cancer. Unresectable locally advanced or recurrent gastric cancer and gastroesophageal junction cancers. Advanced or metastatic appendiceal adenocarcinoma.
Exclusion Criteria	N/A
Required Medical Information	For colorectal cancer (including appendiceal adenocarcinoma): The disease is advanced or metastatic. For gastric, esophageal, 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
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **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 non-small cell lung cancer (NSCLC), proto-oncogene tyrosine-protein kinase ROS1 (ROS1) rearrangement-positive recurrent, advanced, or metastatic NSCLC, symptomatic or relapsed/refractory ALK-positive Erdheim-Chester Disease, inflammatory myofibroblastic tumor (IMT) with ALK translocation (including advanced, recurrent/metastatic, or inoperable uterine sarcoma for IMT with ALK translocation), central nervous system (CNS) brain metastases from ALK rearrangement-positive NSCLC, relapsed or refractory ALK-positive Diffuse Large B-Cell Lymphoma
Exclusion Criteria	N/A
Required Medical Information	For recurrent, advanced, or metastatic non-small cell lung cancer: 1) Disease is ALK-positive AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to ONE of the following products: Alecensa (alectinib) or Alunbrig (brigatinib) OR 3) Disease is positive for ROS1 rearrangement and the requested drug is being used following disease progression on crizotinib, entrectinib, or ceritinib.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **LUMAKRAS**

#### **Products Affected**

#### Lumakras

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent KRAS G12C-positive non-small cell lung cancer (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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## LUMIZYME

## **Products Affected**

## • Lumizyme

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For Pompe disease: Diagnosis was confirmed by an enzyme assay demonstrating a deficiency of acid alpha-glucosidase (GAA) enzyme activity or by genetic testing.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **LUPKYNIS**

## **Products Affected**

• Lupkynis

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Use in combination with cyclophosphamide
Required Medical Information	For lupus nephritis: 1) patient is currently receiving background immunosuppressive therapy regimen for lupus nephritis (for example, mycophenolate mofetil, corticosteroids) OR 2) patient has an intolerance or has a contraindication to background immunosuppressive therapy regimen for lupus nephritis. For lupus nephritis continuation: patient is receiving benefit from therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **LUPRON-PROSTATE CA**

#### **Products Affected**

- Lupron Depot (1-month)
- Lupron Depot (3-month)

- Lupron Depot (4-month)
- Lupron Depot (6-month)

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Malignant sex cord-stromal 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **LYBALVI**

## **Products Affected**

• Lybalvi

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **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, uterine leiomyosarcoma.
Exclusion Criteria	N/A
Required Medical Information	For recurrent or metastatic breast cancer: the disease is BRCA 1/2-germline mutated. For prostate cancer: 1) The patient has a BRCA mutation and the requested drug will be used in combination with abiraterone and an oral corticosteroid OR 2) The patient has progressed on prior treatment with an androgen receptor-directed therapy. For ovarian, fallopian tube, or primary peritoneal cancer: The requested drug is used for maintenance therapy for stage II-IV or recurrent disease who are in complete or partial response to chemotherapy. For uterine leiomyosarcoma: 1) the patient has had at least one prior therapy AND 2) the patient has BRCA-altered disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **LYTGOBI**

## **Products Affected**

• Lytgobi

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **M**AVYRET

## **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, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **M**EKINIST

## **Products Affected**

#### Mekinist

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Langerhans cell histiocytosis, Erdheim-Chester disease, Rosai- Dorfman disease.
Exclusion Criteria	N/A
Required Medical Information	For 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, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, b) adjuvant systemic therapy. For uveal melanoma: The requested drug will be used as a single agent. For ovarian cancer, fallopian tube cancer, and primary peritoneal cancer: The requested drug will be used to treat persistent or recurrent disease. For papillary, follicular, and oncocytic thyroid carcinoma: 1) The disease is positive for BRAF V600E mutation, AND 2) The disease is not amenable to radioactive iodine (RAI) therapy, AND 3) The requested drug will be used in combination with dabrafenib. For solid tumors: 1) The tumor is positive for a BRAF V600E mutation, AND 2) The requested drug will be used in combination with dabrafenib.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **M**EKTOVI

## **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, Langerhans Cell Histiocytosis, recurrent non-small cell lung cancer (NSCLC)
Exclusion Criteria	N/A
Required Medical Information	For melanoma: 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 encorafenib, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, b) adjuvant systemic therapy. For non-small cell lung cancer: 1) The tumor is positive for BRAF V600E mutation, AND 2) The requested drug will be used in combination with encorafenib, AND 3) The disease is advanced, recurrent, or metastatic.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **M**ETHOTREXATE

#### **Products Affected**

- Methotrexate INJ 50MG/2ML
- Methotrexate Sodium INJ 1GM/40ML, 250MG/10ML, 50MG/2ML

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

# **M**IGLUSTAT

#### **Products Affected**

• Miglustat

## • Yargesa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For type 1 Gaucher disease (GD1): The diagnosis was confirmed by an enzyme assay demonstrating a deficiency of betaglucocerebrosidase enzyme activity or by genetic testing.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **M**IPLYFFA

#### **Products Affected**

• Miplyffa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For Niemann-Pick disease type C, initial: 1) The diagnosis was confirmed by genetic testing demonstrating a variant of either the NPC1 or NPC2 gene, 2) The patient has neurological manifestations of disease (e.g., loss of fine motor skills, swallowing, speech, ambulation), AND 3) The requested medication will not be used in combination with Aqneursa (levacetylleucine). For Niemann-Pick disease type C, continuation: The patient is experiencing benefit from therapy (e.g., stabilization or improvement in fine motor skills, swallowing, speech, ambulation).
Age Restrictions	2 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **M**ODAFINIL

#### **Products Affected**

#### Modafinil TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Idiopathic hypersomnia
Exclusion Criteria	N/A
Required Medical Information	For excessive sleepiness associated with narcolepsy: The diagnosis has been confirmed by sleep lab evaluation. For excessive sleepiness associated with obstructive sleep apnea (OSA): The diagnosis has been confirmed by polysomnography. For idiopathic hypersomnia, initial request, the diagnosis has been confirmed by ALL of the following: 1) Patient has experienced lapses into sleep or an irrepressible need to sleep during daytime, on a daily basis, for at least 3 months, AND 2) Insufficient sleep syndrome is confirmed absent, AND 3) Cataplexy is absent, AND 4) Fewer than 2 sleep onset rapid eye movement periods (SOREMPs) or no SOREMPs, if the rapid eye movement latency on an overnight sleep study was less than or equal to 15 minutes, AND 5) Average sleep latency of less than or equal to 8 minutes on Multiple Sleep Latency Test or total 24-hour sleep time is greater than or equal to 11 hours, AND 6) Another condition (sleep disorder, medical or psychiatric disorder, or drug/medication use) does not better explain the hypersomnolence and test results. For idiopathic hypersomnia, continuation of therapy: The patient has experienced a decrease in daytime sleepiness from baseline.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.
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# **M**ODEYSO

## **Products Affected**

• Modeyso

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

# **MOVANTIK**

## **Products Affected**

#### Movantik

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Must have documented diagnosis of opioid-induced constipation caused by opioids taken for chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **M**VASI

#### **Products Affected**

Mvasi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Ampullary adenocarcinoma, appendiceal adenocarcinoma, breast cancer, central nervous system (CNS) cancers (including pediatric diffuse high-grade gliomas), pleural mesothelioma, peritoneal mesothelioma, pericardial mesothelioma, tunica vaginalis testis mesothelioma, soft tissue sarcomas, uterine neoplasms, endometrial carcinoma, vulvar cancers, small bowel adenocarcinoma, 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.
Exclusion Criteria	N/A
Required Medical Information	For all indications except ophthalmic-related disorders: The patient had an intolerable adverse event to Zirabev and that adverse event was NOT attributed to the active ingredient as described in the prescribing information.
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.

## **M**YCAPSSA

#### **Products Affected**

## • Mycapssa

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 insulinlike 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **M**YFEMBREE

#### **Products Affected**

## • Myfembree

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For heavy menstrual bleeding associated with uterine leiomyomas (fibroids) and moderate to severe pain associated with endometriosis in a premenopausal patient: the patient has not already received greater than or equal to 24 months of treatment with the requested drug.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months, max 24 months total
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **N**ERLYNX

#### **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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **N**EULASTA

### **Products Affected**

#### Neulasta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Stem cell transplantation-related indications
Exclusion Criteria	N/A
Required Medical Information	If receiving chemotherapy, the requested drug will be administered at least 24 hours after chemotherapy. For prophylaxis of myelosuppressive chemotherapy-induced febrile neutropenia: the patient must meet both of the following: 1) Patient has a solid tumor or non-myeloid cancer, AND 2) Patient 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **N**EXAVAR

#### **Products Affected**

• 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, lymphoid and/or myeloid neoplasms with eosinophilia and FLT3 rearrangement in chronic or blast phase
Exclusion Criteria	N/A
Required Medical Information	For acute myeloid leukemia: the disease is FMS-like tyrosine kinase 3-internal tandem duplication (FLT3-ITD) mutation-positive and any of the following is met :1) the requested drug will be used as maintenance therapy after hematopoietic stem cell transplant, OR 2) the requested drug is being used for low-intensity treatment induction, post-induction therapy, or consolidation therapy, OR 3) the disease is relapsed/refractory. For thyroid carcinoma: histology is follicular, papillary, oncocytic, or medullary. For gastrointestinal stromal tumor (GIST): 1) the disease is residual, unresectable, recurrent, or metastatic/tumor rupture, AND 2) the disease has progressed after use of at least two FDA-approved therapies (e.g., imatinib, sunitinib, regorafenib, ripretinib).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **N**EXLETOL

## **Products Affected**

#### Nexletol

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **N**EXLIZET

## **Products Affected**

#### Nexlizet

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **N**GENLA

### **Products Affected**

• Ngenla

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 pediatric growth hormone deficiency (GHD), initial: A) Patient (pt) has pre-treatment (pre-tx) 1-year height (ht) velocity more than 2 standard deviations (SD) below mean OR a pre-tx ht more than 2 SD below mean and a 1-year ht velocity more than 1 SD below mean AND pt meets any of the following: 1) failed 2 pre-tx growth hormone (GH) stimulation tests (peak below 10 ng/mL), 2) pituitary/central nervous system (CNS) disorder (e.g., genetic defects, acquired structural abnormalities, congenital structural abnormalities) and pre-tx insulin-like growth factor-1 (IGF-1) more than 2 SD below mean OR B) Pt was diagnosed with GHD as a neonate. For pediatric GHD, continuation of therapy: Pt is experiencing improvement.
Age Restrictions	3 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **NILOTINIB**

### **Products Affected**

• Nilotinib

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), myeloid and/or lymphoid neoplasms with eosinophilia and ABL1 rearrangement in the chronic phase or blast phase, pigmented villonodular synovitis/tenosynovial giant cell tumor, cutaneous melanoma.
Exclusion Criteria	N/A
Required Medical Information	For chronic myeloid leukemia (CML), including patients newly diagnosed with CML and patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) 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 acute lymphoblastic leukemia (ALL), including patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) If the patient has experienced resistance to an alternative tyrosine kinase inhibitor for ALL, patient is negative for T315I, Y253H, E255K/V, F359V/C/I and G250E mutations. For gastrointestinal stromal tumor (GIST): 1) Disease is residual, unresectable, recurrent/progressive, or metastatic/tumor rupture, AND 2) Disease has progressed on at least 2 Food and Drug Administration (FDA)-approved therapies (e.g. imatinib, sunitinib, regorafenib, ripretinib). For cutaneous melanoma: 1) Disease is metastatic or unresectable, AND 2) Disease is positive for c-KIT activating mutations, AND 3) Requested drug will be used as subsequent therapy, AND 4) Patient has had disease progression, intolerance, or risk of progression with BRAF-targeted therapy.
Age Restrictions	N/A

Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **N**INLARO

### **Products Affected**

#### Ninlaro

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Relapsed/refractory systemic light chain amyloidosis, Waldenstrom macroglobulinemia, lymphoplasmacytic 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **N**ITISINONE

## **Products Affected**

Nitisinone

#### • Orfadin SUSP

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 (HT-1): Diagnosis of HT-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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **N**ORTHERA

### **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): For 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, patient has experienced a sustained reduction in symptoms of nOH (i.e., decrease in dizziness, lightheadedness, or feeling faint). For both initial and continuation of therapy, 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **NOXAFIL SUSP**

### **Products Affected**

#### • Posaconazole SUSP

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 orally. For treatment of oropharyngeal candidiasis: patient has experienced an inadequate treatment response, intolerance, or has a contraindication to fluconazole.
Age Restrictions	13 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Oropharyngeal candidiasis: 1 month. All other indications: 6 months
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **N**UEDEXTA

## **Products Affected**

#### Nuedexta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For pseudobulbar affect (PBA) (continuation): The patient has experienced a decrease in pseudobulbar affect (PBA) episodes since starting therapy with the requested drug.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 4 months, Continuation: Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **N**UPLAZID

### **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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **N**URTEC

## **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 one triptan 5-HT1 receptor agonist. Preventive treatment of migraine, continuation: The patient received at least 3 months of treatment with the requested drug and had a reduction in migraine days per month from baseline.
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
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **O**CALIVA

## **Products Affected**

#### Ocaliva

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For primary biliary cholangitis (PBC) without cirrhosis or with compensated cirrhosis without evidence of portal hypertension: For initial therapy: 1) Diagnosis of PBC (previously known as primary biliary cirrhosis) is confirmed by at least two of the following: a) Biochemical evidence of cholestasis with elevation of alkaline phosphatase (ALP) level for at least 6 months duration, b) Presence of antimitochondrial antibodies (AMA) (titer greater than 1:40 by immunofluorescence or immunoenzymatic reactivity) or PBC-specific antinuclear antibodies ANA (e.g., anti-gp210, anti-sp100), c) Histologic evidence of PBC on liver biopsy (e.g., non-suppurative inflammation and destruction of interlobular and septal bile ducts), AND 2) Patient has an elevated serum ALP level prior to initiation of therapy with the requested drug and meets one of the following requirements: a) Has experienced an inadequate response to at least 12 months of prior therapy with ursodeoxycholic acid (UDCA)/ursodiol and the patient will continue concomitant therapy with UDCA/ursodiol, b) Is intolerant to prior therapy with UDCA/ursodiol. For PBC (continuation): patient achieved or maintained a clinical benefit from Ocaliva therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months, Continuation: Plan Year
Other Criteria	N/A

## **O**CTREOTIDE

#### **Products Affected**

 Octreotide Acetate INJ 1000MCG/ML, 100MCG/ML, 200MCG/ML, 500MCG/ML, 50MCG/ML

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 insulinlike 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# 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	For idiopathic pulmonary fibrosis (new starts 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **O**GIVRI

## **Products Affected**

• Ogivri

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, leptomeningeal metastases from HER2-positive breast cancer, brain metastases from HER2-positive breast cancer, HER2-positive esophageal and esophagogastric junction adenocarcinoma, HER2-positive advanced, recurrent, or metastatic uterine serous carcinoma, HER2-amplified and RAS and BRAF wild-type colorectal cancer (including appendiceal adenocarcinoma), HER2-positive recurrent salivary gland tumor, HER2-positive unresectable or metastatic hepatobiliary carcinoma (gallbladder cancer, intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma), HER2 overexpression positive locally advanced, unresectable, or recurrent gastric adenocarcinoma, HER2-positive endometrial cancer.
Exclusion Criteria	N/A
Required Medical Information	All indications: the patient had an intolerable adverse event to Trazimera and that adverse event was NOT attributed to the active ingredient as described in the prescribing information. For colorectal cancer (including appendiceal adenocarcinoma): 1) the disease is HER2-amplified and RAS and BRAF wild-type and 2) the requested drug is used in combination with pertuzumab, tucatinib or lapatinib and 3) the patient has not had previous treatment with a HER2 inhibitor. For hepatobiliary carcinoma: 1) the disease is HER2-positive AND 2) the requested drug is used in combination with pertuzumab. For endometrial cancer: 1) the disease is HER2-positive AND 2) the requested drug is used in combination with paclitaxel and continued as a single agent for maintenance 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.
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **O**GSIVEO

## **Products Affected**

Ogsiveo

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **O**JEMDA

### **Products Affected**

## • Ojemda

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For relapsed or refractory pediatric low-grade glioma (LGG): the patient's tumor is positive for either a) BRAF fusion or rearrangement OR b) BRAF V600 mutation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **O**JJAARA

### **Products Affected**

• Ojjaara

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Accelerated or blast phase myeloproliferative neoplasms
Exclusion Criteria	N/A
Required Medical Information	For myelofibrosis, patient meets ALL of the following: 1) the patient has a diagnosis of intermediate or high-risk primary myelofibrosis or secondary myelofibrosis (i.e., post-polycythemia vera or post-essential thrombocythemia), AND 2) the patient has anemia defined as hemoglobin less than 10 grams per deciliter (g/dL) or having transfusion-dependent anemia, AND 3) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Jakafi (ruxolitinib) OR has hemoglobin less than 8 g/dL.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

### **OMNIPOD**

#### **Products Affected**

- Omnipod 5 Dexcom G7g6 Intro Kit (gen 5)
- Omnipod 5 Dexcom G7g6 Pods (gen 5)
- Omnipod 5 Libre2 Plus G6 Intro Gen 5
- Omnipod 5 Libre2 Plus G6 Pods
- Omnipod Classic Pods (gen 3)
- Omnipod Dash Intro Kit (gen 4)

- Omnipod Dash Pdm Kit (gen 4)
- Omnipod Dash Pods (gen 4)
- Omnipod Go 10 Units/day
- Omnipod Go 15 Units/day
- Omnipod Go 20 Units/day
- Omnipod Go 25 Units/day
- Omnipod Go 30 Units/day
- Omnipod Go 35 Units/day
- Omnipod Go 40 Units/day

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: 1) The patient has diabetes requiring insulin management with multiple daily injections AND 2) The patient is self-testing glucose levels 4 or more times per day OR the patient is using a continuous glucose monitor AND 3) The patient has experienced any of the following with the current diabetes regimen: inadequate glycemic control, recurrent hypoglycemia, wide fluctuations in blood glucose, dawn phenomenon with persistent severe early morning hyperglycemia, severe glycemic excursions.
Age Restrictions	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, Some Medically accepted Indications.
Off-Label Uses	Peripheral T-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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **OPIPZA**

## **Products Affected**

Opipza

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 meets both of the following: a) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following generic products: aripiprazole, asenapine, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, AND b) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following brand products: Caplyta, Lybalvi, Rexulti, Secuado, Vraylar, OR 2) The patient is unable to swallow oral formulations. For adjunctive treatment of major depressive disorder (MDD), 1) the patient meets both of the following: a) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following generic products: aripiprazole, olanzapine, quetiapine, AND b) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following brand products: Rexulti, Vraylar, OR 2) The patient is unable to swallow oral formulations. For treatment of irritability associated with autistic disorder: 1) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following generic products: aripiprazole, risperidone, OR 2) The patient is unable to swallow oral formulations. For the treatment of Tourette's disorder: 1) The patient experienced an inadequate treatment response or intolerance to generic aripiprazole, OR 2) The patient is unable to swallow oral formulations.
Age Restrictions	N/A
Prescriber Restrictions	N/A

Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **ORENITRAM**

### **Products Affected**

- Orenitram
- Orenitram Titration Kit Month 1
- Orenitram Titration Kit Month 2
- Orenitram Titration Kit Month 3

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): PAH was confirmed by right heart catheterization. For 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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **ORIAHNN**

## **Products Affected**

#### Oriahnn

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in a premenopausal patient: the patient has not already received greater than or equal to 24 months of treatment with any elagolix-containing drug.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months, max 24 months total
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **O**RSERDU

## **Products Affected**

#### Orserdu

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **OSPHENA**

## **Products Affected**

## • Osphena

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **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 mild plaque psoriasis (new starts only): patient has experienced an inadequate treatment response or intolerance to at least one topical corticosteroid OR the patient has a contraindication that would prohibit a trial with topical corticosteroids. 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, scalp, neck, groin, intertriginous areas) are affected at the time of diagnosis AND 2) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: Cosentyx (secukinumab), Cyltezo (adalimumab-adbm), Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumabrzaa), Stelara (ustekinumab), Wezlana (ustekinumab-stba), Tremfya (guselkumab), Wezlana (ustekinumab-auub), Yuflyma (adalimumab-aaty). For active psoriatic arthritis (PsA) (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: Cosentyx (secukinumab), Cyltezo (adalimumab-adbm), Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib)/Rinvoq LQ (upadacitinb), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Tremfya (guselkumab), Steqeyma(ustekinumab-stba), Wezlana (ustekinumab-auub), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib) extended-release), Yuflyma (adalimumab-aaty).
Age Restrictions	N/A
Prescriber Restrictions	N/A

Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **PALYNZIQ**

### **Products Affected**

## • Palynziq

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **PANRETIN**

## **Products Affected**

#### Panretin

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Topical treatment of cutaneous lesions in patients with non-AIDS-related Kaposi sarcoma
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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **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 lower-risk myelofibrosis), systemic mastocytosis, adult T-cell leukemia/lymphoma, mycosis fungoides/sezary syndrome, primary cutaneous CD30+ T-cell lymphoproliferative disorders, hairy cell leukemia, Erdheim-Chester disease, initial treatment during pregnancy for chronic myeloid leukemia.
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: 12-48wks. HBV: 48wks. Other: Plan Yr
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **PHENYLBUTYRATE**

### **Products Affected**

• Olpruva

- 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 disorders (UCD): Diagnosis of 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **POMALYST**

## **Products Affected**

## Pomalyst

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Relapsed/refractory systemic light chain amyloidosis, primary central nervous system (CNS) lymphoma, POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome
Exclusion Criteria	N/A
Required Medical Information	For multiple myeloma, patient has previously received at least two prior therapies, including an immunomodulatory agent AND a proteasome inhibitor.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **PREVYMIS**

### **Products Affected**

• Prevymis PACK

## • Prevymis TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For prophylaxis of cytomegalovirus (CMV) infection or disease in hematopoietic stem cell transplant (HSCT): 1) the patient is CMV-seropositive, AND 2) the patient is a recipient of an allogeneic HSCT. For prophylaxis of CMV disease in kidney transplant: 1) the patient is CMV-seronegative, AND 2) the patient is a high risk recipient of kidney transplant.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	7 months
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **PROCRIT**

## **Products Affected**

• Procrit

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

# **PROLIA**

## **Products Affected**

#### • Jubbonti

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

## **PYRUKYND**

### **Products Affected**

• Pyrukynd

• Pyrukynd Taper Pack

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For hemolytic anemia in a patient with pyruvate kinase (PK) deficiency: Diagnosis was confirmed by an enzyme assay demonstrating deficiency of PK enzyme activity or by genetic testing. For hemolytic anemia in a patient with PK deficiency (continuation of therapy): Patient achieved or maintained a positive clinical response (e.g., improvement in hemoglobin levels, reduction in blood transfusions).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 7 months, Continuation: Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **QINLOCK**

### **Products Affected**

#### Qinlock

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Gastrointestinal stromal tumor (GIST) for residual, unresectable, tumor rupture, recurrent, or progressive disease. Metastatic or unresectable cutaneous melanoma.
Exclusion Criteria	N/A
Required Medical Information	For residual, unresectable, tumor rupture, advanced, recurrent/metastatic, or progressive gastrointestinal stromal tumor (GIST): 1) Patient has received prior treatment with 3 or more kinase inhibitors, including imatinib OR 2) Patient has experienced disease progression following treatment with avapritinib and dasatinib OR 3) Patient has received prior treatment with imatinib and is intolerant of second-line sunitinib. For cutaneous melanoma: 1) Disease is metastatic or unresectable AND 2) Disease is positive for KIT activating mutations AND 3) Requested drug will be used as subsequent therapy AND 4) Patient has had disease progression, intolerance, or risk of progression with BRAF-targeted therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **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	For babesiosis: the requested drug is used in combination with clindamycin.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 month
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **Q**ULIPTA

## **Products Affected**

## • Qulipta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Preventive treatment of migraine, continuation: The patient received at least 3 months of treatment with the requested drug and had a reduction in migraine days per month from baseline.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 3 months, Continuation: Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **RADICAVA**

#### **Products Affected**

• Edaravone

- Radicava Ors
- Radicava Ors Starter Kit

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For amyotrophic lateral sclerosis (ALS): 1) Diagnosis is classified as definite or probable ALS, AND 2) For new starts only: Patient has scores of at least 2 points on all 12 areas of the revised ALS Functional Rating Scale (ALSFRS-R). For continuation of therapy for ALS: There is a clinical benefit from therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **RAVICTI**

## **Products Affected**

#### Ravicti

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For urea cycle disorders (UCD): Diagnosis of 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **R**ECORLEV

## **Products Affected**

#### Recorlev

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 endocrinologist
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **RELISTOR INJ**

### **Products Affected**

#### Relistor INJ

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

# **RELISTOR TAB**

### **Products Affected**

#### • Relistor TABS

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

## REMICADE

### **Products Affected**

Infliximab

• Remicade

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Behcet's syndrome, hidradenitis suppurativa, juvenile idiopathic arthritis, pyoderma gangrenosum, sarcoidosis, Takayasu's arteritis, uveitis.
Exclusion Criteria	N/A
Required Medical Information	For moderately to severely active rheumatoid arthritis (new starts only): 1) Pt meets ANY of the following: a) requested drug will be used in combination with methotrexate (MTX) or leflunomide OR b) intolerance or contraindication to MTX AND leflunomide, AND 2) Pt meets ANY of the following: a) inadequate treatment response, intolerance or contraindication to MTX OR b) inadequate treatment response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis (new starts only): an inadequate treatment response or intolerance to a non-steroidal anti-inflammatory drug (NSAID) OR contraindication that would prohibit a trial of 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 time of diagnosis, AND 2) Pt meets ANY of the following: a) Pt has experienced inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with MTX, cyclosporine, or acitretin, OR b) pharmacologic treatment with MTX, cyclosporine, or acitretin is contraindicated, OR c) Pt has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected).
Age Restrictions	N/A

Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	For hidradenitis suppurativa (new starts only): Pt has severe, refractory disease. For uveitis (new starts only): Inadequate treatment response or intolerance or has a contraindication to a trial of immunosuppressive therapy for uveitis. For all indications: The patient experienced an intolerable adverse event to Renflexis and that adverse event was NOT attributed to the active ingredient as described in the prescribing information.
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **RENFLEXIS**

### **Products Affected**

#### • Renflexis

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Behcet's syndrome, hidradenitis suppurativa, juvenile idiopathic arthritis, pyoderma gangrenosum, sarcoidosis, Takayasu's arteritis, uveitis
Exclusion Criteria	N/A
Required Medical Information	For moderately to severely active rheumatoid arthritis (new starts only): 1) Pt meets ANY of the following: a) requested drug will be used in combination with methotrexate (MTX) or leflunomide OR b) intolerance or contraindication to MTX AND leflunomide, AND 2) Pt meets ANY of the following: a) inadequate treatment response, intolerance or contraindication to MTX OR b) inadequate treatment response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis (new starts only): an inadequate treatment response or intolerance to a non-steroidal anti-inflammatory drug (NSAID) OR contraindication that would prohibit a trial of 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 time of diagnosis, AND 2) Pt meets ANY of the following: a) Pt has experienced inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with MTX, cyclosporine, or acitretin, OR b) pharmacologic treatment with MTX, cyclosporine, or acitretin is contraindicated, OR c) Pt has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected).
Age Restrictions	N/A

Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	For hidradenitis suppurativa (new starts only): Pt has severe, refractory disease. For uveitis (new starts only): Inadequate treatment response or intolerance or has a contraindication to a trial of immunosuppressive therapy for uveitis.
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **REPATHA**

# **Products Affected**

• Repatha

- Repatha Pushtronex System
- Repatha Sureclick

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **R**ETACRIT

### **Products Affected**

#### Retacrit

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

# **RETEVMO**

### **Products Affected**

#### Retevmo TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent rearranged during transfection (RET)-rearrangement positive non-small cell lung cancer (NSCLC), brain metastases from RET fusion-positive NSCLC, Langerhans Cell Histiocytosis with a RET gene fusion, symptomatic or relapsed/refractory Erdheim-Chester Disease with a RET gene fusion, symptomatic or relapsed/refractory Rosai-Dorfman Disease with a RET gene fusion, occult primary cancer with RET gene fusion, solid tumors with RET-gene fusion for recurrent disease
Exclusion Criteria	N/A
Required Medical Information	For non-small cell lung cancer (NSCLC), 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. For solid tumors, patient must meet all of the following: 1) The disease is recurrent, persistent, progressive, unresectable, locally advanced, or metastatic, 2) The patient has progressed on or following prior systemic treatment or has no satisfactory alternative treatment options, AND 3) The tumor is RET fusion-positive.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **REVLIMID**

### **Products Affected**

#### • Lenalidomide

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 (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome, myeloproliferative neoplasms, Kaposi Sarcoma, Langerhans cell histiocytosis, Rosai-Dorfman disease, peripheral T-Cell lymphomas not otherwise specified, angioimmunoblastic T-cell lymphoma (AITL), enteropathy-associated T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma, nodal peripheral T-cell lymphoma, adult T-cell leukemia/lymphoma, hepatosplenic T-cell lymphoma, primary central nervous system (CNS) lymphoma, chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), human immunodeficiency virus (HIV)-related B-cell lymphomas, monomorphic post-transplant lymphoproliferative disorder, diffuse large B-cell lymphomas, histologic transformation of indolent lymphoma to diffuse large B-cell lymphoma
Exclusion Criteria	N/A
Required Medical Information	For myelodysplastic syndrome (MDS): patient has 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **REVUFORJ**

## **Products Affected**

## Revuforj

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **R**EZDIFFRA

### **Products Affected**

#### • Rezdiffra

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For noncirrhotic nonalcoholic steatohepatitis (NASH) (initial): patient has moderate to advanced liver fibrosis (consistent with Stages F2 to F3) at baseline, which was confirmed by liver biopsy or magnetic resonance elastography (MRE). For NASH (continuation): The patient demonstrates a beneficial response to therapy (for example, improvement in liver function such as reduction in alanine aminotransferase (ALT), reduction of liver fat content by imaging such as magnetic resonance imaging-protein density fat fraction (MRI-PDFF) or FibroScan controlled attenuation parameter (CAP)).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist or hepatologist.
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **REZLIDHIA**

## **Products Affected**

#### • Rezlidhia

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **RINVOQ**

## **Products Affected**

• Rinvoq

• Rinvoq Lq

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

## **RIVFLOZA**

### **Products Affected**

#### • Rivfloza

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For primary hyperoxaluria type 1 (PH1): diagnosis has been confirmed by a molecular genetic test showing a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene or liver enzyme analysis demonstrating absent or significantly reduced alanine:glyoxylate aminotransferase (AGT) activity. For PH1 (continuation): the patient has experienced decreased or normalized levels of urinary oxalate since initiating therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **ROMVIMZA**

## **Products Affected**

#### • Romvimza

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **ROZLYTREK**

## **Products Affected**

## Rozlytrek

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent ROS1-positive non-small cell lung cancer (NSCLC), Non-metastatic neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors, first-line treatment of NTRK gene fusion-positive solid tumors, ROS1-gene fusion-positive cutaneous melanoma
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. For ROS1-positive non-small cell lung cancer: the patient has recurrent, advanced, or metastatic disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **R**UBRACA

### **Products Affected**

#### • Rubraca

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Uterine leiomyosarcoma, pancreatic adenocarcinoma, advanced (stage II-IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer
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, AND 2) patient has been treated with a taxane-based chemotherapy or the patient is not fit for chemotherapy, AND 3) the requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy. For maintenance treatment of BRCA mutated ovarian, fallopian tube, primary peritoneal cancer: 1) the patient has advanced (stage II-IV) disease and is in complete or partial response to primary therapy, OR 2) the patient has recurrent disease and is in complete or partial response to platinum-based chemotherapy. For uterine leiomyosarcoma: 1) the requested drug is used as second-line therapy, AND 2) the patient has BRCA-altered disease. For pancreatic adenocarcinoma: 1) the patient has metastatic disease, AND 2) the patient has somatic or germline BRCA or PALB-2 mutations.
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-induction therapy for AML, re-induction in residual disease for AML
Exclusion Criteria	N/A
Required Medical Information	For acute myeloid leukemia (AML): AML is FMS-like tyrosine kinase 3 (FLT3) mutation-positive. For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and Fibroblast growth factor receptor type 1 (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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **R**YZNEUTA

### **Products Affected**

## • Ryzneuta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For prophylaxis of myelosuppressive chemotherapy-induced febrile neutropenia, the patient must meet all of the following: 1) Patient has a solid tumor or non-myeloid cancer, AND 2) Patient is currently receiving or will be receiving treatment with myelosuppressive anti-cancer therapy, AND 3) The requested drug will be administered at least 24 hours after chemotherapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **SAPROPTERIN**

## **Products Affected**

Javygtor

• 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 (PKU): 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 (e.g., 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **S**AVELLA

### **Products Affected**

Savella

#### • Savella Titration Pack

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For fibromyalgia: The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to duloxetine or pregabalin.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **S**CEMBLIX

### **Products Affected**

#### • Scemblix

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Myeloid and/or lymphoid neoplasms with eosinophilia and ABL1 rearrangement in chronic phase or blast phase.
Exclusion Criteria	N/A
Required Medical Information	For chronic myeloid leukemia (CML) in the chronic phase: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) Patient meets one of the following: A) Patient has newly diagnosed CML and has resistance or intolerance to imatinib, dasatinib, or nilotinib OR B) Patient has previously treated CML AND at least one of the prior treatments was imatinib, dasatinib, or nilotinib OR C) Patient is positive for the T315I mutation, AND 3) Patient is negative for the following mutations: A337T, P465S.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **S**EROSTIM

### **Products Affected**

• Serostim INJ 4MG, 5MG, 6MG

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

## **S**IGNIFOR

## **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	Prescribed by or in consultation with an endocrinologist
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## SILDENAFIL

#### **Products Affected**

• Sildenafil Citrate SUSR

• 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): 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) If the request is for an adult, 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **S**IRTURO

## **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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **SKYCLARYS**

## **Products Affected**

• Skyclarys

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For Friedreich's ataxia (FRDA): 1) The patient has a confirmed genetic mutation in the frataxin (FXN) gene, AND 2) The patient is exhibiting clinical manifestations of the disease (e.g., muscle weakness, decline in coordination, frequent falling). For FRDA continuation of therapy: The patient has experienced a beneficial response to therapy (e.g., slowing of clinical decline).
Age Restrictions	16 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a physician who specializes in Friedreich's ataxia or a neurologist
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **SKYRIZI**

### **Products Affected**

• Skyrizi INJ 150MG/ML, 180MG/1.2ML, 360MG/2.4ML

• Skyrizi Pen

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

## SOGROYA

### **Products Affected**

## • Sogroya

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Pediatric growth hormone deficiency (GHD): Pediatric patient with closed epiphyses
Required Medical Information	For adult GHD: Patient meets ANY of the following: 1) failed 2 pretreatment growth hormone (GH) stimulation tests, OR 2) pretreatment insulin-like growth factor-1 (IGF-1) more than 2 standard deviations (SD) below mean AND failed 1 pre-treatment GH stimulation test, 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-treatment 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.
Age Restrictions	Pediatric growth hormone deficiency (GHD): 2.5 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	Plan Year

Other Criteria	For pediatric growth hormone deficiency (GHD): 1) Patient (pt) has pre-treatment (pre-tx) 1-year height (ht) velocity more than 2 standard deviations (SD) below mean OR a pre-tx ht more than 2 SD below mean and 1-year ht velocity more than 1 SD below mean, AND pt meets any of the following: a) failed 2 pre-tx growth hormone (GH) stimulation tests (peak below 10 ng/mL), b) pituitary/central nervous system (CNS) disorder (e.g., genetic defects, acquired structural abnormalities, congenital structural abnormalities) and pre-tx insulin-like growth factor-1 (IGF-1) more than 2 SD below mean, OR 2) Pt was diagnosed with GHD as a neonate. For pediatric and adult GHD, continuation of therapy: Patient is experiencing improvement.
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **S**OHONOS

## **Products Affected**

#### • Sohonos

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For reduction in volume of new heterotopic ossification in fibrodysplasia ossificans progressiva (FOP): The patient has a confirmed genetic mutation in the activin A receptor type I (ACVR1) gene.
Age Restrictions	8 years of age or older if female and 10 years of age or older if male
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **SOMATULINE DEPOT**

#### **Products Affected**

#### Lanreotide Acetate

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Tumor control of neuroendocrine tumors (NETs) (including tumors of the lung, thymus, well-differentiated grade 3 NETs not of gastroenteropancreatic origin with favorable biology, and pheochromocytoma/paraganglioma)
Exclusion Criteria	N/A
Required Medical Information	For acromegaly, initial: 1) Patient has a high pretreatment insulinlike 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **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 insulinlike 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **SPEVIGO**

#### **Products Affected**

• Spevigo INJ 150MG/ML, 300MG/2ML

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **SPRYCEL**

## **Products Affected**

#### Dasatinib

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Gastrointestinal stromal tumor (GIST), metastatic and/or widespread chondrosarcoma, recurrent chordoma, T-cell acute lymphoblastic leukemia (ALL), and Philadelphia (Ph)-like B-ALL, myeloid and/or lymphoid neoplasms with eosinophilia and ABL1 rearrangement in the chronic phase or blast phase, cutaneous melanoma
Exclusion Criteria	N/A
Required Medical Information	For chronic myeloid leukemia (CML), including patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia (Ph) chromosome or BCR-ABL gene AND 2) If patient experienced resistance to an alternative tyrosine kinase inhibitor, patient is negative for all of the following mutations: T315l/A, F317L/V/I/C, and V299L. For acute lymphoblastic leukemia (ALL), the patient has a diagnosis of one of the following: 1) Philadelphia chromosome positive ALL, including patients who have received a hematopoietic stem cell transplant: Diagnosis that has been confirmed by detection of the Ph chromosome or BCR-ABL gene AND if patient experienced resistance to an alternative tyrosine kinase inhibitor, patient is negative for all of the following mutations: T315l/A, F317L/V/I/C, and V299L OR 2) Ph-like B-ALL with ABL-class kinase fusion OR 3) Relapsed or refractory T-cell ALL with ABL-class translocation. For gastrointestinal stromal tumor (GIST): 1) Patient meets all of the following: A) Disease is residual, unresectable, recurrent/progressive, or metastatic/tumor rupture, B) Patient has received prior therapy with avapritinib AND C) Patient is positive for platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutations. For cutaneous melanoma: 1) Disease is metastatic or unresectable, 2) Disease is positive for c-KIT activating mutations AND 3) Requested drug will be used as subsequent therapy AND 4) Patient has had disease progression, intolerance, or risk of progression with BRAF-targeted therapy.

Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **S**TELARA

#### **Products Affected**

- Stelara
- Steqeyma INJ 45MG/0.5ML, 90MG/ML
- Ustekinumab INJ 45MG/0.5ML, 90MG/ML
- Wezlana INJ 45MG/0.5ML, 90MG/ML

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

## **S**TIVARGA

## **Products Affected**

## • Stivarga

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

## Sunosi

## **Products Affected**

#### • Sunosi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For excessive daytime sleepiness associated with narcolepsy, initial request: 1) The diagnosis has been confirmed by sleep lab evaluation, AND 2) The patient has experienced an inadequate treatment response or intolerance to at least one central nervous system (CNS) wakefulness promoting drug (e.g., armodafinil, modafinil), OR has a contraindication that would prohibit a trial of central nervous system (CNS) wakefulness promoting drugs (e.g., armodafinil, modafinil). For excessive daytime sleepiness associated with obstructive sleep apnea (OSA), initial request: 1) The diagnosis has been confirmed by polysomnography, AND 2) The patient has experienced an inadequate treatment response or intolerance to at least one central nervous system (CNS) wakefulness promoting drug (e.g., armodafinil, modafinil), OR has a contraindication that would prohibit a trial of central nervous system (CNS) wakefulness promoting drugs (e.g., armodafinil, modafinil). If the request is for a continuation of therapy, then the patient experienced a decrease in daytime sleepiness with obstructive sleep apnea (OSA).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a sleep disorder specialist or neurologist
Coverage Duration	Plan Year
Other Criteria	N/A

## **S**UTENT

### **Products Affected**

#### • Sunitinib Malate

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Thyroid carcinoma (follicular, medullary, papillary, and oncocytic), soft tissue sarcoma (angiosarcoma, solitary fibrous tumor, and alveolar soft part sarcoma subtypes), recurrent chordoma, thymic carcinoma, lymphoid and/or myeloid neoplasms with eosinophilia and FLT3 rearrangement in chronic or blast phase, pheochromocytoma, paraganglioma, well differentiated grade 3 neuroendocrine tumors
Exclusion Criteria	N/A
Required Medical Information	For renal cell carcinoma (RCC): 1) The disease is relapsed, advanced, or stage IV OR 2) the requested drug is being used as adjuvant treatment for patients that are at high risk of recurrent RCC following nephrectomy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **SYMPAZAN**

### **Products Affected**

## • Sympazan

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Seizures associated with Dravet syndrome
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Seizures associated with Lennox-Gastaut syndrome (LGS): 2 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **T**ABRECTA

## **Products Affected**

#### • Tabrecta

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 mesenchymal-epithelial transition (MET) amplification, central nervous system (CNS) brain metastases from MET exon-14 mutated NSCLC
Exclusion Criteria	N/A
Required Medical Information	For recurrent, advanced, or metastatic non-small cell lung cancer (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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# TADALAFIL (BPH)

### **Products Affected**

• Tadalafil TABS 2.5MG, 5MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Must have a documented diagnosis of Benign prostatic hyperplasia and have a documentted 30 day trial and failure, adverse reaction, or contraindication to at least two of the following medications: alfuzosin, doxazosin, dutasteride, dutasteride1tamsulosin, finasteride, tamsulosin, or terazosin.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# 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): 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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **TAFINLAR**

### **Products Affected**

#### • Tafinlar

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Langerhans cell histiocytosis, Erdheim-Chester disease.
Exclusion Criteria	N/A
Required Medical Information	For 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, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, b) adjuvant systemic therapy. For non-small cell lung cancer: 1) The tumor is positive for a BRAF V600E mutation, AND 2) The requested drug will be used as a single agent or in combination with trametinib. For papillary, follicular, and oncocytic thyroid carcinoma: 1) The tumor is BRAF V600E-positive, AND 2) The disease is not amenable to radioactive iodine (RAI) therapy, AND 3) the requested drug will be used in combination with trametinib. For Langerhans Cell Histiocytosis and Erdheim-Chester Disease: The disease is positive for a BRAF V600E mutation. For solid tumors: 1) The tumor is positive for a BRAF V600E mutation, AND 2) The requested drug will be used in combination with trametinib.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **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 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 non-small cell lung cancer (NSCLC), the requested drug is used in any of the following settings: 1) The patient meets both of the following: a) patient has unresectable, metastatic, advanced, or recurrent NSCLC (including brain and/or leptomeningeal metastases from NSCLC) and b) patient has a sensitizing epidermal growth factor receptor (EGFR) mutation-positive disease, OR 2) The 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **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	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **TARGRETIN TOPICAL**

### **Products Affected**

#### • Bexarotene GEL

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Mycosis fungoides (MF)/Sezary syndrome (SS), chronic or smoldering adult T-cell leukemia/lymphoma (ATLL), 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **TASIGNA**

### **Products Affected**

• Nilotinib Hydrochloride

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), myeloid and/or lymphoid neoplasms with eosinophilia and ABL1 rearrangement in the chronic phase or blast phase, pigmented villonodular synovitis/tenosynovial giant cell tumor, cutaneous melanoma.
Exclusion Criteria	N/A
Required Medical Information	For chronic myeloid leukemia (CML), including patients newly diagnosed with CML and patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) 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 acute lymphoblastic leukemia (ALL), including patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) If the patient has experienced resistance to an alternative tyrosine kinase inhibitor for ALL, patient is negative for T315I, Y253H, E255K/V, F359V/C/I and G250E mutations. For gastrointestinal stromal tumor (GIST): 1) Disease is residual, unresectable, recurrent/progressive, or metastatic/tumor rupture, AND 2) Disease has progressed on at least 2 Food and Drug Administration (FDA)-approved therapies (e.g. imatinib, sunitinib, regorafenib, ripretinib). For cutaneous melanoma: 1) Disease is metastatic or unresectable, AND 2) Disease is positive for c-KIT activating mutations, AND 3) Requested drug will be used as subsequent therapy, AND 4) Patient has had disease progression, intolerance, or risk of progression with BRAF-targeted therapy.
Age Restrictions	N/A

Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **TAVNEOS**

## **Products Affected**

#### Tavneos

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For continuation of treatment for severe anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis: the patient has experienced benefit from therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **TAZAROTENE**

### **Products Affected**

• Tazarotene CREA

#### • Tazarotene GEL

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For plaque psoriasis, the patient meets the following criteria: 1) the patient has less than or equal to 20 percent of affected body surface area (BSA), 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
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **TECFIDERA**

### **Products Affected**

• Dimethyl Fumarate CPDR

 Dimethyl Fumarate Starterpack CDPK 0

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# Терметко

## **Products Affected**

## • Tepmetko

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 mesenchymal-epithelial transition (MET) amplification, central nervous system (CNS) cancer including brain metastases and leptomeningeal metastases from MET exon-14 mutated NSCLC
Exclusion Criteria	N/A
Required Medical Information	For recurrent, advanced, or metastatic non-small cell lung cancer (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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **TERIFLUNOMIDE**

## **Products Affected**

#### • Teriflunomide

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **TERIPARATIDE**

#### **Products Affected**

## • Teriparatide

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

## **TESTOSTERONE CYPIONATE INJ**

#### **Products Affected**

 Depo-testosterone INJ 100MG/ML, 200MG/ML  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	For primary hypogonadism or hypogonadotropic hypogonadism, initial therapy: The patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For primary hypogonadism or hypogonadotropic hypogonadism, continuation of therapy: The patient had a confirmed low morning serum total testosterone concentration based on the reference laboratory range or current practice guidelines before starting testosterone therapy [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For 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

Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.
Required	

## **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	For primary hypogonadism or hypogonadotropic hypogonadism, initial therapy: The patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For primary hypogonadism or hypogonadotropic hypogonadism, continuation of therapy: The patient had a confirmed low morning serum total testosterone concentration based on the reference laboratory range or current practice guidelines before starting testosterone therapy [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **TESTOSTERONE UNDECANOATE**

### **Products Affected**

Undecatrex

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 primary hypogonadism or hypogonadotropic hypogonadism, initial therapy: The patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For primary hypogonadism or hypogonadotropic hypogonadism, continuation of therapy: The patient had a confirmed low morning serum total testosterone concentration based on the reference laboratory range or current practice guidelines before starting testosterone therapy [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **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 tardive dyskinesia and treatment of chorea associated with Huntington's disease: The patient has experienced an inadequate treatment response or intolerable adverse event to deutetrabenazine.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **THALOMID**

#### **Products Affected**

• Thalomid CAPS 100MG, 50MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Myelofibrosis-associated anemia, acquired immunodeficiency syndrome (AIDS)-related aphthous stomatitis, Kaposi sarcoma, multicentric Castleman's disease, Rosai-Dorfman disease, Langerhans cell histiocytosis
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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **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, central nervous system (CNS) cancers (astrocytoma, oligodendroglioma)
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 2) 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 locally advanced, unresectable, resected gross residual, or metastatic cholangiocarcinoma: the requested drug will be used as subsequent treatment for progression on or after systemic treatment. For CNS cancers: 1) disease is recurrent or progressive, AND 2) patient has oligodendroglioma or astrocytoma.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# TOBI INHALER

#### **Products Affected**

#### • Tobi Podhaler

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: 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **TOPICAL TESTOSTERONES**

#### **Products Affected**

- Testosterone Pump
- Testosterone GEL 10MG/ACT, 20.25MG/1.25GM, 25MG/2.5GM, 40.5MG/2.5GM, 50MG/5GM
- Testosterone SOLN

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 primary hypogonadism or hypogonadotropic hypogonadism, initial therapy: The patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For primary hypogonadism or hypogonadotropic hypogonadism, continuation of therapy: The patient had a confirmed low morning serum total testosterone concentration based on the reference laboratory range or current practice guidelines before starting testosterone therapy [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **TOPICAL TRETINOIN**

#### **Products Affected**

• Tretinoin CREA

#### • Tretinoin GEL

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **TRAZIMERA**

## **Products Affected**

#### • Trazimera

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, leptomeningeal metastases from HER2-positive breast cancer, brain metastases from HER2-positive breast cancer, HER2-positive esophageal and esophagogastric junction adenocarcinoma, HER2-positive advanced, recurrent, or metastatic uterine serous carcinoma, HER2-amplified and RAS and BRAF wild-type colorectal cancer (including appendiceal adenocarcinoma), HER2-positive recurrent salivary gland tumor, HER2-positive unresectable or metastatic hepatobiliary carcinoma (gallbladder cancer, intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma), HER2 overexpression positive locally advanced, unresectable, or recurrent gastric adenocarcinoma, HER2-postiive endometrial cancer.
Exclusion Criteria	N/A
Required Medical Information	For colorectal cancer (including appendiceal adenocarcinoma): 1) the disease is HER2-amplified and RAS and BRAF wild-type and 2) the requested drug is used in combination with pertuzumab, tucatinib or lapatinib and 3) the patient has not had previous treatment with a HER2 inhibitor. For hepatobiliary carcinoma: 1) the disease is HER2 positive and 2) the requested drug is used in combination with pertuzumab. For endometrial cancer: 1) the requested drug is being used in combination with carboplatin and paclitaxel and 2) continued as a single agent for maintenance 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.
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **TRELSTAR**

### **Products Affected**

## • Trelstar Mixject

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Gender dysphoria, ovarian suppression in breast cancer
Exclusion Criteria	N/A
Required Medical Information	For gender dysphoria, patient meets ONE of the following): 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 gender-affirming hormones. For breast cancer, patient meets ALL of the following: 1) the requested drug is being used for ovarian suppression in premenopausal patients, and 2) the requested drug will be used in combination with endocrine therapy, and 3) the disease is hormone receptor positive, and 4) the disease is at a higher risk of recurrence (e.g., young age, high-grade tumor, lymph-node involvement).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **TREMFYA**

#### **Products Affected**

• Tremfya INJ 100MG/ML, 200MG/2ML

• Tremfya Induction Pack For Crohns Disease/ulcerative Colitis

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

## **T**RIKAFTA

## **Products Affected**

#### • Trikafta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For cystic fibrosis: The requested medication will not be used in combination with other medications containing ivacaftor.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **TRUQAP**

### **Products Affected**

• Truqap TABS

## • Truqap TBPK 200MG

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **TRUXIMA**

## **Products Affected**

#### • Truxima

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, extranodal marginal zone lymphoma), Burkitt lymphoma, high-grade B-cell lymphoma, histological transformation from indolent lymphomas to diffuse large B-cell lymphoma, histological transformation chronic lymphocytic leukemia (CLL)/SLL to diffuse large B-cell lymphoma, primary cutaneous B-cell lymphoma, Castleman disease, human immunodeficiency virus (HIV)-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 macroglobulinemia/lymphoplasmacytic lymphoma, chronic graft-versus-host disease (GVHD), Sjogren syndrome, thrombotic thrombocytopenic purpura, refractory myasthenia gravis, Hodgkin's lymphoma (nodular lymphocyte-predominant), primary central nervous system (CNS) lymphoma, leptomeningeal metastases from lymphomas, acute lymphoblastic leukemia, prevention of Epstein-Barr virus (EBV)-related PTLD, multiple sclerosis, immune checkpoint inhibitor-related toxicities, Rosai-Dorfman disease, pemphigus vulgaris, pediatric aggressive mature B-cell lymphomas (including Burkitt-like lymphoma, primary mediastinal large B-cell lymphoma), and pediatric mature B-cell acute leukemia
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
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **TRYNGOLZA**

## **Products Affected**

## • Tryngolza

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For familial chylomicronemia syndrome (FCS) (e.g., lipoprotein lipase deficiency (LPLD) or Type 1 hyperlipoproteinemia), initial: 1) Diagnosis has been confirmed by genetic testing confirming biallelic mutations in FCS-causing genes (e.g., LPL, APOC2, APOA5, LMF1, GPIHBP1), AND 2) Patient has fasting triglycerides (TG) greater than or equal to 880 mg/dL. For FCS, continuation: Patient demonstrates positive clinical response to therapy (e.g., reduction in TG level from baseline, reduction in episodes of acute pancreatitis).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or lipidologist
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **TRYVIO**

## **Products Affected**

• Tryvio

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

## **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
Exclusion Criteria	N/A
Required Medical Information	For colorectal cancer (including appendiceal adenocarcinoma): 1) the patient has advanced, unresectable, or metastatic disease, AND 2) the patient has human epidermal growth factor receptor 2 (HER2)-positive disease, AND 3) the patient has RAS wild-type disease, AND 4) the requested drug will be used in combination with trastuzumab, AND 5) the patient has not previously been treated with a HER2 inhibitor.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **TURALIO**

### **Products Affected**

#### • Turalio CAPS 125MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Langerhans cell histiocytosis, Erdheim-Chester disease, Rosai- Dorfman disease
Exclusion Criteria	N/A
Required Medical Information	For Langerhans cell histiocytosis: 1) disease has colony stimulating factor 1 receptor (CSF1R) mutation. For Erdheim-Chester disease and Rosai-Dorfman disease: 1) disease has CSF1R mutation AND patient has any of the following: a) symptomatic disease OR b) relapsed/refractory disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **TYENNE**

### **Products Affected**

• Tyenne INJ 162MG/0.9ML

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

# **U**BRELVY

## **Products Affected**

• Ubrelvy

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For acute treatment of migraine: The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to at least one triptan 5-HT1 receptor agonist.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **U**DENYCA

## **Products Affected**

• Udenyca

• Udenyca Onbody

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Stem cell transplantation-related indications
Exclusion Criteria	N/A
Required Medical Information	If receiving chemotherapy, the requested drug will be administered at least 24 hours after chemotherapy. For prophylaxis of myelosuppressive chemotherapy-induced febrile neutropenia: the patient must meet both of the following: 1) Patient has a solid tumor or non-myeloid cancer, AND 2) Patient 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **U**PTRAVI

#### **Products Affected**

• Uptravi TABS

• Uptravi Titration Pack

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): PAH was confirmed by right heart catheterization. For 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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **V**ALCHLOR

## **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 (ATLL), Stage 2 or higher mycosis fungoides (MF)/Sezary syndrome (SS), primary cutaneous marginal zone lymphoma, primary cutaneous follicle center lymphoma, CD30-positive lymphomatoid papulosis (LyP), unifocal Langerhans cell histiocytosis (LCH) with isolated skin disease
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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **V**ALTOCO

## **Products Affected**

- Valtoco 10 Mg Dose
- Valtoco 15 Mg Dose

- Valtoco 20 Mg Dose
- Valtoco 5 Mg Dose

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with documented epilepsy
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by a neurologist or must be prescribed after consultation with a neurologist.
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **V**ANFLYTA

#### **Products Affected**

## • Vanflyta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Relapsed or refractory acute myeloid leukemia
Exclusion Criteria	N/A
Required Medical Information	For acute myeloid leukemia (AML): AML is FMS-like tyrosine kinase 3 (FLT3) internal tandem duplication (ITD)-positive.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **V**ANRAFIA

#### **Products Affected**

#### Vanrafia

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

# **V**ELCADE

## **Products Affected**

#### • Boruzu

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, Kaposi's sarcoma, pediatric Classic Hodgkin lymphoma, POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) 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.
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **V**ENCLEXTA

## **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), Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma, relapsed or refractory systemic light chain amyloidosis with translocation t(11:14), accelerated or blast phase myeloproliferative neoplasms, B-cell acute lymphoblastic leukemia/T-cell acute lymphoblastic leukemia (B-ALL/T-ALL), hairy cell leukemia
Exclusion Criteria	N/A
Required Medical Information	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 2) patient has poor/adverse risk disease and is a candidate for intensive induction therapy, OR 3) patient has relapsed or refractory AML. For blastic plasmacytoid dendritic cell neoplasm (BPDCN): 1) patient has systemic disease being treated with palliative intent, OR 2) patient has relapsed or refractory disease. For multiple myeloma: 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. For Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma: 1) patient has previously treated disease that did not respond to primary therapy, OR 2) patient has progressive or relapsed disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A

Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **V**EOZAH

## **Products Affected**

#### Veozah

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **V**ERSACLOZ

## **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 has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following generic products: aripiprazole, asenapine, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following brand products: Caplyta, Lybalvi, Rexulti, Secuado, Vraylar.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **V**ERZENIO

## **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. Endometrial cancer, in combination with letrozole for estrogen receptor positive tumor.
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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## V-go

## **Products Affected**

• V-go 20

- V-go 30V-go 40

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: 1) The patient has diabetes requiring insulin management with multiple daily injections AND 2) The patient is self-testing glucose levels 4 or more times per day OR the patient is using a continuous glucose monitor AND 3) The patient has experienced any of the following with the current diabetes regimen: inadequate glycemic control, recurrent hypoglycemia, wide fluctuations in blood glucose, dawn phenomenon with persistent severe early morning hyperglycemia, severe glycemic excursions.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **VIGABATRIN**

#### **Products Affected**

- VigabatrinVigadrone

- Vigafyde
- Vigpoder

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 (i.e., focal impaired awareness seizures): patient has experienced an inadequate treatment response to at least two antiepileptic drugs for complex partial seizures (i.e., focal impaired awareness seizures).
Age Restrictions	Infantile Spasms: 1 month to 2 years of age. Complex partial seizures (i.e., focal impaired awareness seizures): 2 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **V**IJOICE

## **Products Affected**

• Vijoice

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **V**ITRAKVI

## **Products Affected**

#### Vitrakvi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Non-metastatic 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **V**IZIMPRO

## **Products Affected**

## • Vizimpro

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Recurrent 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 epidermal growth factor receptor (EGFR) mutation-positive disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# Vonjo

## **Products Affected**

• Vonjo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Accelerated or blast phase myeloproliferative neoplasms
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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **V**OQUEZNA

## **Products Affected**

## Voquezna

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Helicobacter pylori (H. pylori): Must meet all the following: 1) The patient must have a documented diagnosis of H. pylori infection 2) the requested drug will be used in combination with amoxicillin and clarithromycin or amoxicillin alone AND 3) patient has had a trial and failure, contraindication, or intolerance to bismuth quadruple therapy (e.g., bismuth and metronidazole and tetracycline and proton pump inhibitor [PPI]). For both Healing and Maintenance, Relief of Heartburn associated with Erosive Esophagitis (HRH and MHRH): Must meet all the following: 1) The patient must have a documented diagnosis of erosive esophagitis AND 2) patient has had a trial and inadequate response, contraindication, or intolerance to TWO of the following generic PPIs: a) omeprazole, b) esomeprazole, c) pantoprazole, d) lansoprazole, e) rabeprazole, or f) dexlansoprazole. Non-Erosive Gastrointestinal Reflux Disease (NERD): Must meet all the following: 1) The patient must have a documented diagnosis of non-erosive gastroesophageal reflux disease AND 2) patient has had a trial and inadequate response, contraindication, or intolerance to TWO of the following generic PPIs: a) omeprazole, b) esomeprazole, c) pantoprazole, d) lansoprazole, e) rabeprazole, or f) dexlansoprazole, d) lansoprazole, e) rabeprazole, or f) dexlansoprazole,
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	H. pylori: 14 days NERD: 1 month HRH: 2 months MHRH: 6 months
Other Criteria	N/A

## **VORANIGO**

#### **Products Affected**

• Voranigo

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **VORICONAZOLE**

#### **Products Affected**

#### Voriconazole INJ

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **V**OSEVI

## **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, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **V**OTRIENT

## **Products Affected**

• Pazopanib Hydrochloride

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Thyroid carcinoma (follicular, papillary, oncocytic, or medullary), uterine sarcoma, chondrosarcoma, gastrointestinal stromal tumor
Exclusion Criteria	N/A
Required Medical Information	For renal cell carcinoma: 1) the disease is advanced, relapsed, or stage IV, OR 2) the requested drug will be used for von Hippel-Lindau (VHL)-associated renal cell carcinoma. For gastrointestinal stromal tumor (GIST): 1) the disease is residual, unresectable, recurrent, or metastatic/tumor rupture AND 2) the patient meets one of the following: a) the disease has progressed after at least two FDA-approved therapies (e.g., imatinib, sunitinib, regorafenib, ripretinib), b) the disease is succinate dehydrogenase (SDH)-deficient GIST. For soft tissue sarcoma (STS): the patient does not have an adipocytic soft tissue sarcoma.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **Vowst**

## **Products Affected**

#### Vowst

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For the prevention of recurrence of Clostridioides difficile infection (CDI): 1) The diagnosis of CDI has been confirmed by a positive stool test for C. difficile toxin, AND 2) The requested drug will be administered at least 48 hours after the last dose of antibiotics used for the treatment of recurrent CDI.
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	1 month
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **V**OYDEYA

## **Products Affected**

Voydeya

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For paroxysmal nocturnal hemoglobinuria (PNH) (initial): 1) the diagnosis of PNH was confirmed by detecting a deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-APs) AND 2) flow cytometry is used to demonstrate GPI-AP deficiency AND 3) the requested drug is being used as add-on therapy to ravulizumab or eculizumab for the treatment of extravascular hemolysis (EVH). For PNH (continuation): 1) there is no evidence of unacceptable toxicity or disease progression while on the current regimen AND 2) the patient has demonstrated a positive response to therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months, Continuation: Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **V**YKAT **X**R

#### **Products Affected**

• Vykat Xr

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Patient must have a documented diagnosis of Prader-Willi syndrome (PWS).
Age Restrictions	4 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **V**YNDAMAX

#### **Products Affected**

## • Vyndamax

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For cardiomyopathy of hereditary or wild-type transthyretin-mediated amyloidosis (ATTR-CM): Initiation: 1) patient exhibits clinical manifestation of disease (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema), AND 2) cardiac involvement was confirmed by echocardiography or cardiac magnetic resonance imaging (e.g., end-diastolic interventricular septal wall thickness exceeding 12 millimeters), AND 3) patient meets one of the following: a) if the request is for hereditary ATTR-CM the patient is positive for a mutation of the transthyretin (TTR) gene, b) if the request is for wild-type ATTR-CM the patient has transthyretin precursor proteins confirmed by testing. Continuation: patient demonstrates a beneficial response to therapy (e.g., slowing of clinical decline).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **VYNDAQEL**

#### **Products Affected**

Vyndaqel

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For cardiomyopathy of hereditary or wild-type transthyretin-mediated amyloidosis (ATTR-CM): Initiation: 1) patient exhibits clinical manifestation of disease (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema), AND 2) cardiac involvement was confirmed by echocardiography or cardiac magnetic resonance imaging (e.g., end-diastolic interventricular septal wall thickness exceeding 12 millimeters), AND 3) patient meets one of the following: a) if the request is for hereditary ATTR-CM the patient is positive for a mutation of the transthyretin (TTR) gene, b) if the request is for wild-type ATTR-CM the patient has transthyretin precursor proteins confirmed by testing. Continuation: patient demonstrates a beneficial response to therapy (e.g., slowing of clinical decline).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# VYVGART HYTRULO

#### **Products Affected**

## Vyvgart Hytrulo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Patient must have a documented diagnosis of: 1) anti-acetylcholine receptor (AChR) antibody positive generalized myasthenia gravis (gMG) OR 2) chronic inflammatory demyelinating polyneuropathy (CIDP).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **W**AINUA

#### **Products Affected**

#### Wainua

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For polyneuropathy of hereditary transthyretin (TTR)-mediated amyloidosis, initial therapy: Patient is positive for a mutation of the TTR gene and exhibits clinical manifestation of disease (for example, amyloid deposition in biopsy specimens, TTR protein variants in serum, progressive peripheral sensory-motor polyneuropathy). For polyneuropathy of hereditary TTR-mediated amyloidosis, continuation: Patient demonstrates a beneficial response to therapy (for example, improvement of neuropathy severity and rate of disease progression).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **W**ELIREG

## **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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **W**INREVAIR

#### **Products Affected**

#### Winrevair

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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# 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, symptomatic or relapsed/refractory anaplastic lymphoma kinase (ALK)-fusion positive Erdheim-Chester Disease, symptomatic or relapsed/refractory (ALK)-fusion positive Rosai-Dorfman Disease, (ALK)-fusion positive Langerhans Cell Histiocytosis, metastatic or unresectable ROS1 gene fusion positive cutaneous melanoma.
Exclusion Criteria	N/A
Required Medical Information	For non-small cell lung cancer (NSCLC), the requested drug is used in any of the following settings: 1) the patient has recurrent, advanced or metastatic anaplastic lymphoma kinase (ALK)-positive NSCLC AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to ONE of the following products: Alecensa (alectinib) or Alunbrig (brigatinib), OR 3) the patient has recurrent, advanced or metastatic ROS-1 positive NSCLC, OR 4) the patient has NSCLC with high-level MET amplification or MET exon 14 skipping mutation. For inflammatory myofibroblastic tumor (IMT), the disease is ALK-positive. For anaplastic large cell lymphoma (ALCL): 1) the disease is relapsed or refractory, AND 2) the disease is ALK-positive.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# **X**ATMEP

#### **Products Affected**

## Xatmep

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The member must have a diagnosis of acute lymphoblastic leukemia (ALL) or polyarticular juvenile idiopathic arthritis (pJIA).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	Subject to Part B vs D review.
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **X**ELJANZ

#### **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, intolerance or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor (e.g., Cyltezo [adalimumab-adbm], Enbrel [etanercept], Humira [adalimumab], Yuflyma [adalimumab-aaty]). For active psoriatic arthritis (new starts only): 1) Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one TNF inhibitor (e.g., Cyltezo [adalimumab-adbm], Enbrel [etanercept], Humira [adalimumab], Yuflyma [adalimumab-aaty]) AND 2) the requested drug is used in combination with a nonbiologic DMARD. For active ankylosing spondylitis (new starts only): Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor (e.g., Cyltezo [adalimumab-adbm], Enbrel [etanercept], Humira [adalimumab], Yuflyma [adalimumab-aaty]). For moderately to severely active ulcerative colitis (new starts only): Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor (e.g., Cyltezo [adalimumab-adbm], Humira [adalimumab], Yuflyma [adalimumab-aaty]). For active polyarticular course juvenile idiopathic arthritis (new starts only): Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor (e.g., Cyltezo [adalimumab-adbm], Enbrel [etanercept], Humira [adalimumab], Yuflyma [adalimumab], Yuflyma [adalimumab], Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor (e.g., Cyltezo [adalimumab-adbm], Enbrel [etanercept], Humira [adalimumab], Yuflyma [adalimumab-adbm], Enbrel [etanercept],
Age Restrictions	N/A

Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# XGEVA

## **Products Affected**

• Wyost

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.
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **X**IFAXAN

### **Products Affected**

#### • Xifaxan TABS 550MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Small intestinal bacterial overgrowth syndrome (SIBO)
Exclusion Criteria	N/A
Required Medical Information	For irritable bowel syndrome with diarrhea (IBS-D): 1) The patient has not previously received treatment with the requested drug, OR 2) The patient has previously received treatment with the requested drug, AND a) the patient is experiencing a recurrence of symptoms, AND b) 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. For small intestinal bacterial overgrowth (SIBO): 1) the patient is experiencing a recurrence after completing a successful course of treatment with the requested drug OR 2) diagnosis has been confirmed by one of the following: a) quantitative culture of upper gut aspirate, b) breath testing (e.g., lactulose hydrogen or glucose hydrogen breath test).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Reduction in risk of overt HE recurrence: 6 months, IBS-D and SIBO: 14 days
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## XIFAXAN 200MG

### **Products Affected**

#### • Xifaxan TABS 200MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Must have a documented diagnosis of Traveler's diarrhea caused by Noninvasive strains of E coli.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# XOLAIR

## **Products Affected**

Xolair

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

# XOLREMDI

### **Products Affected**

#### • Xolremdi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis), initial: 1) Diagnosis has been confirmed via testing to detect mutations in the CXCR4 gene AND 2) The patient exhibits at least one clinical manifestation of the disease (such as warts, hypogammaglobulinemia, infections, myelokathexis) AND 3) The patient has a confirmed low neutrophil count based on the reference laboratory range or current practice guidelines. For WHIM syndrome, continuation: The patient has demonstrated a positive response to therapy.
Age Restrictions	12 years of age or older.
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months, Continuation: Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **X**OSPATA

## **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 FMS-like tyrosine kinase 3 (FLT3) 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **X**POVIO

### **Products Affected**

• Xpovio

- Xpovio 60 Mg Twice Weekly
- Xpovio 80 Mg Twice Weekly

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma, Human Immunodeficiency Virus (HIV)-related B-cell lymphoma, high-grade B-cell lymphoma, post-transplant lymphoproliferative disorders
Exclusion Criteria	N/A
Required Medical Information	For multiple myeloma: Patient must have been treated with at least one prior therapy. For B-cell lymphomas: Patient must have been treated with at least two lines of systemic therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

# **X**TANDI

## **Products Affected**

### • Xtandi

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 castration-resistant prostate cancer or metastatic castration-sensitive prostate cancer: 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# XURIDEN

## **Products Affected**

#### • Xuriden

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Must have a documented diagnosis of hereditary orotic aciduria.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **X**YREM

## **Products Affected**

## • Sodium Oxybate

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

## Yonsa

## **Products Affected**

### • Yonsa

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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **YORVIPATH**

### **Products Affected**

## • Yorvipath

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Acute post-surgical hypoparathyroidism (within 6 months of surgery) and expected recovery from hypoparathyroidism.
Required Medical Information	For hypoparathyroidism, initial: prior to initiation, the patient's albumin-corrected serum calcium has been or will be confirmed to be greater than or equal to 7.8 mg/dL. For hypoparathyroidism, continuation: the patient is experiencing benefit from therapy (for example, maintenance or normalization of serum calcium levels compared to baseline).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months, Continuation: Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **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
Exclusion Criteria	N/A
Required Medical Information	If receiving chemotherapy, the requested drug will be administered at least 24 hours after chemotherapy. 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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **Z**EJULA

### **Products Affected**

## • Zejula TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Uterine leiomyosarcoma
Exclusion Criteria	N/A
Required Medical Information	For uterine leiomyosarcoma: 1) the requested drug is used as second-line therapy AND 2) the patient has BRCA-altered disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **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, central nervous system cancer (i.e., glioma, glioblastoma, pediatric diffuse high-grade glioma), adjuvant systemic therapy for cutaneous melanoma, Langerhans cell histiocytosis.
Exclusion Criteria	N/A
Required Medical Information	For central nervous system (CNS) cancer (i.e., glioma, astrocytoma, glioblastoma, pediatric diffuse high-grade glioma): 1) The tumor is positive for BRAF V600E mutation, AND 2) The requested drug will be used in combination with cobimetinib OR the requested drug is being used for the treatment of pediatric diffuse high-grade glioma. For 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, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, or b) adjuvant systemic therapy. For Erdheim-Chester Disease and Langerhans Cell Histiocytosis: Tumor is positive for BRAF V600 mutation. For non-small cell lung cancer: 1) The tumor is positive for the BRAF V600E mutation, AND 2) The patient has recurrent, advanced, or metastatic disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# ZELSUVMI

### **Products Affected**

### Zelsuvmi

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

# **Z**ILBRYSQ

## **Products Affected**

• Zilbrysq

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For generalized myasthenia gravis (gMG), continuation: 1) There is no evidence of unacceptable toxicity or disease progression while on the current regimen AND 2) Patient has demonstrated a positive response to therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months, Continuation: Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **Z**IRABEV

## **Products Affected**

#### Zirabev

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Ampullary adenocarcinoma, appendiceal adenocarcinoma, breast cancer, central nervous system (CNS) cancers (including pediatric diffuse high-grade gliomas), pleural mesothelioma, peritoneal mesothelioma, pericardial mesothelioma, tunica vaginalis testis mesothelioma, soft tissue sarcomas, uterine neoplasms, endometrial carcinoma, vulvar cancers, small bowel adenocarcinoma, 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
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.

# ZOLINZA

## **Products Affected**

#### Zolinza

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Mycosis fungoides (MF)/Sezary syndrome (SS)
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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## 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
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **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
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

## **Z**URZUVAE

### **Products Affected**

#### Zurzuvae

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 postpartum depression (PPD): diagnosis was confirmed using standardized rating scales that reliably measure depressive symptoms (e.g., Hamilton Depression Rating Scale [HDRS], Edinburgh Postnatal Depression Scale [EPDS], Patient Health Questionnaire 9 [PHQ9], Montgomery-Asberg Depression Rating Scale [MADRS], Beck's Depression Inventory [BDI], etc.).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 month
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES NOT require use of a prerequisite Part D drug.

# **Z**YDELIG

## **Products Affected**

• Zydelig

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Small lymphocytic lymphoma (SLL)
Exclusion Criteria	N/A
Required Medical Information	For chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL): the requested drug is used as second-line or subsequent therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

## **Z**YKADIA

### **Products Affected**

## • Zykadia TABS

PA Criteria	Criteria Details
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

## 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
Prerequisite Therapy Required	Criteria DOES require use of a prerequisite Part D drug.

### PART B VERSUS PART D

#### **Products Affected**

- Abelcet
- Acetylcysteine SOLN
- Albuterol Sulfate NEBU 0.083%, 0.63MG/3ML, 1.25MG/3ML, 2.5MG/0.5ML
- Alyglo
- Aminosyn II INJ 107.6MEQ/L; 1490MG/100ML; 1527MG/100ML; 1050MG/100ML; 1107MG/100ML; 750MG/100ML; 450MG/100ML; 990MG/100ML; 1500MG/100ML; 1575MG/100ML; 258MG/100ML; 405MG/100ML; 447MG/100ML; 1083MG/100ML; 795MG/100ML; 50MEQ/L; 600MG/100ML; 300MG/100ML; 750MG/100ML, 993MG/100ML; 1018MG/100ML; 700MG/100ML; 738MG/100ML; 500MG/100ML; 300MG/100ML; 660MG/100ML; 1000MG/100ML; 1050MG/100ML; 172MG/100ML; 270MG/100ML; 298MG/100ML; 722MG/100ML; 530MG/100ML; 400MG/100ML; 200MG/100ML; 500MG/100ML
- Aminosyn-pf INJ 46MEQ/L;
   698MG/100ML; 1227MG/100ML;
   527MG/100ML; 820MG/100ML;
   385MG/100ML; 312MG/100ML;
   760MG/100ML; 1200MG/100ML;
   677MG/100ML; 180MG/100ML;
   427MG/100ML; 812MG/100ML;
   495MG/100ML; 70MG/100ML;
   512MG/100ML; 180MG/100ML;
   44MG/100ML; 673MG/100ML

- 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; 300MG/100ML; 570MG/100ML; 347MG/100ML; 50MG/100ML; 44MG/100ML; 452MG/100ML
- Amphotericin B INJ
- Amphotericin B Liposome
- Aprepitant
- Arformoterol Tartrate
- Astagraf XL
- Azasan
- Azathioprine TABS
- Bivigam INJ 10%, 5GM/50ML
- Budesonide SUSP
- 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%
- Cromolyn Sodium NEBU
- Cyclophosphamide CAPS
- Cyclophosphamide TABS
- Cyclosporine CAPS
- Cyclosporine Modified
- Doxorubicin Hydrochloride INJ 2MG/ML
- Dronabinol
- Emend SUSR
- Engerix-b
- Envarsus Xr
- Everolimus TABS 0.25MG, 0.5MG, 0.75MG, 1MG

- Flebogamma Dif INJ 10GM/200ML, 20GM/400ML, 5GM/100ML
- Formoterol Fumarate NEBU
- 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
- Gengraf CAPS 100MG, 25MG
- Gengraf SOLN
- Granisetron Hydrochloride TABS
- Heplisav-b
- Imovax Rabies (h.d.c.v.)
- Intralipid INJ 20GM/100ML, 30GM/100ML
- Ipratropium Bromide INHALATION SOLN 0.02%
- Ipratropium Bromide/albuterol Sulfate
- Levalbuterol NEBU
- Levalbuterol Hcl NEBU 0.31MG/3ML, 1.25MG/3ML
- Levalbuterol Hydrochloride NEBU 0.63MG/3ML
- Mycophenolate Mofetil CAPS
- Mycophenolate Mofetil SUSR
- Mycophenolate Mofetil TABS
- Mycophenolic Acid Dr
- Myhibbin
- Nutrilipid
- Octagam INJ 10GM/100ML, 10GM/200ML, 1GM/20ML, 2.5GM/50ML, 20GM/200ML, 2GM/20ML, 30GM/300ML, 5GM/100ML, 5GM/50ML
- Ohtuvayre
- Ondansetron Hcl SOLN
- Ondansetron Hydrochloride TABS

- Ondansetron Odt
- Panzyga
- 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
- 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
- Privigen
- Prograf PACK
- Prosol
- Pulmozyme SOLN 2.5MG/2.5ML
- Rabavert
- Recombivax Hb
- Sirolimus SOLN
- Sirolimus TABS
- Tacrolimus CAPS
- Tobramycin NEBU
- 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; 34MG/100ML; 152MG/100ML

Trophamine INJ 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

#### **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.