### ACTEMRA SC (S)

#### **Products Affected**

• Actemra Actpen

• Actemra INJ 162MG/0.9ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: a) Either a trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib) or attestation demonstrating a trial may be inappropriate, OR b) For continuation of prior therapy. Giant Cell Arteritis (GCA) (Initial): Diagnosis of GCA. Trial and failure, contraindication, or intolerance to a glucocorticoid (eg, prednisone). Systemic Juvenile Idiopathic Arthritis (SJIA) (Initial): Diagnosis of active SJIA. Trial and failure, contraindication, or intolerance to one of the following: NSAID (eg, ibuprofen, naproxen), methotrexate, or systemic glucocorticoid (eg, prednisone). Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of active PJIA. One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior therapy. Systemic sclerosis- associated interstitial lung disease (SSc-ILD) (Initial): Diagnosis of SSc- ILD as documented by the following: a) Exclusion of other known causes of ILD AND b) One of the following: i) In patients not subjected to surgical lung biopsy, the presence of idiopathic interstitial pneumonia (eg, fibrotic nonspecific interstitial pneumonia [NSIP], usual interstitial pneumonia [UIP] and centrilobular fibrosis) pattern on high-resolution computed tomography (HRCT) revealing SSc-ILD or probable SSc-ILD, OR ii) In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD.
Age Restrictions	N/A

Prescriber Restrictions	RA, GC, SJIA, PJIA (initial): Prescribed by or in consultation with a rheumatologist. SSc-ILD (initial): Prescribed by or in consultation with a pulmonologist or rheumatologist.
Coverage Duration	RA, GC, SJIA, PJIA, SSc-ILD (initial, reauth): 12 months
Other Criteria	RA, GC, SJIA, PJIA, SSc-ILD (Reauth): Documentation of positive clinical response to therapy.

### ACTIMMUNE (S)

#### **Products Affected**

• Actimmune

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of one of the following: 1) Chronic granulomatous disease (CGD), or 2) severe malignant osteopetrosis (SMO).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## ADCIRCA (S)

#### **Products Affected**

• Tadalafil TABS 20MG

• Alyq

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
Age Restrictions	N/A
Prescriber Restrictions	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: Initial: 6 months. Reauth: 12 months.
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.

### ADEMPAS (S)

#### **Products Affected**

• Adempas

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH AND PAH is symptomatic AND One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. Chronic thromboembolic pulmonary hypertension (CTEPH) (Initial): One of the following: A) Both of the following: 1) Diagnosis of inoperable or persistent/recurrent CTEPH and 2) CTEPH is symptomatic OR B) Patient is currently on any therapy for the diagnosis of CTEPH.
Age Restrictions	N/A
Prescriber Restrictions	PAH, CTEPH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH, CTEPH: Initial: 6 months. Reauth: 12 months.
Other Criteria	PAH, CTEPH (Reauth): Documentation of positive clinical response to therapy.

### **AFINITOR (S)**

#### **Products Affected**

• Afinitor TABS 10MG

• Everolimus TABS 10MG, 2.5MG, 5MG, 7.5MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Subependymal Giant Cell Astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC): Diagnosis of SEGA associated with TSC that requires therapeutic intervention but patient is not a candidate for curative surgical resection. Renal cell carcinoma: Diagnosis of advanced or metastatic renal cell carcinoma AND trial and failure, contraindication, or intolerance to SUTENT (sunitinib) or NEXAVAR (sorafenib). Neuroendocrine tumors of pancreatic origin (pNET): Diagnosis of progressive pNET that are unresectable, locally advanced, or metastatic. Renal angiomyolipoma: Diagnosis of renal angiomyolipoma and TSC AND Patient does not require immediate surgery. Breast Cancer: Patient is a postmenopausal woman AND Diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer AND trial and failure, contraindication, or intolerance to FEMARA (letrozole) or ARIMIDEX (anastrozole) AND used in combination with AROMASIN (exemestane). Neuroendocrine tumors of gastrointestinal (GI) or lung origin: Diagnosis of progressive, well-differentiated, non-functional NET of GI or lung origin AND patient has unresectable, locally advanced or metastatic disease.
Age Restrictions	N/A
Prescriber Restrictions	All uses: Prescribed by or in consultation with an oncologist
Coverage Duration	All uses: 12 months
Other Criteria	All Indications: Approve for continuation of prior therapy.

### **AFINITOR DISPERZ (S)**

#### **Products Affected**

• Afinitor Disperz

**PA** Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A Exclusion N/A Criteria Required Subependymal Giant Cell Astrocytoma (SEGA): Diagnosis of SEGA Medical associated with tuberous sclerosis complex (TSC) that requires Information therapeutic intervention but patient is not a candidate for curative surgical resection. TSC-associated partial-onset seizures: Diagnosis of TSCassociated partial-onset seizures. Used as adjunctive therapy. **Age Restrictions** N/A Prescriber SEGA: Prescribed by or in consultation with an oncologist. TSC-Restrictions associated partial-onset seizures: Prescribed by or in consultation with a neurologist. Coverage 12 months Duration **Other Criteria** Approve for continuation of prior therapy.

**Everolimus TBSO** 

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## AIMOVIG (S)

#### **Products Affected**

• Aimovig

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Episodic Migraines (EM) (initial): Diagnosis of EM. Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month. Chronic Migraines (CM) (initial): Diagnosis of CM. Medication overuse headache has been considered and potentially offending medication(s) have been discontinued. Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months. All Indications (initial): Two of the following: a) History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine), OR patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine), b) History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate), OR patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate), c) History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol, OR patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol, or d) History of failure (after at least a two month trial) or intolerance to Atacand (candesartan), OR patient has a contraindication to Atacand (candesartan). Medication will not be used in combination with another injectable CGRP inhibitor.
Age Restrictions	EM, CM (initial): 18 years of age or older.
Prescriber Restrictions	EM, CM (initial, reauth): Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.
Coverage Duration	EM, CM (initial): 6 months. EM, CM (reauth): 12 months.

Other Criteria	EM, CM (reauth): Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity. Use of acute migraine medications (e.g., non-steroidal anti-inflammatory drugs [NSAIDs] [e.g., ibuprofen, naproxen], triptans [e.g., eletriptan, rizatriptan, sumatriptan]) has decreased since the start of CGRP therapy. Medication will not be used in combination with another injectable CGRP inhibitor. CM (reauth): Patient continues to be monitored for medication
	overuse headache.

### ALDURAZYME (S)

#### **Products Affected**

• Aldurazyme

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Mucopolysaccharidosis I: confirmed diagnosis of Hurler and Hurler- Scheie forms of Mucopolysaccharidosis I (MPS I), OR confirmed diagnosis of Scheie form of Mucopolysaccharidosis I (MPS I) who have moderate to severe symptoms.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

### ALECENSA (S)

#### **Products Affected**

• Alecensa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): A) Diagnosis of metastatic NSCLC AND B) Patient has anaplastic lymphoma kinase (ALK)-positive disease as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### **ALPHA-1 PROTEINASE INHIBITOR, NON-PREFERRED (S)**

#### **Products Affected**

• Zemaira

• Aralast Np INJ 1000MG, 500MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Alpha-1 antitrypsin (AAT) deficiency: Diagnosis of congenital AAT deficiency. Diagnosis of emphysema. Continued optimal conventional treatment for emphysema (e.g., bronchodilators). One of the following: 1) PiZZ, PiZ(null), or Pi(null)(null) protein phenotypes (homozygous) OR 2) other rare AAT disease genotypes associated with pre-treatment serum AAT level less than 11 $\mu$ M/L [e.g., Pi(Malton, Malton), Pi(SZ)]. One of the following: Circulating pre-treatment serum AAT level less than 11 $\mu$ M/L (which corresponds to less than 80 mg/dL if measured by radial immunodiffusion or less than 57 mg/dL if measured by nephelometry) OR the patient has a concomitant diagnosis of necrotizing panniculitis. Trial and failure, or intolerance to Prolastin.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

### **ALPHA-1 PROTEINASE INHIBITOR, PROLASTIN (S)**

#### **Products Affected**

• Prolastin-c INJ 1000MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Alpha-1 antitrypsin (AAT) deficiency: Diagnosis of congenital AAT deficiency. Diagnosis of emphysema. Continued optimal conventional treatment for emphysema (e.g., bronchodilators). One of the following: 1) PiZZ, PiZ(null), or Pi(null)(null) protein phenotypes (homozygous) OR 2) other rare AAT disease genotypes associated with pre-treatment serum AAT level less than 11 $\mu$ M/L [e.g., Pi(Malton, Malton), Pi(SZ)]. Circulating pre-treatment serum AAT level less than 11 $\mu$ M/L (which corresponds to less than 80 mg/dL if measured by radial immunodiffusion or less than 57 mg/dL if measured by nephelometry), unless the patient has a concomitant diagnosis of necrotizing panniculitis.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

# ALUNBRIG (S)

#### **Products Affected**

• Alunbrig

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC. Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### AMPYRA (S)

#### **Products Affected**

• Dalfampridine Er

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS) (initial): Diagnosis of MS. Physician confirmation that patient has difficulty walking (eg, timed 25 foot walk test). One of the following: expanded disability status scale (EDSS) score less than or equal to 7, or not restricted to using a wheelchair (if EDSS is not measured).
Age Restrictions	N/A
Prescriber Restrictions	MS (initial): Prescribed by or in consultation with a neurologist.
Coverage Duration	MS (Initial): 6 months. (Reauth): 12 months.
Other Criteria	MS (Reauth): Physician confirmation that the patient's walking improved with therapy. One of the following: EDSS score less than or equal to 7, or not restricted to using a wheelchair (if EDSS is not measured).

### ARCALYST (S)

#### **Products Affected**

• Arcalyst

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cryopyrin-Associated Periodic Syndromes (CAPS) (Initial): Diagnosis of CAPS, including Familial Cold Auto-inflammatory Syndrome (FCAS) and/or Muckle-Wells Syndrome (MWS). The medication will not be used in combination with another biologic. Deficiency of Interleukin-1 Receptor Antagonist (DIRA): Diagnosis of DIRA. Patient weighs at least 10 kg. Patient is currently in remission (e.g., no fever, skin rash, and bone pain/no radiological evidence of active bone lesions/C-reactive protein [CRP] less than 5 mg/L). Recurrent Pericarditis (Initial): Diagnosis of recurrent pericarditis as evidenced by at least 2 episodes that occur a minimum of 4 to 6 weeks apart. Trial and failure, contraindication, or intolerance (TF/C/I) to at least one of the following: nonsteroidal anti- inflammatory drugs (e.g., ibuprofen, naproxen), colchicine, or corticosteroids (e.g., prednisone).
Age Restrictions	N/A
Prescriber Restrictions	CAPS (initial): Prescribed by or in consultation with an immunologist, allergist, dermatologist, rheumatologist, neurologist or other medical specialist. Recurrent Pericarditis (initial): Prescribed by or in consultation with a cardiologist.
Coverage Duration	CAPS, Recurrent Pericarditis (initial, reauth): 12 months. DIRA: 12 months.
Other Criteria	CAPS (Reauth): Patient has experienced disease stability or improvement in clinical symptoms while on therapy as evidence by one of the following: A) improvement in rash, fever, joint pain, headache, conjunctivitis, B) decreased number of disease flare days, C) normalization of inflammatory markers (CRP, ESR, SAA), D) corticosteroid dose reduction, OR E) improvement in MD global score or active joint count. Recurrent Pericarditis (Reauth): Documentation of positive clinical response to therapy.

## AURYXIA (S)

### **Products Affected**

• Auryxia

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Exclude if used for iron deficiency anemia in chronic kidney disease (CKD) not on dialysis.
Required Medical Information	Hyperphosphatemia in chronic kidney disease: Diagnosis of hyperphosphatemia. Patient has chronic kidney disease (CKD). Patient is on dialysis.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

### AUSTEDO (S)

#### **Products Affected**

• Austedo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chorea associated with Huntington's disease (initial): Diagnosis of Chorea associated with Huntington's disease. Tardive dyskinesia (initial): Diagnosis of moderate to severe tardive dyskinesia. One of the following: 1) Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication or 2) Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication.
Age Restrictions	N/A
Prescriber Restrictions	Huntington's disease chorea (initial): Prescribed by a neurologist. Tardive dyskinesia (initial): Prescribed by or in consultation with a neurologist or psychiatrist.
Coverage Duration	Initial: 3 months. Reauth: 12 months
Other Criteria	All indications (Reauth): Documentation of positive clinical response to therapy.

### AYVAKIT (S)

#### **Products Affected**

• Ayvakit

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Gastrointestinal stromal tumor (GIST): Diagnosis of GIST. Disease is one of the following: unresectable or metastatic. Presence of platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations. Advanced Systemic Mastocytosis (AdvSM): Diagnosis of AdvSM. Patient has one of the following: a) aggressive systemic mastocytosis (ASM), b) systemic mastocytosis with an associated hematological neoplasm (SM-AHN), or c) mast cell leukemia (MCL).
Age Restrictions	N/A
Prescriber Restrictions	GIST: Prescribed by or in consultation with an oncologist. AdvSM: Prescribed by or in consultation with an oncologist/hematologist, allergist, or immunologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# **BAFIERTAM (S)**

#### **Products Affected**

• Bafiertam

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS) (initial): Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: a) Failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS: 1) Aubagio (teriflunomide), 2) Gilenya (fingolimod), or 3) Brand Tecfidera/generic dimethyl fumarate, OR b) for continuation of prior therapy.
Age Restrictions	N/A
Prescriber Restrictions	MS (initial, reauth): Prescribed by or in consultation with a neurologist
Coverage Duration	MS (initial, reauth): 12 months
Other Criteria	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).

### **BALVERSA (S)**

#### **Products Affected**

• Balversa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Urothelial Carcinoma: Diagnosis of urothelial carcinoma (UC). One of the following: Locally advanced or Metastatic AND Patient has fibroblast growth factor receptor (FGFR) 3 or FGFR2 genetic alterations as detected by an U.S. Food and Drug Administration (FDA)-approved test (therascreen FGFR RGQ RT-PCR Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). One of the following: 1) Patient has progressed during or following at least one line of prior chemotherapy or immunotherapy OR 2) Patient has progressed within 12 months of neoadjuvant or adjuvant platinum- containing chemotherapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### **BENLYSTA (S)**

#### **Products Affected**

• Benlysta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Systemic lupus erythematosus (SLE) (init): Diagnosis of active SLE. Autoantibody positive (ie, anti-nuclear antibody [ANA] titer greater than or equal to 1:80 or anti-dsDNA level greater than or equal to 30 IU/mL). Currently receiving at least one standard of care treatment for active SLE (eg, antimalarials [eg, Plaquenil (hydroxychloroquine)], corticosteroids [eg, prednisone], or immunosuppressants [eg, methotrexate, Imuran (azathioprine)]). Lupus Nephritis (init): Diagnosis of active lupus nephritis. Currently receiving standard of care treatment for active lupus nephritis (e.g., corticosteroids [e.g., prednisone] with mycophenolate or cyclophosphamide).
Age Restrictions	N/A
Prescriber Restrictions	SLE (init): Prescribed by or in consultation with a rheumatologist. Lupus Nephritis (init): Prescribed by or in consultation with a nephrologist or rheumatologist.
Coverage Duration	SLE, Lupus Nephritis (init, reauth): 6 months
Other Criteria	SLE, Lupus Nephritis (reauth): Documentation of positive clinical response to therapy.

# **BESREMI (S)**

### **Products Affected**

• Besremi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of polycythemia vera as confirmed by all of the following: 1) One of the following: a) Hemoglobin greater than 16.5 g/dL for men or hemoglobin greater than 16.0 g/dL for women, b) Hematocrit greater than 49% for men or hematocrit greater than 48% for women, or c) Increased red cell mass, AND 2) Bone marrow biopsy showing hypercellularity for age with trilineage growth (panmyelosis) including prominent erythroid, granulocytic and megakaryocytic proliferation with pleomorphic, mature megakaryocytes, AND 3) One of the following: a) Presence of JAK2 or JAK2 exon 12 mutation or b) Subnormal serum erythropoietin level. Both of the following: 1) Trial and failure, contraindication or intolerance (TF/C/I) to hydroxyurea, AND 2) TF/C/I to one interferon therapy (e.g., Intron A, Pegasys, etc).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# **BOSULIF (S)**

### **Products Affected**

• Bosulif

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic myelogenous/myeloid leukemia (CML): Diagnosis of Philadelphia chromosome-positive (Ph+) CML.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# **BRAFTOVI (S)**

#### **Products Affected**

• Braftovi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma. Cancer is BRAF V600E or V600K mutant type (MT) as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with Mektovi (binimetinib). Colorectal Cancer: One of the following diagnoses: Colon Cancer or Rectal Cancer. One of the following: 1) Unresectable or advanced disease or 2) Metastatic disease. Patient has received prior therapy. Cancer is BRAF V600E mutant type as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with Erbitux (cetuximab).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

# **BRIVIACT (S)**

### **Products Affected**

• Briviact TABS

• Briviact SOLN

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Partial-onset seizures: Diagnosis of partial-onset seizures.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# **BRUKINSA (S)**

#### **Products Affected**

• Brukinsa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Mantle Cell Lymphoma (MCL): Diagnosis of relapsed or refractory MCL. Trial and failure, contraindication, or intolerance to at least ONE combination treatment of rituximab and chemotherapy (e.g., BR, R- CHOP, R-CVP, R-FCM). Waldenstrom's Macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma (LPL): Diagnosis of WM/LPL. Marginal Zone Lymphoma (MZL): Diagnosis of MZL. Disease is relapsed or refractory. Patient has received at least one prior anti-CD20- based regimen for MZL (e.g., rituximab, obinutuzumab).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist/hematologist.
Coverage Duration	12 months.
Other Criteria	Approve for continuation of prior therapy.

# CABLIVI (S)

#### **Products Affected**

• Cablivi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acquired thrombotic thrombocytopenic purpura (aTTP): Diagnosis of aTTP. First dose was/will be administered by a healthcare provider as a bolus intravenous injection. Used in combination with immunosuppressive therapy (e.g. rituximab, glucocorticoids). One of the following: 1) Used in combination with plasma exchange or 2) both of the following: patient has completed plasma exchange and less than 59 days have or will have elapsed beyond the last plasma exchange.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist.
Coverage Duration	3 months
Other Criteria	N/A

## CABOMETYX (S)

#### **Products Affected**

• Cabometyx

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Renal cell carcinoma (RCC): Diagnosis of RCC. RCC is advanced. Hepatocellular Carcinoma (HCC): Diagnosis of HCC. One of the following: a) Trial and failure, contraindication, or intolerance to Nexavar (sorafenib tosylate), or b) Patient has metastatic disease, or c) Patient has extensive liver tumor burden, or d) Patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only), or e) Disease is unresectable. Differentiated Thyroid Cancer (DTC): Diagnosis of DTC. Disease is one of the following: a) locally advanced or b) metastatic. Disease has progressed following prior VEGFR-targeted therapy (e.g., Lenvima [lenvatinib], Nexavar [sorafenib]). Disease or patient is refractory to radioactive iodine treatment or ineligible.
Age Restrictions	N/A
Prescriber Restrictions	RCC: Prescribed by or in consultation with one of the following: an oncologist or nephrologist. HCC: Prescribed by or in consultation with one of the following: oncologist, hepatologist, or gastroenterologist. DTC: Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## CALQUENCE (S)

#### **Products Affected**

• Calquence

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Mantle Cell Lymphoma: Diagnosis of mantle cell lymphoma (MCL) AND patient has received at least one prior therapy for MCL. Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL): Diagnosis of CLL or SLL.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# CAPRELSA (S)

#### **Products Affected**

• Caprelsa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Thyroid Cancer: Diagnosis of medullary thyroid cancer (MTC).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with oncologist or endocrinologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# CAYSTON (S)

### **Products Affected**

• Cayston

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cystic fibrosis (CF) (Initial, Reauth): Diagnosis of CF AND Patient has evidence of Pseudomonas aeruginosa in the lungs.
Age Restrictions	CF (Initial): 7 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	CF (Initial, reauth): 12 months
Other Criteria	CF (Reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations).

# **CERDELGA (S)**

### **Products Affected**

• Cerdelga

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Gaucher disease (Initial): Diagnosis of Gaucher disease type 1. Patient is an extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) of cytochrome P450 enzyme (CYP) 2D6 as detected by an FDA-cleared test.
Age Restrictions	Gaucher disease (initial): 18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Gaucher disease (initial, reauth): 12 months
Other Criteria	Gaucher disease (Reauth): Patient continues to need requested medication.

# CHOLBAM (S)

#### **Products Affected**

• Cholbam

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Bile acid synthesis disorders due to single enzyme defects (BAS) (initial): diagnosis of a bile acid synthesis disorder due to a single enzyme defect. Peroxisomal disorders (PD) (initial): All of the following: 1) diagnosis of peroxisomal disorder, 2) patient exhibits at least one of the following: a) liver disease (eg, jaundice, elevated serum transaminases), OR b) steatorrhea, OR c) complications from decreased fat-soluble vitamin absorption (eg, poor growth), AND 3) will be used as an adjunctive treatment.
Age Restrictions	N/A
Prescriber Restrictions	All uses (initial): Prescribed by a hepatologist, medical geneticist, pediatric gastroenterologist, OR other specialist that treats inborn errors of metabolism.
Coverage Duration	All uses (initial, reauth): 12 months
Other Criteria	All uses (reauth): documentation of positive clinical response to therapy.

### CICLOPIROX (S)

### **Products Affected**

Ciclodan SOLN

Ciclopirox Nail Lacquer

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	All of the following: 1) Patient does not have lunula (matrix) involvement, 2) one of the following: a) Diagnosis of onychomycosis of the toenails, OR b) Diagnosis of onychomycosis of the fingernails, 3) Diagnosis of onychomycosis has been confirmed by one of the following: a) positive potassium hydroxide (KOH) preparation, OR b) culture, OR c) histology, 4) If toenail onychomycosis, patient has mild to moderate disease involving at least 1 target toenail, AND 5) Trial and failure, contraindication, or intolerance to oral terbinafine.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	48 weeks.
Other Criteria	N/A

## CINRYZE (S)

### **Products Affected**

• Cinryze

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prophylaxis of hereditary angioedema (HAE) attacks: Diagnosis of HAE. Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by one of the following: a) C1-INH antigenic level below the lower limit of normal OR b) C1-INH functional level below the lower limit of normal. For prophylaxis against HAE attacks.
Age Restrictions	N/A
Prescriber Restrictions	HAE (prophylaxis): Prescribed by or in consultation with an immunologist or an allergist
Coverage Duration	12 months
Other Criteria	N/A

# **COMETRIQ (S)**

#### **Products Affected**

• Cometriq

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medullary thyroid cancer (MTC): Diagnosis of Metastatic MTC.
Age Restrictions	N/A
Prescriber Restrictions	MTC: Prescribed by or in consultation with an oncologist/hematologist or endocrinologist.
Coverage Duration	All uses: 12 months
Other Criteria	Approve for continuation of prior therapy.

# **COPIKTRA (S)**

### **Products Affected**

• Copiktra

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): Diagnosis of CLL or SLL. Disease is relapsed or refractory. Trial and failure, contraindication, or intolerance to at least two prior therapies for CLL/SLL (e.g., Leukeran [chlorambucil], Gazyva [obinutuzumab], Arzerra [ofatumumab], Bendeka [bendamustine], Imbruvica [ibrutinib], Rituxan [rituximab], etc.).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# CORLANOR (S)

### **Products Affected**

• Corlanor TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic heart failure (CHF) (initial): Diagnosis of CHF. Patient has NYHA Class II, III, or IV symptoms. Patient has a left ventricular ejection fraction less than or equal to 35%. Patient is in sinus rhythm. Patient has a resting heart rate of greater than or equal to 70 beats per minute. Patient has been hospitalized for worsening HF in the previous 12 months. Trial and failure, contraindication, or intolerance to two of the following at a maximally tolerated dose: A) One of the following: 1) ACE inhibitor (e.g., captopril, enalapril, lisinopril), 2) ARB (e.g., candesartan, losartan, valsartan), or 3) ARNI (e.g., Entresto [sacubitril and valsartan]), B) One of the following: 1) bisoprolol, 2) carvedilol, or 3) metoprolol succinate extended release, C) Sodium-glucose co-transporter 2 (SGLT2) inhibitor [e.g., Jardiance (empagliflozin), Farxiga (dapagliflozin), Xigduo XR (dapagliflozin and metformin)], or D) Mineralocorticoid receptor antagonist (MRA) [e.g., eplerenone, spironolactone]. Dilated Cardiomyopathy (DCM) (initial): Diagnosis of heart failure due to DCM. Patient has NYHA Class II, III, or, IV symptoms. Patient is in sinus rhythm. Patient has an elevated heart rate. Trial and failure, contraindication or intolerance to one of the following: 1) Beta blocker (e.g., bisoprolol, metoprolol succinate extended release), 2) Angiotensin- converting enzyme (ACE) inhibitor (e.g., captopril, enalapril), or 3) Diuretic Agent (e.g., spironolactone, furosemide).
Age Restrictions	N/A
Prescriber Restrictions	CHF, DCM (initial): Prescribed by or in consultation with a cardiologist
Coverage Duration	CHF, DCM (initial, reauth): 12 months
Other Criteria	CHF, DCM (reauth): Documentation of positive clinical response to therapy.

# **COSENTYX (S)**

#### **Products Affected**

• Cosentyx Sensoready Pen

• Cosentyx

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: Trial and failure, contraindication (eg, safety concerns, not indicated for patient's age/weight), or intolerance to one of the following: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab), OR for continuation of prior therapy. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: a) Either trial and failure, contraindication (eg, safety concerns, not indicated for patient's age/weight), or intolerance to two of the following, or attestation demonstrating a trial may be inappropriate: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib/ER), OR b) for continuation of prior therapy. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. One of the following: a) Trial and failure, contraindication, or intolerance to two of the following: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib/ER), or attestation demonstrating a trial may be inappropriate, OR b) for continuation of prior therapy. Non- radiographic axial spondyloarthritis (nr-axSpA, initial): Dx of active nr- axSpA with objective signs of inflammation (eg, 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.) TF/C/I to two non-steroidal anti-inflammatory drugs (NSAIDs) (eg, ibuprofen, meloxicam, naproxen). Enthesitis-Related Arthritis (ERA) (Initial): Diagnosis of active ERA. Trial and failure, contraindication, or intolerance to TWO non-steroidal anti-inflammatory drugs (NSAIDs) (eg, ibuprofen, meloxicam, naproxen).
Age Restrictions	ERA (initial): Patient is 4 years of age or older.

Prescriber Restrictions	Plaque psoriasis (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a rheumatologist or dermatologist. AS, nr-axSpA, ERA (initial): Prescribed by or in consultation with a rheumatologist.
Coverage Duration	All uses (initial, reauth): 12 months
Other Criteria	<ul> <li>PsA, AS, nr-axSpA (Reauth): Documentation of positive clinical response to therapy. Psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. ERA (Reauth): Documentation of a positive clinical response to therapy as evidenced by at least one of the following: Reduction in the total active (swollen and tender) joint count from baseline, OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline.</li> </ul>

# **COTELLIC (S)**

### **Products Affected**

• Cotellic

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Melanoma: Diagnosis of unresectable or metastatic melanoma. Patient has a BRAF V600E or V600K mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., cobas 4800 BRAF V600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with vemurafenib.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# CYSTARAN (S)

### **Products Affected**

• Cystaran

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cystinosis: Diagnosis of cystinosis, confirmed by elevated leukocyte cystine levels (LCL), genetic analysis of the CTNS gene or corneal cystine crystal accumulation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

### **D.H.E. 45 (S)**

#### **Products Affected**

• Dihydroergotamine Mesylate INJ

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Migraines (initial): Diagnosis of migraine headaches with or without aura. Will be used for the acute treatment of migraine. One of the following: Trial and failure or intolerance to one triptan (e.g., eletriptan, rizatriptan, sumatriptan) or contraindication to all triptans. If patient has 4 or more headache days per month, patient must meet one of the following: a) currently being treated with Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications, OR b) currently being treated with Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications, OR c) currently being treated with a beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications. Cluster Headaches (CH) (initial): Diagnosis of cluster headache. Trial and failure, contraindication, or intolerance to sumatriptan injection.
Age Restrictions	N/A
Prescriber Restrictions	Initial, Reauth: Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.
Coverage Duration	Migraines, CH (initial): 3 months. Migraines, CH (reauth): 12 months.
Other Criteria	Migraines (reauth): Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea). CH (reauth): Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity.

### **DALIRESP (S)**

#### **Products Affected**

• Daliresp

**PA** Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A Exclusion N/A Criteria Required Chronic Obstructive Pulmonary Disease (COPD) (initial): Diagnosis of Medical COPD. History of COPD exacerbations which required the use of Information systemic corticosteroids, antibiotics, or hospital admission. Trial and failure, intolerance, or contraindication to two prior therapies for COPD (e.g., Combivent, Spiriva). **Age Restrictions** N/A N/A Prescriber Restrictions Coverage COPD (init, reauth): 12 months Duration **Other Criteria** COPD (reauth): Documentation of positive clinical response to therapy.

• Roflumilast

# DANYELZA (S)

#### **Products Affected**

• Danyelza

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Neuroblastoma: Diagnosis of high-risk neuroblastoma in bone or bone marrow. Disease is relapsed or refractory. Used in combination with granulocyte-macrophage colony-stimulating factor [e.g., Leukine (sargramostim)]. Patient has had prior therapy with one of the following responses: partial response, minor response, or stable disease.
Age Restrictions	Neuroblastoma: Patient is 1 year of age or older.
Prescriber Restrictions	Neuroblastoma: Prescribed by or in consultation with an oncologist or hematologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# **DARAPRIM (S)**

#### **Products Affected**

• Pyrimethamine TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Toxoplasmosis: 1) Patient is using pyrimethamine for the treatment of toxoplasmic encephalitis, secondary prophylaxis of toxoplasmic encephalitis, or treatment of congenital toxoplasmosis OR 2) Patient is using pyrimethamine for the primary prophylaxis of toxoplasmic encephalitis, patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX), and one of the following: patient has been re-challenged with TMP-SMX using a desensitization protocol and is still unable to tolerate, or evidence of life-threatening reaction to TMP-SMX in the past (eg, toxic epidermal necrolysis, Stevens-Johnson syndrome). Malaria: Patient is using pyrimethamine for the treatment of acute malaria or chemoprophylaxis of malaria. Patient does not have megaloblastic anemia due to folate deficiency. The provider acknowledges that pyrimethamine is not recommended by the Centers for Disease Control and Prevention (CDC) for the treatment and/or prophylaxis of malaria.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist
Coverage Duration	12 months
Other Criteria	Toxoplasmosis only: Approve for continuation of prior therapy.

### **DARZALEX FASPRO (S)**

#### **Products Affected**

• Darzalex Faspro

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Relapsed/Refractory Multiple Myeloma (MM): Diagnosis of MM. One of the following: A) Both of the following: Used as monotherapy and One of the following: i) Patient has received at least three prior treatment regimens which included both a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis]) and an immunomodulatory agent (e.g., lenalidomide [Revlimid], thalidomide [Thalomid]) or ii) patient is double- refractory to a proteasome inhibitor and an immunomodulatory agent. OR B) Both of the following: used in combination with one of the following treatment regimens: lenalidomide and dexamethasone, or bortezomib and dexamethasone, AND patient has received at least one prior therapy (e.g., bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro], lenalidomide [Revlimid], thalidomide [Thalomid). Newly Diagnosed MM: Newly diagnosed MM. One of the following: A) Both of the following: pPatient is ineligible for autologous stem cell transplant AND one of the following: 1) used in combination with all of the following: bortezomib, melphalan, and prednisone or 2) used in combination with both of the following: lenalidomide and dexamethasone. OR B) Both of the following: patient is eligible for autologous stem cell transplant AND used in combination with all of the following: bortezomib, melphalan, and prednisone or 2) used in combination with both of the following: lenalidomide and dexamethasone. OR B) Both of the following: patient is eligible for autologous stem cell transplant AND used in combination with all of the following: bortezomib, thalidomide, and dexamethasone. Light Chain (AL) Amyloidosis: Newly diagnosed light chain (AL) amyloidosis. Used in combination with all of the following: patient does not have New York Association (NYHA) Class IIIB disease, patient does not have NYHA class IV disease, and patient does not have Mayo Stage IIIB disease.
Age Restrictions	N/A
Prescriber Restrictions	MM: Prescribed by or in consultation with an oncologist/hematologist. Light Chain (AL) Amyloidosis: Prescribed by or in consultation with a hematologist.

Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

# **D**AURISMO (S)

#### **Products Affected**

• Daurismo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acute myeloid leukemia (AML): Diagnosis of newly-diagnosed acute myeloid leukemia (AML) AND Used in combination with low-dose cytarabine AND One of the following: 1) Patient is greater than or equal to 75 years old, or 2) Patient has comorbidities that preclude the use of intensive induction chemotherapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### **DEFERASIROX (S)**

#### **Products Affected**

• Deferasirox

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic Iron Overload Due to Blood Transfusions (Initial): Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis). Patient has a baseline ferritin level more than 1,000 mcg/L. Patient has required the transfusion of at least 100 mL/kg packed red blood cells. Myelodysplastic Syndrome (MDS) (Initial): Diagnosis of MDS. Patient has Low or Intermediate-1 disease or is a potential transplant patient. Patient has received more than 20 red blood cell transfusions. Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT) (Initial): Diagnosis of chronic iron overload due to NTDT. Liver iron concentration (LIC) 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) or higher. Serum ferritin level greater than 300 mcg/L.
Age Restrictions	Iron Overload Due to Blood Transfusions (initial): 2 years of age or older. NTDT (initial): 10 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Iron Overload Due to Blood Transfusions, MDS (initial, reauth):12 mo. NTDT (initial, reauth): 6mo.
Other Criteria	Iron Overload Due to Blood Transfusions, MDS (Reauth): Patient experienced a reduction from baseline in serum ferritin level or LIC. NTDT (Reauth): Patient has LIC 3 mg Fe/g dw or higher. Patient experienced a reduction from baseline in serum ferritin level or LIC.

# **DIACOMIT (S)**

#### **Products Affected**

• Diacomit

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of seizures associated with Dravet syndrome (DS). Used in combination with clobazam.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# **DUPIXENT (S)**

#### **Products Affected**

• Dupixent

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Atopic dermatitis (AD) (init): Diagnosis (dx) of mod to severe AD. Trial and failure, contraindication (eg, safety concerns, not indicated for patient's age/weight), or intolerance (TF/C/I) to one med to high potency topical corticosteroid (eg, betamethasone, triamcinolone). One of the following: A) TF/C/I to pimecrolimus topical cream, unless patient is not a candidate for pimecrolimus therapy (eg, immunocompromised, severe atopic dermatitis), B) TF/C/I to tacrolimus topical ointment, unless patient is not a candidate for tacrolimus ointment therapy (eg, immunocompromised), or C) Eucrisa (crisaborole). Eosinophilic Asthma (EA) (init): Dx of mod to severe asthma. Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells/microliter. One of the following: 1) Patient has had at least one or more asthma exacerbations requiring systemic corticosteroids (eg, prednisone) within the past 12 mo, 2) Any prior intubation for an asthma exacerbation, or 3) Prior asthma- related hospitalization within the past 12 mo. One of the following: a) TF/C/I to Fasenra (benralizumab), Nucala (mepolizumab), or Cinqair (reslizumab) or b) For continuation of prior therapy. Corticosteroid Dependent Asthma (CDA) (init): Dx of mod to severe asthma. Patient is currently dependent on oral corticosteroids for the treatment of asthma. EA, CDA (init): Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) High-dose inhaled corticosteroid (ICS) [e.g., greater than 500 mcg fluticasone propionate equivalent/day] and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist (eg, montelukast), long-acting beta-2 agonist (LABA) (eg, salmeterol), tiotropium], OR b) One max-dosed combination ICS/LABA product [eg, Advair, Symbicort, Breo Ellipta].

Age Restrictions	Asthma (initial): Age greater than or equal to 6 years. Atopic dermatitis (initial): Age greater than or equal to 6 months. CRSwNP: no age restriction. EoE (initial): Patient is at least 12 years of age.
Prescriber Restrictions	Atopic dermatitis (Initial): Prescribed by or in consultation with one of the following: dermatologist, allergist/immunologist. Asthma (initial, reauth): Prescribed by or in consultation with a pulmonologist or allergist/immunologist.CRSwNP (initial, reauth): Prescribed by or in consultation with an otolaryngologist, allergist/immunologist, or pulmonologist. EoE (initial): Prescribed by or in consultation with a gastroenterologist or allergist/immunologist.
Coverage Duration	AD, CRSwNP, EoE (Init/Reauth): 12 months. Asthma (Init): 6 mo. Asthma (reauth): 12 mo.

Other Criteria	Chronic rhinosinusitis with nasal polyposis (CRSwNP) (initial): Diagnosis of CRSwNP. Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (eg, fluticasone, mometasone). Used in combination with another agent for CRSwNP. Eosinophilic esophagitis (EoE) (initial): Dx of EoE. Patient has symptoms of esophageal dysfunction (eg, dysphagia, food impaction, gastroesophageal reflux disease [GERD]/heartburn symptoms, chest pain, abdominal pain). Patient has at least 15 intraepithelial cosinophilis per high power field (HPF). Other causes of esophageal eosinophilia have been excluded. Patient weighs at least 40 kg. Trial and failure, contraindication, or intolerance to at least an 8-week trial of one of the following: proton pump inhibitors (eg, pantoprazole, omeprazole) or topical (esophageal) corticosteroids (eg, budesonide, fluticasone). Atopic dermatitis (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in body surface area involvement, reduction in prurius severity). EA (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications). CDA (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in exacerbations, improvement in FEV1, reduction in oral corticosteroid dose). EA, CDA (reauth): Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications. CRSwNP (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS, 0-8 scale], improvement in nasal congestion/obstruction score [NC, 0-3 scale]). Used in combination w

# **ELAPRASE (S)**

#### **Products Affected**

• Elaprase

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of Hunter Syndrome (Mucopolysaccharidosis II (MPS II))
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

# **EMGALITY (S)**

#### **Products Affected**

• Emgality

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Episodic Migraines (EM) (120 mg/mL strength only) (initial): Diagnosis of EM. Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month. Chronic Migraines (CM) (120 mg strength/mL only) (initial): Diagnosis of CM. Medication overuse headache has been considered and potentially offending medication(s) have been discontinued. Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months. Episodic Cluster Headache (ECH) (100 mg/mL strength only) (initial): Diagnosis of episodic cluster headache. Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months. EM, CM (120 mg/mL strength only) (initial): Two of the following: a) History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine), OR patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine), b) History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate), OR patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate), c) History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol, OR patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol, or d) History of failure (after at least a two month trial) or intolerance to Atacand (candesartan), OR patient has a contraindication to Atacand (candesartan). All Indications (initial): Medication will not be used in combination with another injectable CGRP inhibitor.
Age Restrictions	EM, CM, ECH (initial): 18 years of age or older.
Prescriber Restrictions	EM, CM, ECH (initial, reauth): Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.

Coverage Duration	EM, CM (initial): 6 months. ECH (initial): 3 months. EM, CM, ECH (reauth): 12 months.
Other Criteria	EM, CM (120 mg/mL strength only) (reauth): Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity. Use of acute migraine medications (e.g., non-steroidal anti-inflammatory drugs [NSAIDs] [e.g., ibuprofen, naproxen], triptans [e.g., eletriptan, rizatriptan, sumatriptan]) has decreased since the start of CGRP therapy. CM (120 mg/mL strength only) (reauth): Patient continues to be monitored for medication overuse headache. ECH (100 mg/mL strength only) (reauth): Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity. All Indications (reauthorization): Medication will not be used in combination with another injectable CGRP inhibitor.

### **ENBREL (S)**

#### **Products Affected**

• Enbrel

- Enbrel Mini
- Enbrel Sureclick

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Trial and failure, contraindication, or intolerance to one disease-modifying antirheumatic drug (DMARD) [eg, methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)]. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Trial and failure, contraindication, or intolerance to one of the following DMARDs: Arava (leflunomide) or methotrexate (Rheumatrex/Trexall). Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Trial and failure, contraindication, or intolerance to two NSAIDs (e.g., diclofenac, ibuprofen, meloxicam, naproxen).
Age Restrictions	N/A
Prescriber Restrictions	RA (initial), PJIA (initial), AS (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a rheumatologist or dermatologist. Plaque Psoriasis (initial): Prescribed by or in consultation with a dermatologist.
Coverage Duration	All uses (initial, reauth): 12 months
Other Criteria	RA, PJIA, PsA, AS (Reauth): Documentation of positive clinical response to therapy. Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline.

### **ENSPRYNG (S)**

#### **Products Affected**

• Enspryng

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Neuromyelitis Optica Spectrum Disorder (NMOSD) (initial): Diagnosis of NMOSD. Patient is anti-aquaporin-4 (AQP4) antibody positive.
Age Restrictions	N/A
Prescriber Restrictions	NMOSD (initial): Prescribed by or in consultation with a neurologist or ophthalmologist.
Coverage Duration	NMOSD (initial, reauth): 12 months
Other Criteria	NMOSD (reauth): Documentation of positive clinical response to therapy.

### **EPCLUSA PREFERRED (S)**

#### **Products Affected**

• Sofosbuvir/velpatasvir

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Criteria will be applied consistent with current AASLD/IDSA guideline. Diagnosis of chronic hepatitis C. Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine.
Coverage Duration	12 to 24 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.
Other Criteria	N/A

# **EPIDIOLEX (S)**

#### **Products Affected**

• Epidiolex

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Lennox-Gastaut syndrome (LGS): Diagnosis of seizures associated with LGS. Trial of, contraindication, or intolerance to two formulary anticonvulsants (e.g., topiramate, lamotrigine, valproate). Dravet syndrome (DS): Diagnosis of seizures associated with DS. Tuberous sclerosis complex (TSC): Diagnosis of seizures associated with TSC.
Age Restrictions	N/A
Prescriber Restrictions	LGS, DS, TSC: Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### **EPOETIN ALFA (S)**

#### **Products Affected**

• Procrit

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Anemia with Chronic Kidney Disease (CKD) (Initial): Diagnosis (Dx) of CKD. Anemia by lab values (Hct less than 30% or Hgb less than 10 g/dL) collected within 30 days of request. One of the following: a) both of the following: Patient is on dialysis, patient is without ESRD OR b) all of the following: patient is not on dialysis, the rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion, and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal. Anemia with chemo (Initial):Other causes of anemia have been ruled out. Anemia by lab values (Hct less than 30%, Hgb less than 10 g/dL) collected within the prior 2 weeks of request. Cancer is a non-myeloid malignancy. Patient is receiving chemo. Preoperative for reduction of allogeneic blood transfusion: Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery. Hgb is greater than 10 to less than or equal to 13 g/dL. Patient is at high risk for perioperative transfusions. Patient is unwilling or unable to donate autologous blood pre-operatively. Anemia in hepatitis C virus (HCV)-infected pts due to ribavirin in combination with interferon/peg-interferon (Initial): Dx of HCV infection. Anemia by labs (Hct less than 36% or Hgb less than 12 g/dL) collected within 30 days of request. Serum erythropoietin level less than or equal to 500 mU/mL. Receiving zidovudine therapy or dx of HIV. Anemia in Myelodysplastic Syndrome (MDS) (Initial): Dx of MDS. Serum erythropoietin level is 500 mU/mL or less, or dx of transfusion-dependent MDS.
Age Restrictions	N/A
Prescriber Restrictions	N/A

Coverage	CKD,HIV(Init):6mo. CKD,HIV(reauth):12mo. Chemo,HCV(all):3mo.
Duration	MDS:(init) 3mo,(reauth)12mo. Preop:1mo.
Other Criteria	Subject to ESRD review. CKD, Chemo, MDS (init): History of use or unavailability of both Aranesp and Retacrit. HIV, Preop, HCV (init): History of use or unavailability of Retacrit. CKD (Reauth): Dx of CKD. One of the following: 1) Most recent or average (avg) Hct over 3 months is 33% or less (Hgb is 11 g/dL or less) for patients on dialysis, without ESRD, 2) Most recent or avg Hct over 3 mo is 30% or less (Hgb 10 g/dL or less) for patients not on dialysis, OR 3) Most recent or avg Hct over 3 mo is 36% or less (Hgb 12 g/dL or less) for pediatric patients. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. HIV (Reauth): Most recent or avg Hct over 3 months is below 36% or most recent or avg Hgb over 3 months is below 12 g/dl. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Chemo (Reauth): Anemia by lab values (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 weeks of request. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Patient is receiving chemo. HCV (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. If patient has demonstrated response to therapy, authorization will be issued for the full course of ribavirin therapy. MDS (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. If patient has demonstrated response to therapy, authorization will be issued for the full course of ribavirin therapy. MDS (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Decrease in the need for blood transfusion or Hgb increased by 1

# **ERIVEDGE (S)**

#### **Products Affected**

• Erivedge

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Basal cell carcinoma: One of the following: A) Diagnosis of metastatic basal cell carcinoma OR B) Both of the following: 1) Diagnosis of locally advanced basal cell carcinoma AND 2) One of the following: a) Disease recurred following surgery or b) Patient is not a candidate for surgery and radiation.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# ERLEADA (S)

#### **Products Affected**

• Erleada

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-metastatic castration-resistant or castration-recurrent prostate cancer (NM-CRPC): Diagnosis of non-metastatic, castration-resistant (chemical or surgical) or recurrent prostate cancer. Metastatic castration-sensitive prostate cancer (M-CSPC): Diagnosis of metastatic, castration-sensitive prostate cancer.
Age Restrictions	N/A
Prescriber Restrictions	NM-CRPC, M-CSPC: Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## **ESBRIET (S)**

#### **Products Affected**

• Esbriet

**PA** Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A Exclusion N/A Criteria Required Idiopathic pulmonary fibrosis (IPF) (initial): Diagnosis of IPF as Medical documented by all of the following: a) exclusion of other known causes of interstitial lung disease (ILD) (eg, domestic and occupational Information environmental exposures, connective tissue disease, drug toxicity), AND b) one of the following: i) in patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF. N/A **Age Restrictions** Prescriber IPF (initial): Prescribed by or in consultation with a pulmonologist Restrictions Coverage initial, reauth: 12 months Duration **Other Criteria** IPF (reauth): Documentation of positive clinical response to therapy.

Pirfenidone

•

# **EUCRISA (S)**

### **Products Affected**

• Eucrisa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Atopic dermatitis (initial): Diagnosis of mild to moderate atopic dermatitis. Trial and failure, contraindication, or intolerance to one prescription strength topical corticosteroid, unless the affected area is sensitive (i.e., face, axillae, groin).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Reauth: Documentation of a positive clinical response to therapy (e.g., reduction in body surface area involvement, reduction in pruritus severity).

## **EVRYSDI (S)**

### **Products Affected**

• Evrysdi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Spinal muscular atrophy (SMA) (initial): Diagnosis of spinal muscular atrophy (SMA) type I, II, or III. Both of the following: a) The mutation or deletion of genes in chromosome 5q resulting in one of the following: 1) Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13) or 2) Compound heterozygous mutation (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2]) AND b) Patient has at least 2 copies of SMN2. Patient is not dependent on both of the following: 1) Invasive ventilation or tracheostomy and 2) Use of non-invasive ventilation beyond use for naps and nighttime sleep. At least one of the following exams (based on patient age and motor ability) has been conducted to establish baseline motor ability: Hammersmith Infant Neurological Exam 2 (HINE-2) (infant to early childhood), Hammersmith Functional Motor Scale Expanded (HFMSE), Revised Upper Limb Module (RULM) Test (Non ambulatory), or Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND), or Motor Function Measure 32 (MFM-32) Scale or Item 22 of the Bayley Scales of Infant and Toddler Development Third Edition (BSID-III). Patient is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Spinraza). One of the following: a) patient has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma) or b) patient has previously received gene therapy for the treatment of SMA (e.g., Zolgensma) AND submission of medical records (e.g., chart notes) documenting that three has been an inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months).
Age Restrictions	N/A
Prescriber Restrictions	SMA (Initial, Reauth): Prescribed by or in consultation with a neurologist with expertise in the diagnosis and treatment of SMA

Coverage Duration	Initial, Reauth: 12 months
Other Criteria	SMA (Reauth): Documentation of positive clinical response to therapy. Patient (Pt) continues to not be dependent on both of the following: 1) Invasive ventilation or tracheostomy AND 2) use of non-invasive ventilation beyond use for naps and nighttime sleep. Pt is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Spinraza). One of the following: a) pt has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma) or b) pt has previously received gene therapy for the treatment of SMA (e.g., Zolgensma) AND submission of medical records (e.g., chart notes) documenting that there has been an inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months).

# EXKIVITY (S)

### **Products Affected**

• Exkivity

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of non-small cell lung cancer (NSCLC). Disease is one of the following: a) locally advanced or b) metastatic. Disease is epidermal growth factor receptor (EGFR) exon 20 insertion mutation positive as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has progressed on or following prior treatment with a platinum-containing regimen (e.g., carboplatin, cisplatin).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# FARYDAK (S)

### **Products Affected**

• Farydak

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Myeloma (MM): Diagnosis of MM. Used in combination with both of the following: Velcade (bortezomib) and dexamethasone. Patient has received at least two prior treatment regimens which included both of the following: Velcade (bortezomib) and an immunomodulatory agent [eg, Revlimid (lenalidomide), Thalomid (thalidomide)].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# FASENRA (S)

#### **Products Affected**

• Fasenra Pen

• Fasenra

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Asthma (initial): Diagnosis of severe asthma. Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter. One of the following: 1) Patient has had at least one or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months, OR 2) Any prior intubation for an asthma exacerbation, OR 3) Prior asthma-related hospitalization within the past 12 months. Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) High-dose inhaled corticosteroid (ICS) [e.g., greater than 500 mcg fluticasone propionate equivalent/day] and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist (e.g., montelukast), long-acting beta-2 agonist (LABA) (e.g., salmeterol), tiotropium], OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone/vilanterol)].
Age Restrictions	Asthma (Initial): Patient is 12 years of age or older
Prescriber Restrictions	Asthma (Initial/Reauth): Prescribed by or in consultation with a pulmonologist or allergist/immunologist
Coverage Duration	Asthma (init): 6 months. Asthma (reauth): 12 months

Other Criteria	Asthma (Reauth): Documentation of positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications). Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-
	acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications.

## FENTANYL (S)

#### **Products Affected**

• Fentanyl Citrate Oral Transmucosal

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For the management of breakthrough cancer pain. Patient is currently taking a long-acting opioid around the clock for cancer pain. Patient must have at least a one week history of ONE of the following medications to demonstrate tolerance to opioids: Morphine sulfate at doses of greater than or equal to 60 mg/day, Fentanyl transdermal patch at doses greater than or equal to 25 $\mu$ g/hr, Oxycodone at a dose of greater than or equal to 8 mg/day, Oral hydromorphone at a dose of greater than or equal to 25 mg/day, or an alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with one of the following: Pain specialist, Oncologist, Hematologist, Hospice care specialist, or Palliative care specialist.
Coverage Duration	12 months
Other Criteria	N/A

# **FERRIPROX (S)**

#### **Products Affected**

• Deferiprone

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Transfusional iron overload (Initial): Diagnosis of transfusional iron overload due to one of the following: thalassemia syndromes, sickle cell disease, or other transfusion-dependent anemias. Patient has Absolute Neutrophil Count (ANC) greater than 1.5 x 10^9/L. One of the following: A) Trial and failure, defined as serum ferritin greater than 2,500 mcg/L, to one chelation therapy (i.e., deferoxamine, deferasirox) OR B) History of contraindication or intolerance to one chelation therapy (i.e., deferoxamine, deferasirox).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	All uses (reauth): Documentation of positive clinical response to therapy (e.g., greater than or equal to 20% decline in serum ferritin levels from baseline, decrease in liver iron concentration). ANC greater than 1.5 x $10^9/L$ .

# FINTEPLA (S)

#### **Products Affected**

• Fintepla

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	One of the following: 1) Diagnosis of seizures associated with Dravet syndrome, OR 2) Diagnosis of seizures associated with Lennox-Gastaut syndrome.
Age Restrictions	Lennox-Gastaut syndrome: Patient is 2 years of age or older.
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

#### **Products Affected**

• Icatibant Acetate

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by one of the following: a) C1-INH antigenic level below the lower limit of normal OR b) C1-INH functional level below the lower limit of normal. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks.
Age Restrictions	N/A
Prescriber Restrictions	HAE: Prescribed by or in consultation with an immunologis or an allergist
Coverage Duration	12 months
Other Criteria	N/A

• Sajazir

## FIRMAGON (S)

#### **Products Affected**

• Firmagon INJ 120MG/VIAL, 80MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of advanced or metastatic prostate cancer.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# FOTIVDA (S)

#### **Products Affected**

• Fotivda

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of renal cell carcinoma. Disease is one of the following: relapsed or refractory. Patient has received two or more prior systemic therapies (e.g., cabozantinib + nivolumab, lenvatinib + pembrolizumab, etc.).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist, nephrologist, or urologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# GALAFOLD (S)

#### **Products Affected**

• Galafold

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Fabry Disease (FD) (initial): Diagnosis of FD. Patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data. FD (initial, reauthorization): Will not be used in combination with Fabrazyme (agalsidase beta).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	FD (initial, reauth): 12 months.
Other Criteria	FD (reauthorization): Documentation of positive clinical response to therapy.

## GAMASTAN S/D (S)

#### **Products Affected**

• Gamastan

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication).
Required Medical Information	Immune globulin is being used intramuscularly. The immune globulin will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. Patient requires immunization for hepatitis A, measles, rubella, or varicella.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months (Approve one dose only)
Other Criteria	Subject to Part B vs D review.

# GAVRETO (S)

#### **Products Affected**

• Gavreto

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Presence of metastatic rearranged during transfection (RET) gene fusion-positive tumor(s). Medullary Thyroid Cancer (MTC): Diagnosis of medullary thyroid cancer (MTC). Disease is one of the following: advanced or metastatic. Disease has presence of rearranged during transfection (RET) gene mutation tumor(s). Disease requires treatment with systemic therapy. Thyroid Cancer: Diagnosis of thyroid cancer. Disease is one of the following: advanced or metastatic. Disease has presence of rearranged during transfection (RET) gene fusion-positive tumor(s). Disease requires treatment with systemic therapy. Thyroid Cancer: Diagnosis of thyroid cancer. Disease is one of the following: advanced or metastatic. Disease has presence of rearranged during transfection (RET) gene fusion-positive tumor(s). Disease requires treatment with systemic therapy. One of the following: patient is radioactive iodine-refractory or radioactive iodine therapy is not appropriate.
Age Restrictions	N/A
Prescriber Restrictions	NSCLC, MTC: Prescribed by or in consultation with an oncologist. Thyroid Cancer: Prescribed by or in consultation with an endocrinologist or an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

# GILENYA (S)

#### **Products Affected**

• Fingolimod

• Gilenya

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS) (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions).
Age Restrictions	N/A
Prescriber Restrictions	MS (initial, reauth): Prescribed by or in consultation with a neurologist
Coverage Duration	MS (initial, reauth): 12 months
Other Criteria	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).

# GILOTRIF (S)

#### **Products Affected**

• Gilotrif

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): A) Diagnosis of advanced or metastatic (stage IIIB or IV) NSCLC AND B) One of the following: 1) Both of the following: a) Tumors have non-resistant epidermal growth factor (EGFR) mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) AND b) GILOTRIF will be used as first-line treatment, OR 2) All of the following: a) disease progressed after platinum-based chemotherapy and b) squamous NSCLC.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### **GLATIRAMER ACETATE (S)**

#### **Products Affected**

• Glatiramer Acetate

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS) (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions).
Age Restrictions	N/A
Prescriber Restrictions	MS (initial, reauth): Prescribed by or in consultation with a neurologist
Coverage Duration	MS (initial, reauth): 12 months
Other Criteria	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).

# **GLEEVEC (S)**

#### **Products Affected**

• Imatinib Mesylate

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	One of the following: A) Diagnosis of Philadelphia chromosome positive (Ph+)/BCR ABL-positive chronic myelogenous leukemia (CML) OR B) Ph+/BCR ABL+ acute lymphoblastic leukemia (ALL) OR C) Gastrointestinal stromal tumor (GIST) AND one of the following: 1) Patient has documented c-KIT (CD117) positive unresectable or metastatic malignant GIST, OR 2) Patient had resection of c-KIT (CD117) positive GIST and imatinib will be used as adjuvant therapy OR D) Dermatofibrosarcoma protuberans that is unresectable, recurrent, or metastatic OR E) Hypereosinophilic syndrome or chronic eosinophilic leukemia OR F) Myelodysplastic syndrome (MDS) or myeloproliferative disease associated with platelet-derived growth factor receptor gene rearrangements OR G) Aggressive systemic mastocytosis without the D816V c-KIT mutation or with c-KIT mutational status unknown.
Age Restrictions	N/A
Prescriber Restrictions	Hypereosinophilic syndrome or chronic eosinophilic leukemia, Aggressive systemic mastocytosis: Prescribed by or in consultation with an oncologist, hematologist, allergist, or immunologist. Dermatofibrosarcoma Protuberans: Prescribed by or in consultation with an oncologist, hematologist or dermatologist. GIST: Prescribed by or in consultation with an oncologist, hematologist or gastroenterologist. All other uses: Prescribed by or in consultation with an oncologist.
Coverage Duration	All uses: 12 months
Other Criteria	All uses: Approve for continuation of prior therapy.

## **GROWTH HORMONE, PREFERRED (S)**

#### **Products Affected**

• Genotropin Miniquick

• Genotropin

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	PGHD(initial):less than 4mo w/suspected GD based on clinical presentation (eg, persistent neonatal hypoglycemia, persistent/prolonged neonatal jaundice/elev bilirubin, male infant with microgenitalia, midline anatomical defects, failure to thrive),OR hx neonatal hypoglycemia assoc w/pituitary dz,or panhypopituitarism dx,or all of the following: PGHD dx [confrmd by ht (utilizing age and gender grwth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.2SSD below population(pop) mean (below 1.2 percentile for age and gender),or grwth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg,delayed more than 2yrs compared w/chronological age)]. PWS(reauth):evidence of positive response to tx(eg,incr in total LBM, decr in fat mass) and expctd adult ht not attained and doc of expctd adult ht goal. GFSGA(initial):SGA dx based on catchup grwth failure in 1st 24mo of life using 0-36mo grwth chart confrmd by birth wt or length below 3rd percentile for gestational age(more than 2SD below pop mean). TS,NS(initial):ped grwth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on grwth charts for age and gender. SHOX(initial):ped grwth failure dx w/SHOX gene deficiency confirmed by genetic testing. GFCRI(initial): ped grwth failure dx assoc w/CRI. ISS(initial):SGA dx, diagnostic eval excluded other causes assoc w/short stature(eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender assoc with growth rates unlikely to permit attainment of adult height in the normal range. PGHD,NS,SHOX,GFCRI,ISS (initial): doc male w/bone age less than 16yrs or female w/bone age less than 14yrs. PGHD,GFSGA,TS/NS,SHOX,GFCRI,ISS(reauth):expctd adult ht not attained and doc of expctd adult ht goal.

Age Restrictions	N/A
Prescriber Restrictions	PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist. GFCRI: prescribed by endocrinologist or nephrologist
Coverage Duration	All uses (initial, reauth): 12 months

Other Criteria	AGHD(initial):dx of AGHD with clin records supporting dx of childhood- onset GHD, or adult-onset GHD w/clin records doe hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg,damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1GH stim test (insulin tolerance test [ITT], arginine/GHRH,glucagon,arginine,macimorelin) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L],[GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2],[glucagon at or below 3mcg/L],[Arg at or below 0.4mcg/L],[macimorelin less than 2.8 mg/mL 30, 45, 60 and 90 mins after admin]) or doc deficiency of 3 anterior pituitary hormones (prolactin, ACTH, TSH, FSH/LH) and IGF-1/somatomedinC below age and gender adjstd nrmI range as provided by physicians lab. AGHD,IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level. TransitionPhaseAdolescent Pts(TPAP)(initial): attained expetd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/ GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones: ACTH,TSH,prolactin,FSH/LH), w/IGF- 1/somatomedinC below age and gender adj nrmI range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,GHRH+ARG,ARG,glucagon,macimorelin) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 3mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 2.8 mg/mL 30, 45, 60 and 90 mins after admin], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon, macimorelin) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 3mcg/L], [Arg at or belo

# HERZUMA (S)

#### **Products Affected**

• Herzuma INJ 420MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Breast cancer: Diagnosis of human epidermal growth factor receptor 2 (HER2)-overexpressing breast cancer. One of the following treatment regimens: a) As adjuvant treatment, b) metastatic disease and one of the following: 1) used in combination with a taxane (eg, docetaxel, paclitaxel), or 2) used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease, or c) used in combination with Perjeta (pertuzumab). Gastric Cancer: Diagnosis of HER2-overexpressing gastric or gastroesophageal junction adenocarcinoma (locally advanced, recurrent, or metastatic). Used in combination with one of the following treatment regimens: a) Platinol (cisplatin) and Adrucil (5-fluorouracil), or b) Platinol (cisplatin) and Xeloda (capecitabine). All indications: One of the following: trial and failure, or intolerance to both Kanjinti (trastuzumab-anns) and Trazimera (trastuzumab-qyyp), OR approve for continuation of prior therapy.
Age Restrictions	N/A
Prescriber Restrictions	All uses: Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### **HRM - MEGESTROL SUSPENSION**

#### **Products Affected**

• Megestrol Acetate SUSP 40MG/ML, 625MG/5ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

### HRM - MEGESTROL TABLET

#### **Products Affected**

• Megestrol Acetate TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Applies to New Starts only.

# HUMIRA (S)

#### **Products Affected**

- Humira
- Humira Pediatric Crohns Disease Starter Pack
- Humira Pen

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

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Trial and failure, contraindication, or intolerance (TF/C/I) to one disease modifying antirheumatic drug (DMARD) [eg, methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)]. Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. TF/C/I to one of the following DMARDs: Arava (leflunomide) or methotrexate (Rheumatrex/Trexall). Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. TF/C/I to two NSAIDs (e.g., diclofenac, ibuprofen, meloxicam, naproxen). Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex/Trexall). Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex/Trexall). Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. TF/C/I to one of the following conventional therapies: 6- mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), aminosalicylate [eg, mesalamine (Asacol, Pentasa, Rowasa), Dipentum (olsalazine), Azulfidine (sulfasalazine)]. Hidradenitis suppurativa (Initial): Diagnosis of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). Uveitis (initial): Diagnosis of non- infectious uveitis, classified as intermediate, posterior, or panuveitis.
Age Restrictions	N/A

Prescriber Restrictions	RA, AS, JIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque Psoriasis, HS (initial): Prescribed by or in consultation with a dermatologist. CD, UC (initial): Prescribed by or in consultation with a gastroenterologist. Uveitis (initial): Prescribed by or in consultation with an ophthalmologist or rheumatologist.
Coverage Duration	UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial, reauth): 12 mo.
Other Criteria	RA, JIA, PsA, AS, CD, Hidradenitis suppurativa (HS), Uveitis (Reauth): Documentation of positive clinical response to therapy. Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. UC (Reauth): For patients who initiated therapy within the past 12 weeks: Documentation of clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy OR For patients who have been maintained on therapy for longer than 12 weeks: Documentation of positive clinical response to therapy.

### **IBRANCE (S)**

#### **Products Affected**

• Ibrance

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Breast Cancer: Diagnosis of advanced or metastatic breast cancer. Disease is a) hormone receptor (HR)-positive, and b) human epidermal growth factor receptor 2 (HER2)-negative. One of the following: 1) used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) and one of the following: a) patient is a male, or b) patient is a postmenopausal woman, OR 2) both of the following: used in combination with Faslodex (fulvestrant) and disease has progressed following endocrine therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## ICLUSIG (S)

#### **Products Affected**

• Iclusig

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic myelogenous leukemia: Diagnosis of chronic myelogenous leukemia AND One of the following: A) Trial and failure, contraindication, or intolerance to at least TWO other tyrosine kinase inhibitors (e.g., Gleevec [imatinib], Sprycel, Tasigna, and Bosulif) or B) Patient has the T315I mutation. Acute Lymphoblastic Leukemia: Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) AND One of the following: A) Trial and failure, resistance relapse, contraindication, or intolerance to at least TWO other FDA-approved tyrosine kinase inhibitors (e.g., Gleevec [imatinib], Sprycel), or B) Patient has the T315I mutation.
Age Restrictions	N/A
Prescriber Restrictions	All uses: Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	All uses: 12 months
Other Criteria	All uses: Approve for continuation of prior therapy.

## IDHIFA (S)

#### **Products Affected**

• Idhifa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acute Myeloid Leukemia (AML): Diagnosis of AML. Disease is relapsed or refractory. Patient has an isocitrate dehydrogenase-2 (IDH2) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., Abbott RealTime IDH2 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### ILUMYA (S)

#### **Products Affected**

• Ilumya

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Plaque Psoriasis (initial): Diagnosis of moderate-to-severe plaque psoriasis. Trial and failure, contraindication, or intolerance to two of the following: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab), Cosentyx (secukinumab), or for continuation of prior therapy.
Age Restrictions	N/A
Prescriber Restrictions	Plaque Psoriasis (initial): Prescribed by or in consultation with a dermatologist
Coverage Duration	Initial, reauth: 12 months
Other Criteria	Plaque Psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline.

## **IMBRUVICA (S)**

#### **Products Affected**

• Imbruvica

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Mantle cell lymphoma (MCL): Diagnosis of MCL AND patient has relapsed or is refractory to at least one prior therapy for the treatment of MCL. Chronic lymphocytic leukemia (CLL): Diagnosis of CLL. Waldenstrom's macroglobulinemia: Diagnosis of Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma. Small lymphocytic lymphoma (SLL): Diagnosis of SLL. Marginal zone lymphoma (MZL): Diagnosis of MZL AND patient has received at least one prior anti-CD20- based therapy for MZL [e.g., Rituxan (rituximab), Zevalin (ibritumomab), Gazyva (obinutuzumab, etc.)]. Chronic graft versus host disease (cGVHD): Diagnosis of cGVHD AND trial and failure of one or more lines of systemic therapy (e.g., corticosteroids like prednisone or methylprednisolone, mycophenolate).
Age Restrictions	N/A
Prescriber Restrictions	All uses (except chronic graft versus host disease): Prescribed by or in consultation with an oncologist or hematologist. Chronic graft versus host disease: Prescribed by or in consultation with a hematologist, oncologist, or physician experienced in the management of transplant patients.
Coverage Duration	All Uses: 12 months
Other Criteria	All Uses: Approve for continuation of prior therapy.

## **INCRELEX (S)**

#### **Products Affected**

• Increlex

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Insulin-like Growth Factor-1 (IGF-1) deficiency (initial): Diagnosis of severe primary IGF-1 deficiency. Height standard deviation score of -3.0 or less. Basal IGF-1 standard deviation score of -3.0 or less. Normal or elevated growth hormone (GH). GH gene deletion (initial): Diagnosis of GH gene deletion in patients who have developed neutralizing antibodies to GH.
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with an endocrinologist
Coverage Duration	Initial, reauth: 12 months
Other Criteria	(Reauth): Documentation of positive clinical response to therapy.

### INLYTA (S)

#### **Products Affected**

• Inlyta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Renal cell carcinoma (RCC): Diagnosis of RCC. One of the following: (1) disease has relapsed or (2) diagnosis of stage IV disease.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### INQOVI (S)

#### **Products Affected**

• Inqovi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Myelodysplastic syndrome (MDS): Diagnosis of myelodysplastic syndrome.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## **INREBIC (S)**

#### **Products Affected**

• Inrebic

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Myelofibrosis: Diagnosis of one of the following: primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### INTRON A (S)

#### **Products Affected**

• Intron A

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic hepatitis B: Diagnosis of chronic hepatitis B infection, and patient is without decompensated liver disease. Chronic Hepatitis C: Diagnosis of chronic hepatitis C, patient without decompensated liver disease, patient has not previously been treated with interferon, and one of the following - 1) used in combination with ribavirin or 2) contraindication or intolerance to ribavirin. Metastatic renal cell carcinoma (RCC): diagnosis of metastatic RCC, used in combination with Avastin (bevacizumab). Other: diagnosis of condylomata acuminata (genital or perianal), diagnosis of hairy cell leukemia, diagnosis of AIDS- related Kaposi's sarcoma, diagnosis of malignant melanoma, diagnosis of Stage III or IV follicular Non-Hodgkin's Lymphoma.
Age Restrictions	N/A
Prescriber Restrictions	RCC: Prescribed by or in consultation with an oncologist.
Coverage Duration	HepB, HepC: 48 wks. Condylomata acuminata (genital or perianal): 6 wks. Other: 12 months
Other Criteria	Approve for continuation of prior therapy.

### IRESSA (S)

#### **Products Affected**

• Iressa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC AND Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## **ISOTRETINOIN (S)**

#### **Products Affected**

- Amnesteem
- Claravis

- Isotretinoin CAPS 10MG, 20MG, 30MG, 40MG
- Myorisan
- Zenatane

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acne (initial): Diagnosis of acne. One of the following: A) Prescribed by a dermatologist or, B) Trial and failure, contraindication or intolerance to an adequate trial (at least 6 weeks) on two of the following conventional therapy regimens: a) topical retinoid or retinoid-like agent [eg, Retin- A/Retin-A Micro (tretinoin)], b) oral antibiotic [eg, Ery-Tab (erythromycin), Minocin (minocycline)], c) topical antibiotic with or without benzoyl peroxide [eg, Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl peroxide/erythromycin)].
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Acne (initial): 5 months. Acne (reauth): Retreatment - 5 months, Dose Titration - 1 month
Other Criteria	Acne, Retreatment (reauth): After more than 2 months off therapy, persistent or recurring acne is still present. Acne, Dose Titration (reauth): Confirmation that the total cumulative dose is less than 150 mg/kg.

# **ISTODAX (S)**

#### **Products Affected**

• Romidepsin INJ 27.5MG/5.5ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cutaneous T-cell lymphoma (CTCL): Diagnosis of CTCL. Trial and failure, contraindication, or intolerance to at least one systemic therapy for the treatment of CTCL [e.g., Trexall (methotrexate), Targretin (bexarotene), cyclophosphamide] Peripheral T-cell lymphoma (PTCL): Diagnosis of PTCL. Trial and failure, contraindication, or intolerance to at least one therapy for the treatment of PTCL (e.g., conventional chemotherapy such as CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone), CHOEP (cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone), Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin), HyperCVAD (cyclophosphamide, vincristine, doxorubicin, dexamethasone) alternating with high-dose methotrexate and cytarabine).
Age Restrictions	N/A
Prescriber Restrictions	CTCL, PTCL: Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## **ISTURISA (S)**

## **Products Affected**

• Isturisa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cushing's disease (initial): Diagnosis of Cushing's disease. One of the following: a) Patient is not a candidate for pituitary surgery, OR b) Pituitary surgery has not been curative for the patient.
Age Restrictions	N/A
Prescriber Restrictions	Cushing's disease (initial): Prescribed by or in consultation with an endocrinologist.
Coverage Duration	Cushing's disease (initial, reauth): 12 months
Other Criteria	Cushing's disease (reauth): Documentation of positive clinical response to therapy (e.g., a clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs or symptoms of the disease).

## **IVERMECTIN (S)**

### **Products Affected**

• Ivermectin TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Strongyloidiasis: Diagnosis of intestinal (i.e., nondisseminated) strongyloidiasis due to the nematode parasite Strongyloides stercoralis OR both of the following: member received the drug within the past 120 days and member requires continuation of therapy. Onchocerciasis: Diagnosis of onchocerciasis due to the nematode parasite Onchocerca volvulus OR both of the following: member received the drug within the past 120 days and member requires continuation of therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Strongyloidiasis: 3 weeks. Onchocerciasis: 6 months.
Other Criteria	N/A

### **Products Affected**

• Bivigam INJ 5GM/50ML

• Gammagard S/d Iga Less Than 1mcg/ml INJ 5GM

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	All uses (initial, reauth): Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication).
Required Medical Information	Initial: Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. For IVIG – Ig is being used intravenously (IV) AND One of the following diagnoses: [A] Primary Immunodeficiency 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patient's age at the time of diagnosis and the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). [B] Secondary Acquired Antibody Deficiency 1) B-cell chronic lymphocytic leukemia with an Ig level less than 500 mg/dL OR history of recurrent bacterial infections. 2) HIV infection with an Ig level less than 10 x 109/L. 3) Multiple myeloma in plateau phase and patient has hypogammaglobulinemia. [C] Hematological Autoimmune Disorders 1) Acquired (pure) red cell aplasia (PRCA) that is immunologic and patient had a trial and failure, contraindication, or intolerance (TF/C/I) to a corticosteroid and an immunosuppressant (i.e., cyclophosphamide, cyclosporine) OR patient has viral PRCA caused by parvovirus B19. 2) Fetal alloimmune thrombocytopenia. 3) Hemolytic disease of the newborn and the patient has established hyperbilirubinemia. 4) Idiopathic thrombocytopenic purpura and patient had a TF/C/I to a corticosteroid OR a platelet count less than 30,000 cells/mm3. Continued in Other Criteria Section.
Age Restrictions	HIV (initial): patient is less than or equal to 12 years of age.

Prescriber Restrictions	All uses (initial, reauth): Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist).
Coverage Duration	4 months: Solid organ transplant. 12 months: all other diagnoses.
Other Criteria	<ul> <li>[D] Neuromuscular Autoimmune Disorders 1) Chronic inflammatory demyelinating polyneuropathy. 2) Guillain-Barré syndrome. 3)</li> <li>Inflammatory myopathies (dermatomyositis or polymyositis) AND</li> <li>Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, methotrexate, cyclosporine A, cyclophosphamide, or tacrolimus). 4) Lambert-Eaton myasthenic syndrome AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (e.g., azathioprine). 5) Multifocal motor neuropathy. 6) Myasthenia gravis with severe exacerbations or myasthenic crises AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, cyclophosphamide, or mycophenolate mofetil). 7) Stiff person syndrome AND Patient had a TF/C/I to at least 2 standard therapies (i.e., benzodiazepines, muscle relaxants, or anti-convulsants).</li> <li>[E] Other Disorders 1) Autoimmune blistering disease AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., cyclophosphamide, dapsone, methotrexate, azathioprine, or mycophenolate mofetil). 2) Kawasaki syndrome. 3) Solid organ transplant and IVIG is being used for CMV prophylaxis, or patient is a kidney transplant recipient and has donor specific antibodies, or patient has steroid-resistant rejection and had a TF/C/I to standard therapies. For SCIG (Gamunex-C, Gammagard Liquid, Gammaked only)- Immune globulin is being used subcutaneously AND One of the following PI diagnoses: 1) Common variable immunodeficiency. 2) Congenital agarmaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunologic evaluation including IgG levels below the normal laboratory value for the patient's age at the time of diagnosis and patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxiod or diphtheria toxoid and pneumovax or HiB vaccine). All products: Subject to Part B vs. Part D review. For non-oncology renewal, the patient has experienced an objective improvement on immune globulin therap</li></ul>

## JAKAFI (S)

### **Products Affected**

• Jakafi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Myelofibrosis: Diagnosis of primary myelofibrosis, OR post- polycythemia vera myelofibrosis, OR post-essential thrombocythemia myelofibrosis. Polycythemia vera: Diagnosis of polycythemia vera, AND trial and failure, contraindication, or intolerance to hydroxyurea. Acute graft versus host disease (aGVHD): Diagnosis of aGVHD. Disease is steroid-refractory. Chronic graft versus host disease (cGVHD): Diagnosis of cGVHD. Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.).
Age Restrictions	N/A
Prescriber Restrictions	Myelofibrosis, Polycythemia vera: Prescribed by or in consultation with a hematologist/oncologist. aGVHD, cGVHD: Prescribed by or in consultation with one of the following: hematologist, oncologist, physician experienced in the management of transplant patients.
Coverage Duration	12 months.
Other Criteria	Approve for continuation of prior therapy.

## **JUXTAPID (S)**

### **Products Affected**

• Juxtapid

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Homozygous familial hypercholesterolemia (HoFH) (initial): Submission of medical records (eg, chart notes, laboratory values) documenting diagnosis of HoFH as confirmed by one of the following: a) genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (ie, LDLRAP1 or ARH), or b) both of the following: 1) either untreated/pre-treatment LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL AND 2) either xanthoma before 10 years of age or evidence of heterozygous FH in both parents. One of the following: a) patient is receiving other lipid-lowering therapy, or b) patient has an inability to take other lipid-lowering therapy. Trial and failure, contraindication, or intolerance to Repatha therapy. Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor.
Age Restrictions	N/A
Prescriber Restrictions	HoFH (initial, reauth): Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist.
Coverage Duration	HoFH (initial): 6 months. (reauth): 12 months
Other Criteria	HoFH (reauthorization): One of the following: a) patient continues to receive other lipid-lowering therapy, or b) patient has an inability to take other lipid-lowering therapy. Submission of medical records (eg, chart notes, laboratory values) documenting LDL-C reduction from baseline while on therapy. Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor.

# KALYDECO (S)

### **Products Affected**

• Kalydeco

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cystic Fibrosis (CF) (Initial): Diagnosis of cystic fibrosis. Patient has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data as detected by a U.S. Food and Drug Administration (FDA)-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	CF (Initial): 4 months of age or older
Prescriber Restrictions	CF (initial): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist
Coverage Duration	CF (initial, reauth): 12 months
Other Criteria	CF (Reauth): Documentation of positive clinical response (i.e. improvement in lung function [percent predicted forced expiratory volume in one second (PPFEV1)], decreased number of pulmonary exacerbations) while on therapy.

# KANJINTI (S)

### **Products Affected**

• Kanjinti

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Breast cancer: Diagnosis of human epidermal growth factor receptor 2 (HER2)-overexpressing breast cancer. One of the following treatment regimens: a) As adjuvant treatment, b) metastatic disease and one of the following: 1) used in combination with a taxane (eg, docetaxel, paclitaxel), or 2) used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease, or c) used in combination with Perjeta (pertuzumab). Gastric Cancer: Diagnosis of HER2-overexpressing gastric or gastroesophageal junction adenocarcinoma (locally advanced, recurrent, or metastatic). Used in combination with one of the following treatment regimens: a) Platinol (cisplatin) and Adrucil (5-fluorouracil), or b) Platinol (cisplatin) and Xeloda (capecitabine).
Age Restrictions	N/A
Prescriber Restrictions	All uses: Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# KANUMA (S)

### **Products Affected**

• Kanuma

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Lysosomal acid lipase deficiency: Diagnosis of lysosomal acid lipase deficiency (LAL-D). Diagnosis was confirmed by an enzymatic blood (e.g., dried blood spot test) or genetic test.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a specialist experienced in the treatment of inborn errors of metabolism, gastroenterologist, or lipidologist
Coverage Duration	12 months
Other Criteria	N/A

# **KESIMPTA (S)**

### **Products Affected**

• Kesimpta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS) (Initial): Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing- remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: 1) Failure after a trial of at least 4 weeks, contraindication, or intolerance to one of the following: A) Aubagio (teriflunomide), B) Mavenclad (cladribine), C) Plegridy (peginterferon beta-1a), D) Any one of the interferon beta-1a injections (eg, Avonex), E) Any one of the interferon beta-1b injections (eg, Betaseron, Extavia), F) Any one of the oral fumarates (eg, brand Tecfidera, generic dimethyl fumarate), G) Any one of the glatiramer acetates (eg, Copaxone, Glatopa, generic glatiramer acetate), H) Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (eg, Gilenya [fingolimod], Mayzent [siponimod], Zeposia [ozanimod]), OR 2) For continuation of prior therapy. Not used in combination with another disease-modifying therapy for MS. Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ocrelizumab [Ocrevus]).
Age Restrictions	N/A
Prescriber Restrictions	MS (Initial, Reauth): Prescribed by or in consultation with a neurologist
Coverage Duration	MS (Initial, Reauth): 12 months
Other Criteria	MS (Reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapse, or disease progression). Not used in combination with another disease-modifying therapy for MS. Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ocrelizumab [Ocrevus]).

# KISQALI (S)

### **Products Affected**

• Kisqali

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Breast cancer: Diagnosis of advanced or metastatic breast cancer. Disease is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative. One of the following: A) Used in combination with an aromatase inhibitor [e.g., Femara (letrozole)] OR B) Used in combination with Faslodex (fulvestrant).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

## KISQALI-FEMARA PACK (S)

### **Products Affected**

• Kisqali Femara 200 Dose

- Kisqali Femara 400 Dose
- Kisqali Femara 600 Dose

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Breast cancer: Diagnosis of advanced or metastatic breast cancer. Disease is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative. One of the following: A) Patient is postmenopausal OR B) Both of the following: a) Patient is pre/perimenopausal or male AND b) Treated with a Luteinizing Hormone-Releasing Hormone (LHRH) agonist (e.g. leuprolide).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# KORLYM (S)

### **Products Affected**

• Korlym

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cushing's syndrome (Initial): Diagnosis of endogenous Cushing's syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids). Diagnosis of either type 2 diabetes mellitus or diagnosis of glucose intolerance. Patient has either failed surgery or patient is not a candidate for surgery. Patient is not pregnant.
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with an endocrinologist.
Coverage Duration	Initial, reauth: 6 months
Other Criteria	Reauth: Documentation of one of the following: patient has improved glucose tolerance while on therapy or patient has stable glucose tolerance while on therapy.

# KOSELUGO (S)

### **Products Affected**

• Koselugo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Neurofibromatosis Type 1 (NF1): Diagnosis of NF1. Patient has plexiform neurofibromas that are both of the following: inoperable and causing significant morbidity (e.g., disfigurement, motor dysfunction, pain, airway dysfunction, visual impairment). Patient is able to swallow a capsule whole.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with one of the following: oncologist or neurologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## KUVAN (S)

### **Products Affected**

• Sapropterin Dihydrochloride

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Phenylketonuria (PKU) (initial): Diagnosis of PKU. Patient will have blood Phe levels measured after 1 week of therapy (new starts to therapy only) and periodically for up to 2 months of therapy to determine response.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	PKU (Init): 2 months (Reauth): 12 months
Other Criteria	PKU (reauth): Documentation of a positive clinical response to therapy. Patient will continue to have blood Phe levels measured periodically during therapy.

## **KYNMOBI (S)**

#### **Products Affected**

• Kynmobi

**PA** Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A Exclusion Parkinson's disease (PD) (Initial): Not used with any 5-HT3 antagonist Criteria (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron) Required Parkinson's disease (PD) (Initial): Diagnosis of PD. Patient is Medical experiencing acute intermittent hypomobility (defined as "off" episodes characterized by muscle stiffness, slow movements, or difficulty starting Information movements). Used in combination with other medications for the treatment of PD (e.g., carbidopa/levodopa, pramipexole, ropinirole, etc.). **Age Restrictions** N/A Prescriber PD (Initial): Prescribed by or in consultation with a neurologist. Restrictions Coverage PD (Initial, reauth): 12 months Duration **Other Criteria** PD (Reauth): Documentation of positive clinical response to therapy.

• Kynmobi Titration Kit

## LEMTRADA (S)

## **Products Affected**

• Lemtrada

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: 1) Patient has not been previously treated with alemtuzumab, and failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS: A) Aubagio (teriflunomide), B) Mavenclad (cladribine), C) Plegridy (peginterferon beta-1a), D) Tysabri (natalizumab), E) Any one of the interferon beta-1a injections (eg, Avonex), F) Any one of the interferon beta-1b injections (eg, Betaseron, Extavia), G) Any one of the oral fumarates (eg, brand Tecfidera, generic dimethyl fumarate), H) Any one of the glatiramer acetate injections (eg, Copaxone, Glatopa, generic glatiramer acetate), I) Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (eg, Gilenya [fingolimod], Mayzent [siponimod], Zeposia [ozanimod]), J) Any one of the B-cell targeted therapies (eg, Ocrevus [ocrelizumab], Kesimpta [ofatumumab]), or 2) Patient has previously received treatment with alemtuzumab, and at least 12 months have or will have elapsed since the most recent treatment course with alemtuzumab. Not used in combination with another disease-modifying therapy for MS.
Age Restrictions	N/A
Prescriber Restrictions	MS: Prescribed by or in consultation with a neurologist
Coverage Duration	MS: 12 months.
Other Criteria	N/A

## LENVIMA (S)

#### **Products Affected**

- Lenvima 10 Mg Daily Dose
- Lenvima 12mg Daily Dose
- Lenvima 14 Mg Daily Dose
- Lenvima 18 Mg Daily Dose

- Lenvima 20 Mg Daily Dose
- Lenvima 24 Mg Daily Dose
- Lenvima 4 Mg Daily Dose
- Lenvima 8 Mg Daily Dose

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Differentiated thyroid cancer (DTC): Diagnosis of DTC. Disease is locally recurrent or metastatic. Patient has symptomatic or progressive disease. Disease is refractory to radioactive iodine treatment. Renal Cell Carcinoma (RCC): Diagnosis of advanced RCC. One of the following: 1) Both of the following: a) Used as first-line treatment and b) Used in combination with Keytruda (pembrolizumab), or 2) Both of the following: a) Treatment follows one prior anti-angiogenic therapy and b) Used in combination with everolimus. Hepatocellular Carcinoma (HCC): Diagnosis of HCC. One of the following: patient has metastatic disease, or patient has extensive liver tumor burden, or patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only), or disease is unresectable. Endometrial Carcinoma (EC): Diagnosis of advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR). Patient has disease progression following systemic therapy. Used in combination with Keytruda (pembrolizumab) therapy. Patient is not a candidate for curative surgery or radiation.
Age Restrictions	N/A
Prescriber Restrictions	DTC/RCC/EC: Prescribed by or in consultation with an oncologist. HCC: Prescribed by or in consultation with one of the following: oncologist, hepatologist, or gastroenterologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## LETAIRIS (S)

## **Products Affected**

• Ambrisentan

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
Age Restrictions	N/A
Prescriber Restrictions	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH (Initial): 6 months. PAH (Reauth): 12 months
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.

## **LIDOCAINE TOPICAL (S)**

### **Products Affected**

- Glydo
- Lidocaine OINT 5%
- Lidocaine Hcl PRSY
- Lidocaine Hcl Jelly PRSY

- Lidocaine/prilocaine CREA
- Lidocaine-prilocaine-cream Base CREA 2.5%; 2.5%
- Premium Lidocaine

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	N/A

## LIDODERM (S)

### **Products Affected**

• Lidocaine PTCH 5%

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Post-herpetic neuralgia: Diagnosis of post-herpetic neuralgia.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

## LIVMARLI (S)

### **Products Affected**

• Livmarli

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Alagille syndrome (ALGS) (initial): Both of the following: a) Diagnosis of ALGS, and b) Molecular genetic testing confirms mutations in the JAG1 or NOTCH2 gene. Documentation of ONE of the following: a) Total serum bile acid greater than 3 times the upper limit of normal (ULN), b) Conjugated bilirubin greater than 1 mg/dL, c) Fat soluble vitamin deficiency otherwise unexplainable, or d) Gammaglutamyl transpeptidase (GGT) greater than 3 times the ULN. Patient is experiencing moderate to severe cholestatic pruritus. Patient has had an inadequate response to at least two of the following treatments used for the relief of pruritus: a) Ursodeoxycholic acid (e.g., Ursodiol), b) Antihistamines (e.g., diphenhydramine, hydroxyzine), c) Rifampin, or d) Bile acid sequestrants (e.g., Questran, Colestid, Welchol).
Age Restrictions	ALGS (initial): Patient is 1 year of age or older.
Prescriber Restrictions	ALGS (initial): Prescribed by or in consultation with a hepatologist.
Coverage Duration	ALGS (initial, reauth): 12 months.
Other Criteria	ALGS (reauth): Documentation of positive clinical response to therapy (e.g., reduced bile acids, reduced pruritus severity score).

## LONSURF (S)

### **Products Affected**

• Lonsurf

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Colorectal Cancer: Diagnosis of metastatic colorectal cancer AND trial and failure, contraindication, or intolerance to at least one component in the following: fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI) AND trial and failure, contraindication, or intolerance to at least one anti-VEGF therapy (e.g., bevacizumab)) AND One of the following: A) patient has RAS wild-type tumors and trial and failure, contraindication, or intolerance to at least one anti-EGFR therapy (e.g., Vectibix, Erbitux) OR Patient has RAS mutant tumors. Gastric/Gastroesophageal Junction Adenocarcinoma: Diagnosis of metastatic gastric cancer or diagnosis of metastatic gastroesophageal junction adenocarcinoma. Trial and failure, contraindication or intolerance to at least two of the following: fluropyrimidine-based chemotherapy (e.g. fluorouracil), Platinum-based chemotherapy (e.g., carboplatin, cisplatin, oxaliplatin), Taxane (e.g., docetaxel, paclitaxel) or irinotecan-based chemotherapy, HER2/neu- targeted therapy (e.g., trastuzumab) (if HER2 overexpression).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# LORBRENA (S)

### **Products Affected**

• Lorbrena

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC. Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# LOTRONEX (S)

### **Products Affected**

• Alosetron Hydrochloride

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Severe Diarrhea-Predominant Irritable Bowel Syndrome (IBS) in Women (initial): All of the following: 1) diagnosis of severe diarrhea-predominant IBS, 2) symptoms for at least 6 months, 3) female patient, AND 4) trial and failure, contraindication, or intolerance to an antidiarrheal agent [eg, loperamide].
Age Restrictions	Initial: 18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	IBS (initial): 12 weeks. IBS (reauth): 6 mo.
Other Criteria	IBS (reauthorization): Symptoms of IBS continue to persist, AND documentation of positive clinical response to therapy.

## LUMAKRAS (S)

### **Products Affected**

• Lumakras

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is one of the following: a) locally advanced or b) metastatic. Tumor is KRAS G12C-mutated as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has received at least one prior systemic therapy (e.g., cisplatin/pemetrexed, atezolizumab, nivolumab, capmatinib).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## LUMIZYME (S)

### **Products Affected**

• Lumizyme

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Pompe disease: Diagnosis of Pompe disease [acid alpha-glucosidase (GAA) deficiency].
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

# LUPRON (S)

## **Products Affected**

• Leuprolide Acetate INJ 1MG/0.2ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prostate Cancer: Diagnosis of advanced or metastatic prostate cancer.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Prostate CA: 12 months
Other Criteria	Approve for continuation of prior therapy.

## LUPRON DEPOT (S)

### **Products Affected**

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

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

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prostate Cancer (7.5 mg, 22.5 mg, 30 mg, 45 mg): Diagnosis of advanced or metastatic prostate cancer. Endometriosis (3.75 mg, 11.25 mg): Diagnosis of endometriosis. One of the following: Patient has had surgical ablation to prevent recurrence, or trial and failure, contraindication, or intolerance to one NSAID (e.g., diclofenac, ibuprofen, meloxicam, naproxen) and one oral contraceptive (e.g., norethindrone-ethinyl estradiol, estradiol and norethindrone). Uterine Leiomyomata (UL) (3.75 mg, 11.25 mg): a) For use prior to surgery to reduce size of fibroids to facilitate a surgical procedure (eg, myomectomy, hysterectomy) OR b) all of the following: treatment of anemia, anemia is caused by uterine leiomyomata (fibroids), and for use prior to surgery.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Prostate CA: 12 mo. Endomet:6mo. UL (anemia):3 mo (fibroids):4 mo
Other Criteria	Approve for continuation of prior therapy.

## LYNPARZA TABLET (S)

### **Products Affected**

• Lynparza TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: recurrent epithelial ovarian cancer, recurrent fallopian tube cancer, or recurrent primary peritoneal cancer. Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin). High risk early breast cancer: Diagnosis of high risk early breast cancer. Presence of a deleterious or suspected deleterious germline BRCA-mutation as detected by an FDA- approved test or a test performed at a facility approved by CLIA. Disease is human epidermal growth factor receptor 2 (HER2)-negative. Patient has been previously treated with neoadjuvant and adjuvant chemotherapy (e.g., anthracycline, taxane). Metastatic breast cancer: Diagnosis of metastatic breast cancer. Presence of a deleterious or suspected deleterious germline BRCA-mutation as detected by an FDA- approved test or a test performed at a facility approved by CLIA. Disease is human epidermal growth factor receptor 2 (HER2)-negative. Patient has been previously treated with neoadjuvant and adjuvant chemotherapy (e.g., anthracycline, taxane). Metastatic breast cancer: Diagnosis of metastatic breast cancer. Presence of a deleterious or suspected deleterious germline BRCA-mutation as detected by an FDA-approved test or a test performed at a facility approved by CLIA. Disease is HER2- negative. Patient has been previously treated with chemotherapy (e.g., anthracycline, taxane) in the neoadjuvant, adjuvant, or metastatic setting. One of the following: a) Disease is hormone receptor (HR)-negative, or b) Disease is HR-positive and one of the following: i) patient has been treated with prior endocrine therapy or ii) patient is considered an inappropriate candidate for endocrine therapy.
Age Restrictions	N/A
Prescriber Restrictions	All uses (except prostate cancer): Prescribed by or in consultation with an oncologist. Prostate cancer: Prescribed by or in consultation with an oncologist or urologist.
Coverage Duration	12 months

Other Criteria	First-line maintenance treatment of BRCA-mutated advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: advanced epithelial ovarian cancer, advanced fallopian tube cancer, or advanced primary peritoneal cancer. Presence of deleterious or suspected deleterious BRCA-mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has had a complete or partial response to first-line platinum-based chemotherapy (e.g., carboplatin, cisplatin). Will be used as first-line maintenance treatment. Pancreatic adenocarcinoma: Diagnosis of metastatic pancreatic adenocarcinoma. Presence of a deleterious or suspected deleterious germline BRCA-mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Disease has not progressed while receiving at least 16 weeks of a first-line platinum-based chemotherapy regimen (e.g., FOLFIRINOX, FOLFOX, etc.). First-line maintenance treatment of HRD-positive advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer in combination with bevacizumab: Diagnosis of advanced primary peritoneal cancer. Cancer is associated with homologous recombination deficiency (HRD)-positive status (defined by either: a deleterious or suspected deleterious BRCA mutation, and/or genomic instability) as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has had a complete or partial response to first-line platinum-based chemotherapy (e.g., carboplatin, cisplatin). Used in combination with bevacizumab (e.g., Avastin, Mvasi). Will be used as first-line maintenance treatment. Prostate cancer: Diagnosis of metastatic castration-resistant prostate cancer. Presence of deleterious or suspected deleterious for paretioned at a facilit

## MAKENA (S)

### **Products Affected**

• Makena INJ 275MG/1.1ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Preterm birth prophylaxis: Patient had a previous singleton (single offspring) spontaneous preterm birth. Patient is having a singleton pregnancy. Therapy will be started between 16 weeks, 0 days and 20 weeks, 6 days of gestation. Therapy will be continued until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first.
Age Restrictions	N/A
Prescriber Restrictions	Preterm birth prophylaxis: Prescribed by or in consultation with a specialist in obstetrics and gynecology
Coverage Duration	Preterm birth prophylaxis: 21 weeks
Other Criteria	N/A

# MARINOL (S)

### **Products Affected**

• Dronabinol

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Nausea and Vomiting Associated with Cancer Chemotherapy (CINV): Patient is receiving cancer chemotherapy. Trial and failure, contraindication, or intolerance to one 5HT-3 receptor antagonist (eg, Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]). Trial and failure, contraindication, or intolerance to one of the following: Compazine (prochlorperazine), Decadron (dexamethasone), Haldol (haloperidol), Zyprexa (olanzapine). AIDS anorexia: Diagnosis of anorexia with weight loss in patients with AIDS. Patient is on antiretroviral therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CINV: 6 months. AIDS anorexia: 3 months.
Other Criteria	Subject to Part B vs. Part D review. CINV: Approve for continuation of therapy for treatment covered under Part B when patient is receiving cancer chemotherapy.

## **MAVYRET (S)**

### **Products Affected**

• Mavyret

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Criteria will be applied consistent with current AASLD/IDSA guideline. All patients: Diagnosis of chronic hepatitis C, patient is without decompensated liver disease (defined as Child-Pugh Class B or C), and not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni, Zepatier].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine.
Coverage Duration	8 to 16 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.
Other Criteria	N/A

## **MEKINIST (S)**

### **Products Affected**

• Mekinist

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Melanoma: Diagnosis of unresectable or metastatic melanoma AND cancer is BRAF V600E or V600K mutant type as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Adjuvant Treatment for Melanoma: Diagnosis of melanoma. Cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Involvement of lymph nodes following complete resection. Used as adjunctive therapy. Medication is used in combination with Tafinlar (dabrafenib).Non-small Cell Lung Cancer (NSCLC): All of the following: diagnosis of metastatic non-small cell lung cancer AND cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) AND medication is used in combination with Tafinlar (dabrafenib). Anaplastic Thyroid Cancer (ATC): Diagnosis of locally advanced or metastatic ATC. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID- BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Cancer may not be treated with standard locoregional treatment options. Medication is used in combination with Tafinlar (dabrafenib).
Age Restrictions	Solid tumors: Patient is 6 years of age or older.
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months

Other Criteria	Approve for continuation of prior therapy. Solid tumors: Diagnosis of solid tumors. Disease is unresectable or metastatic. Patient has progressed on or following prior treatment and have no satisfactory alternative treatment options. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
	Medication is used in combination with Tafinlar (dabrafenib).

## **MEKTOVI (S)**

### **Products Affected**

• Mektovi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma. Cancer is BRAF V600E or V600K mutant type (MT) as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with Braftovi (encorafenib).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

### **Products Affected**

• Dihydroergotamine Mesylate NASAL SOLN

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Diagnosis of migraine headaches with or without aura. Will be used for the acute treatment of migraine. One of the following: Trial and failure or intolerance to one triptan (e.g., eletriptan, rizatriptan, sumatriptan) or contraindication to all triptans.
Age Restrictions	N/A
Prescriber Restrictions	Initial, Reauth: Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.
Coverage Duration	Initial: 3 months. Reauth: 12 months.
Other Criteria	Reauth: Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea).

## MONJUVI (S)

### **Products Affected**

• Monjuvi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diffuse Large B-cell Lymphoma (DLBCL): Diagnosis of DLBCL. Disease is one of the following: relapsed or refractory. Used in combination with lenalidomide. Patient is not eligible for autologous stem cell transplant (ASCT).
Age Restrictions	N/A
Prescriber Restrictions	DLBCL: Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### Ms Interferons (preferred) (s)

#### **Products Affected**

• Betaseron

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS) (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions).
Age Restrictions	N/A
Prescriber Restrictions	MS (initial, reauth): Prescribed by or in consultation with a neurologist
Coverage Duration	MS (initial, reauth): 12 months
Other Criteria	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).

### **Products Affected**

• Mvasi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Non-Small Cell Lung Cancer: Excluded if squamous cell histology.
Required Medical Information	Colorectal Cancer: Diagnosis of metastatic colorectal cancer. One of the following: 1) Both of the following: a) used as first- or second-line treatment and b) used in combination with an intravenous 5-fluorouracil-based chemotherapy, OR 2) All of the following: a) used as second-line treatment, b) used in combination with fluoropyrimidine-irinotecan-based chemotherapy or fluoropyrimidine-oxaliplatin-based chemotherapy, and c) patient has progressed on a first-line bevacizumab-containing regimen. Non-Small Cell Lung Cancer (NSCLC): Diagnosis of NSCLC. Disease is unresectable, locally advanced, recurrent, or metastatic. Used as first-line treatment. Used in combination with paclitaxel and carboplatin. Renal Cell Cancer: Diagnosis of metastatic renal cell cancer. Used in combination with paclitaxel and carboplatin. Renal Cell Cancer: Diagnosis of metastatic renal cell cancer. Used in combination with one of the following: a) paclitaxel and cisplatin or b) paclitaxel and topotecan. Glioblastoma: Diagnosis of recurrent glioblastoma. Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer: Diagnosis of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. One of the following: 1) All of the following: a) disease is platinum-resistant recurrent, b) patient has received no more than 2 prior chemotherapy regimens, and c) used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, OR 3) All of the following: a) disease is platinum-sensitive recurrent, b) patient has been treated with bevacizumab as a single agent, c) treatment is following: i) carboplatin and paclitaxel or ii) carboplatin and gencitabine.
Age Restrictions	N/A

Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Hepatocellular Carcinoma (HCC): Diagnosis of hepatocellular carcinoma. Disease is unresectable or metastatic. Used in combination with Tecentriq (atezolizumab). Patient has not received prior systemic therapy. Approve for continuation of prior therapy.

## MYALEPT (S)

### **Products Affected**

• Myalept

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Lipodystrophy (initial): Diagnosis of congenital or acquired generalized lipodystrophy AND one of the following: 1) Diabetes mellitus or insulin resistance despite optimized insulin therapy at maximum tolerated doses OR 2) Hypertriglyceridemia despite optimized therapy with at least two triglyceride-lowering agents from different classes (e.g., fibrates, statins).
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with an endocrinologist
Coverage Duration	Initial, reauth: 12 months
Other Criteria	Lipodystrophy (reauth): Patient has experienced an objective response to therapy, such as A) Sustained reduction in hemoglobin A1c (HbA1c) level from baseline OR B) Sustained reduction in triglyceride (TG) levels from baseline.

### NAGLAZYME (S)

#### **Products Affected**

• Naglazyme

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Mucopolysaccharidosis (MPS VI): Diagnosis of MPS VI (Maroteaux- Lamy Syndrome).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	MPS VI: 12 months
Other Criteria	N/A

### NATPARA (S)

### **Products Affected**

• Natpara

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Hypocalcemia (Initial): Diagnosis of hypocalcemia due to chronic hypoparathyroidism. Not used in the setting of acute post-surgical hypoparathyroidism. Patient does not have a known calcium-sensing receptor mutation. Patient has a documented parathyroid hormone concentration that is inappropriately low for the level of calcium, recorded on at least two occasions within the previous 12 months. Patient has normal thyroid-stimulating hormone concentrations if not on thyroid hormone replacement therapy (or if on therapy, the dose had to have been stable for greater than or equal to 3 months). Patient has normal magnesium and serum 25-hydroxyvitamin D concentrations. Will be used as an adjunct treatment.
Age Restrictions	N/A
Prescriber Restrictions	Hypocalcemia (initial): Prescribed by or in consultation with an endocrinologist.
Coverage Duration	Initial: 6 months. Reauth: 12 months
Other Criteria	Hypocalcemia (Reauth): One of the following: A) Patient has achieved and maintained serum calcium levels in the ideal range (7.5 - 10.6 mg/dL ), OR B) Patient has experienced a 50% or greater reduction from baseline in oral calcium intake, OR C) Patient has experienced a 50% or greater reduction from baseline in oral vitamin D intake.

## NERLYNX (S)

### **Products Affected**

• Nerlynx

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Early Stage Breast cancer: Diagnosis (dx) of early stage breast cancer. Disease is human epidermal growth factor receptor 2 (HER2)-positive. Patient has received adjuvant trastuzumab-based therapy. Advanced or Metastatic Breast Cancer: Dx of advanced or metastatic breast cancer. Disease is human epidermal growth factor receptor 2 (HER2)-positive. Patient has received two or more prior anti-HER2 based regimens (e.g., trastuzumab + pertuzumab + docetaxel, ado-trastuzumab emtansine, etc.). Used in combination with capecitabine.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

#### **Products Affected**

• Neulasta

**PA** Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A Exclusion N/A Criteria Required Febrile neutropenia (FN) prophylaxis: Patient will be receiving Medical prophylaxis for FN due to one of the following: 1) Patient is receiving Information National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown, 3) patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN, 4) both of the following: a) patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN, AND b) patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia, OR 5) Both of the following: a) patient is receiving myelosuppressive anticancer drugs associated with neutropenia, AND b) patient has a history of FN or doselimiting event during a previous course of chemotherapy (secondary prophylaxis). Acute radiation syndrome (ARS): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS). Treatment of FN: Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia. Diagnosis of FN. Patient is at high risk for infection-associated complications. N/A **Age Restrictions** Prescriber All uses: Prescribed by or in consultation with a hematologist/oncologist Restrictions Coverage ARS: 1 mo. FN (prophylaxis, treatment): 3 mo or duration of tx. Duration N/A **Other Criteria** 

• Neulasta Onpro Kit

### NEXAVAR (S)

#### **Products Affected**

• Nexavar

- Sorafenib
- Sorafenib Tosylate TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Renal cell carcinoma (RCC): Diagnosis of RCC. Hepatocellular carcinoma (HCC): Diagnosis of HCC. One of the following: patient has metastatic disease, or patient has extensive liver tumor burden, or patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only), or disease is unresectable. Differentiated thyroid carcinoma (DTC): Diagnosis of DTC (ie, follicular carcinoma, Hurthle cell carcinoma, or papillary carcinoma). One of the following: locally recurrent disease, metastatic disease, or unresectable disease. One of the following: patient has symptomatic disease or patient has progressive disease. Disease is refractory to radioactive iodine (RAI) treatment. Medullary thyroid carcinoma (MTC): Diagnosis of MTC. One of the following: 1) Disease is progressive or 2) Disease is symptomatic with distant metastases. Trial and failure, contraindication, or intolerance to Caprelsa (vandetanib) or Cometriq (cabozantinib).
Age Restrictions	N/A
Prescriber Restrictions	DTC, MTC: Prescribed by or in consultation with an oncologist. RCC: Prescribed by or in consultation with an oncologist or nephrologist. HCC: Prescribed by or in consultation with an oncologist, hepatologist, or gastroenterologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## NINLARO (S)

### **Products Affected**

• Ninlaro

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple myeloma: Diagnosis of multiple myeloma. Used in combination with Revlimid (lenalidomide) and dexamethasone. Patient has received at least one prior therapy for multiple myeloma [eg, Revlimid (lenalidomide), Thalomid (thalidomide), Velcade (bortezomib)].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# NORTHERA (S)

### **Products Affected**

• Droxidopa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Neurogenic orthostatic hypotension (NOH) (init): Diagnosis of symptomatic NOH. NOH is caused by one of the following conditions: primary autonomic failure (eg, Parkinson's disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, non-diabetic autonomic neuropathy. Trial and failure, contraindication, or intolerance to one of the following agents: fludrocortisone acetate, midodrine.
Age Restrictions	N/A
Prescriber Restrictions	NOH (init): Prescribed by or in consultation with a cardiologist, neurologist, or nephrologist
Coverage Duration	NOH (init): 1 month (reauth): 12 months
Other Criteria	NOH (reauth): Documentation of positive clinical response to therapy.

## NUBEQA (S)

### **Products Affected**

• Nubeqa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-metastatic castration-resistant or castration-recurrent prostate cancer (NM-CRPC): Diagnosis of non-metastatic castration-resistant (chemical or surgical) or castration-recurrent prostate cancer. Metastatic hormone-sensitive prostate cancer (mHSPC): Diagnosis of mHSPC. Used in combination with docetaxel.
Age Restrictions	N/A
Prescriber Restrictions	NM-CRPC, mHSPC: Prescribed by or in consultation with an oncologist or urologist.
Coverage Duration	NM-CRPC, mHSPC: 12 months
Other Criteria	NM-CRPC, mHSPC: Approve for continuation of prior therapy.

## NUEDEXTA (S)

### **Products Affected**

• Nuedexta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Pseudobulbar affect (PBA) (initial): Diagnosis of PBA. Patient does not have any of the following contraindications: a) Concomitant use with other drugs containing quinidine, quinine, or mefloquine, b) History of Nuedexta, quinine, mefloquine or quinidine-induced thrombocytopenia, hepatitis, bone marrow depression, or lupus-like syndrome, c) Known hypersensitivity to dextromethorphan (e.g., rash, hives), d) Taking monoamine oxidase inhibitors (MAOIs) (e.g., phenelzine, selegiline, tranylcypromine) or have taken MAOIs within the preceding 14 days, e) Has prolonged QT interval, congenital long QT syndrome or a history suggestive of torsades de pointes, or has heart failure, f) Receiving drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine, pimozide), g) Has complete atrioventricular (AV) block without implanted pacemakers, or at high risk of complete AV block. PBA (reauth): Documentation of clinical benefit from ongoing therapy as demonstrated by a decrease in inappropriate laughing or crying episodes.
Age Restrictions	N/A
Prescriber Restrictions	PBA (initial): Prescribed by or in consultation with one of the following specialists: neurologist, psychiatrist.
Coverage Duration	PBA (initial/reauth): 12 months
Other Criteria	N/A

## NUPLAZID (S)

### **Products Affected**

• Nuplazid

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Parkinson's disease psychosis: Diagnosis of Parkinson's disease. Patient has at least one of the following: hallucinations or delusions.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# NUVIGIL (S)

### **Products Affected**

• Armodafinil

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Obstructive sleep apnea (OSA) (Initial): Diagnosis (dx) of OSA defined by one of the following: a) 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), or b) both of the following: 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), AND 1 of the following symptoms: unintentional sleep episodes during wakefulness, daytime sleepiness, unrefreshing sleep, fatigue, insomnia, waking up breath holding/gasping/choking, loud snoring, or breathing interruptions during sleep. Shift-work disorder (SWD) (Initial):Dx of SWD confirmed by one of the following: 1) symptoms of excessive sleepiness or insomnia for at least 3 months, which is associated with a work period (usually night work) that occurs during the normal sleep period, OR 2) A sleep study demonstrating loss of a normal sleep-wake pattern (ie, disturbed chronobiologic rhythmicity). Confirmation that no other medical conditions or medications are causing the symptoms of excessive sleepiness or insomnia. Narcolepsy (initial): Dx of narcolepsy as confirmed by sleep study (unless prescriber provides justification confirmed by sleep study is not feasible).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	OSA, SWD: Initial, Reauth: 6 mo. Narcolepsy: Initial, Reauth: 12 mo
Other Criteria	OSA, Narcolepsy (Reauth): Documentation of positive clinical response to armodafinil therapy. SWD (Reauth): Documentation of positive clinical response to armodafinil therapy.

## **ODOMZO (S)**

### **Products Affected**

• Odomzo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Basal cell carcinoma: Diagnosis of locally advanced basal cell carcinoma AND One of the following: 1) Cancer has recurred following surgery or radiation therapy or 2) Patient is not a candidate for surgery or radiation therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### **OFEV (S)**

### **Products Affected**

• Ofev

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Idiopathic pulmonary fibrosis (IPF) (initial): Diagnosis of IPF as documented by all of the following: a) exclusion of other known causes of interstitial lung disease (ILD) (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity) AND b) one of the following: i) in patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF. Systemic sclerosis-associated interstitial lung disease (SSc-ILD) (initial): Diagnosis of SSc-ILD as documented by all of the following: a) exclusion of other known causes of ILD (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity) AND b) One of the following: i) In patients not subjected to surgical lung biopsy, the presence of idiopathic interstitial pneumonia (eg, fibrotic nonspecific interstitial pneumonia [NSIP], usual interstitial pneumonia [UIP] and centrilobular fibrosis) pattern on HRCT revealing SSc-ILD or probable SSc-ILD, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD. Chronic Fibrosing Interstitial Lung Diseases (ILDs) with a Progressive Phenotype (initial): 1) diagnosis of chronic fibrosing interstitial lung disease, AND 2) patient has a high-resolution computed tomography (HRCT) showing at least 10% of lung volume with fibrotic features, AND 3) disease has a progressive phenotype as observed by one of the following: decline of forced vital capacity (FVC), worsening of respiratory symptoms, or increased extent of fibros
Age Restrictions	N/A
Prescriber Restrictions	IPF, SSc-ILD, Chronic Fibrosing ILDs with a Progressive Phenotype (initial): Prescribed by or in consultation with a pulmonologist

Coverage Duration	Initial, reauth: 12 months
Other Criteria	IPF, SSc-ILD, Chronic Fibrosing ILDs with a Progressive Phenotype (reauth): Documentation of positive clinical response to therapy.

## **ONUREG (S)**

### **Products Affected**

• Onureg

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acute Myeloid Leukemia (AML): Diagnosis of acute myeloid leukemia (AML). Patient has received previous treatment with an intensive induction chemotherapy regimen (e.g., cytarabine + daunorubicin, cytarabine + idarubicin, etc.). Patient has achieved one of the following: a) first complete remission (CR) or b) complete remission with incomplete blood count recovery (CRi). Patient is not able to complete intensive curative therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## **OPSUMIT (S)**

### **Products Affected**

• Opsumit

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
Age Restrictions	N/A
Prescriber Restrictions	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: Initial: 6 months. Reauth: 12 months.
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.

## **ORENCIA IV (S)**

#### **Products Affected**

• Orencia INJ 250MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: a) Trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), or Xeljanz/Xeljanz XR (tofacitinib), or b) attestation demonstrating a trial may be inappropriate, OR c) For continuation of prior Orencia therapy. Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. JIA, PsA (Initial): One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior therapy.
Age Restrictions	N/A
Prescriber Restrictions	RA, JIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist.
Coverage Duration	All uses (initial, reauth): 12 months
Other Criteria	All indications (Reauth): Documentation of positive clinical response to therapy.

### **ORENCIA SC (S)**

#### **Products Affected**

- Orencia Clickject
- Orencia INJ 125MG/ML, 50MG/0.4ML, 87.5MG/0.7ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: a) Either a trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib), or attestation demonstrating a trial may be inappropriate, OR b) For continuation of prior therapy. Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. One of the following: a) Either a trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR b) for continuation of prior therapy. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: a) Either a trial and failure, contraindication, or intolerance to two of the following, or attestation demonstrating a trial may be inappropriate, OR b) for continuation, or intolerance to two of the following, or attestation demonstrating a trial may be inappropriate: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib/ER), OR b) for continuation of prior therapy.
Age Restrictions	N/A
Prescriber Restrictions	RA, JIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist.
Coverage Duration	All uses (initial, reauth): 12 months
Other Criteria	All indications (Reauth): Documentation of positive clinical response to therapy.

# **O**RGOVYX (S)

### **Products Affected**

• Orgovyx

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prostate Cancer: Diagnosis of advanced prostate cancer. Disease is one of the following: 1) Evidence of biochemical or clinical relapse following local primary intervention with curative intent or 2) Newly diagnosed androgen-sensitive metastatic disease or 3) Advanced localized disease unlikely to be cured by local primary intervention with curative intent.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an urologist or oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# ORKAMBI (S)

### **Products Affected**

• Orkambi TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cystic Fibrosis (CF) (Initial): Diagnosis of CF. Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by a U.S. Food and Drug Administration (FDA)- cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	CF (Initial): Patient is 6 years of age or older
Prescriber Restrictions	CF (initial): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist
Coverage Duration	CF (initial, reauth): 12 months
Other Criteria	CF (Reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations).

### **ORKAMBI GRANULES (S)**

#### **Products Affected**

• Orkambi PACK

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cystic Fibrosis (CF) (Initial): Diagnosis of CF. Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by a U.S. Food and Drug Administration (FDA)- cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). One of the following: A) Patient is 1 through 5 years of age, OR B) Both of the following: Patient is 6 years of age or greater AND Patient is unable to swallow oral tablets.
Age Restrictions	N/A
Prescriber Restrictions	CF (Initial): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist
Coverage Duration	CF (initial, reauth): 12 months
Other Criteria	CF (Reauth): Patient is benefiting from treatment (i.e., improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations). One of the following: A) Patient is 1 through 5 years of age, OR B) Both of the following: Patient is 6 years of age or greater AND Patient is unable to swallow oral tablets.

### **OSPHENA (S)**

### **Products Affected**

• Osphena

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Dyspareunia (initial): Diagnosis of moderate to severe dyspareunia due to vulvar and vaginal atrophy associated with menopause. Vaginal dryness (initial): Diagnosis of moderate to severe vaginal dryness due to vulvar and vaginal atrophy associated with menopause.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All uses (Initial, reauth): 12 months
Other Criteria	Dyspareunia, Vaginal dryness (reauth): Documentation of positive clinical response to therapy.

## **OXANDRIN (S)**

### **Products Affected**

• Oxandrolone TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Promote weight gain (initial): Used as adjunctive therapy to promote weight gain AND Diagnosis of one of the following: Extensive surgery, Chronic infections, Severe trauma, Failure to gain or maintain at least 90% of ideal body weight without definite pathophysiologic reasons AND a nutritional consult was performed. Counterbalance protein catabolism (initial): Used to counterbalance protein catabolism associated with chronic corticosteroid administration. Bone pain: Diagnosis of bone pain associated with osteoporosis.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	bone pain: 1 month. Others (initial, reauth): 3 months
Other Criteria	All diagnoses except bone pain (reauth): Documentation of a positive clinical response to therapy as evidenced by an improvement in weight gain or increase in lean body mass.

### **OXBRYTA (S)**

### **Products Affected**

• Oxbryta TBSO

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Diagnosis of Sickle Cell Disease. Documentation of hemoglobin level that does not exceed 10.5 g/dL prior to therapy initiation. Trial and failure or inadequate response, contraindication, or intolerance to hydroxyurea.
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with one of the following: 1) Hematologist/Oncologist or 2) Specialist w/ expertise in the diagnosis and management of sickle cell disease.
Coverage Duration	Initial, Reauth: 12 months.
Other Criteria	Reauth: Documentation of positive clinical response to therapy (e.g., an increase in hemoglobin level of 1 g/dL or greater from baseline, decreased annualized incidence rate of vaso-occlusive crises [VOCs]). Documentation of hemoglobin level that does not exceed 10.5 g/dL.

#### **Products Affected**

• Pegasys Proclick INJ 180MCG/0.5ML

• Pegasys

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic hepatitis B: Diagnosis of chronic hepatitis B infection, and patient is without decompensated liver disease. Chronic Hepatitis C: Criteria will be applied consistent with current AASLD-IDSA guidance.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	HepB: 48 wks. HepC: Initial: 28 wks. Reauth: 20 wks.
Other Criteria	N/A

### **PEMAZYRE (S)**

### **Products Affected**

• Pemazyre

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cholangiocarcinoma: Diagnosis of cholangiocarcinoma. Disease is one of the following: unresectable locally advanced or metastatic. Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement. Patient has been previously treated. Myeloid/lymphoid neoplasm: Diagnosis of myeloid/lymphoid neoplasms (MLNs). Disease is relapsed or refractory. Disease has presence of a fibroblast growth factor receptor 1 (FGFR1) rearrangement.
Age Restrictions	N/A
Prescriber Restrictions	Cholangiocarcinoma: Prescribed by or in consultation with a hepatologist, gastroenterologist, or oncologist. MLNs: Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### **Products Affected**

#### Diclofenac Sodium EXTERNAL SOLN 1.5%

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Osteoarthritis of the knees (initial): Diagnosis of osteoarthritis of the knees. Patient meets one of the following: 1) Treatment failure with at least two prescription strength topical or oral non-steroidal anti- inflammatory drugs (NSAIDs) (e.g., diclofenac, ibuprofen, meloxicam, naproxen) OR 2) History of peptic ulcer disease/gastrointestinal bleed OR 3) Patient is older than 65 years of age with one additional risk factor for gastrointestinal adverse events (e.g. use of anticoagulants, chronic corticosteroids).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial, reauth: 12 months
Other Criteria	Osteoarthritis of the knees (reauth): Documentation of positive clinical response to therapy (e.g., improvement in pain symptoms of osteoarthritis).

## PHESGO (S)

### **Products Affected**

• Phesgo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Early Breast Cancer (EBC): Diagnosis of breast cancer. Used in combination with chemotherapy. Disease is human epidermal growth factor receptor 2 (HER2)-positive. One of the following: a) Used for neoadjuvant treatment and disease is one of the following: locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive), OR b) Used for adjuvant treatment and disease is early breast cancer at high risk of recurrence. Metastatic Breast Cancer (MBC): Diagnosis of breast cancer. Used in combination with docetaxel. Disease is human epidermal growth factor receptor 2 (HER2)- positive metastatic breast cancer. Patient has not received prior anti-HER2 therapy or chemotherapy for metastatic disease.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### PIQRAY (S)

#### **Products Affected**

• Piqray 200mg Daily Dose

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

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Breast Cancer (BC): Diagnosis of advanced or metastatic BC. Disease is hormone receptor (HR)-positive, and human epidermal growth factor receptor 2 (HER2)-negative. Cancer is PIK3CA-mutated as detected by an FDA-approved test (therascreen PIK3CA RGQ PCR Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient is a postmenopausal woman or male. Used in combination with fulvestrant. Disease has progressed on or after an endocrine-based regimen.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# POLIVY (S)

#### **Products Affected**

• Polivy

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diffuse large B-cell lymphoma (DLBCL): Diagnosis of diffuse large B- cell lymphoma (DLBCL). Disease is relapsed or refractory. Used in combination with bendamustine and a rituximab product. Patient has received at least two prior therapies for DLBCL (e.g., RCHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone], HSCT [hematopoietic stem cell transplantation], CAR T [chimeric antigen receptor T-cell] therapy, RCEPP [rituximab, cyclophosphamide, etoposide, prednisone, procarbazine], GemOx [gemcitabine, oxaliplatin] with or without rituximab).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### **POMALYST (S)**

#### **Products Affected**

• Pomalyst

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Myeloma (MM): Diagnosis of MM. Used in combination with dexamethasone. Patient has received two prior therapies, including Revlimid (lenalidomide) and a proteasome inhibitor [eg, Velcade (bortezomib) or Kyprolis (carfilzomib)] or has a contraindication or intolerance to Revlimid and proteasome inhibitors. Patient has experienced disease progression on or within 60 days of completion of last therapy. Kaposi sarcoma (KS): One of the following: 1) Both of the following: a) Diagnosis of AIDS-related KS and b) Patient has failed highly active antiretroviral therapy (HAART) [e.g., Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide), Dovato (dolutegravir/lamivudine), Triumeq (dolutegravir/abacavir/lamivudine)], OR 2) Both of the following: a) Diagnosis of KS and b) Patient is HIV- negative.
Age Restrictions	N/A
Prescriber Restrictions	All indications: Prescribed by or in consultation with an oncologist or hematologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### **POSACONAZOLE (S)**

#### **Products Affected**

• Noxafil SUSP

• Posaconazole Dr

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prophylaxis of systemic fungal infections (SFI): Used as prophylaxis of invasive fungal infections caused by Aspergillus or Candida for one of the following conditions: 1) Patient is at high risk of infections due to severe immunosuppression from hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD) or hematologic malignancies with prolonged neutropenia from chemotherapy OR 2) patient has a prior fungal infection requiring secondary prophylaxis. Treatment (Tx) of SFI: Used as treatment of systemic fungal infections caused by Aspergillus. Oropharyngeal Candidiasis (OPC): Diagnosis of OPC. One of the following: 1) Candidiasis is refractory or resistant to treatment with fluconazole OR 2) Trial and failure, contraindication, or intolerance to fluconazole.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Prophylaxis of SFI: 6 months. Tx of SFI: 3 months. OPC: 1 month.
Other Criteria	N/A

### **PROMACTA (S)**

#### **Products Affected**

• Promacta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Immune (idiopathic) thrombocytopenic purpura (ITP) (initial): Diagnosis of one of the following: relapsed/refractory ITP, persistent ITP, or chronic ITP. Baseline platelet count is less than 30,000/mcL. Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding. Trial and failure, intolerance, contraindication to corticosteroids (e.g., prednisone, methylprednisolone), immunoglobulins [e.g., Gammagard, immune globulin (human)], or splenectomy. Chronic hepatitis C (initial): Diagnosis of chronic hepatitis C-associated thrombocytpenia. One of the following: 1) Planning to initiate and maintain interferon-based treatment, or 2) currently receiving interferon-based treatment. First-line for severe aplastic anemia (SAA): Diagnosis of SAA. Used for first-line treatment (i.e., patient has not received prior immunosuppressive therapy). Used in combination with standard immunosuppressive therapy. Patient meets at least two of the following: 1) absolute neutrophil count less than 500/mcL, 2) platelet count less than 20,000/mcL, 3) absolute reticulocyte count less than 60,000/mcL. Refractory SAA (initial): Diagnosis of refractory severe aplastic anemia. Patient has a platelet count less than 30,000/mcL. Insufficient response to immunosuppressive therapy.
Age Restrictions	N/A
Prescriber Restrictions	ITP and SAA: Prescribed by or in consultation with a hematologist/oncologist. Chronic hepatitis C associated thrombocytopenia: Prescribed by or in consultation with a hematologist/oncologist, gastroenterologist, hepatologist, infectious disease specialist, or HIV specialist certified through the American Academy of HIV Medicine.
Coverage Duration	ITP(init,reauth):12mo.HepC:3mo(init),12mo(reauth).1stline SAA:6mo.RefractSAA:16wk-init,12mo-reauth

Other Criteria	ITP (reauth): Documentation of positive clinical response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding. Hepatitis C (reauth): One of the following: 1) For patients that started treatment with eltrombopag prior to initiation of treatment with interferon, eltrombopag will be approved when both of the following are met: a) Currently on antiviral interferon therapy for treatment of chronic hepatitis C and b) Documentation that the patient reached a threshold platelet count that allows initiation of antiviral interferon therapy with eltrombopag treatment by week 9, OR 2) For patients that started treatment with eltrombopag while on concomitant treatment with interferon, eltrombopag will be approved based on the following: Currently on antiviral interferon therapy for treatment of chronic hepatitis C. Refractory SAA (reauth): Documentation of positive clinical response to therapy as evidenced by an increase in platelet count.
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## **PROVIGIL (S)**

#### **Products Affected**

• Modafinil

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Obstructive sleep apnea (OSA) (Initial): Diagnosis (dx) of OSA defined by one of the following: 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), or both of the following: 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), and 1 of the following symptoms: unintentional sleep episodes during wakefulness, daytime sleepiness, unrefreshing sleep, fatigue, insomnia, waking up breath holding/gasping/choking, loud snoring, or breathing interruptions during sleep. Shift-work disorder (SWD) (Initial):Dx of SWD confirmed by one of the following: 1) Symptoms of excessive sleepiness or insomnia for at least 3 months, which is associated with a work period (usually night work) that occurs during the normal sleep period, OR 2) A sleep study demonstrating loss of a normal sleep-wake pattern (ie, disturbed chronobiologic rhythmicity). Confirmation that no other medical conditions or medications are causing the symptoms of excessive sleepiness or insomnia. Narcolepsy (initial): Dx of narcolepsy as confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible). MS Fatigue (initial): Dx of multiple sclerosis (MS). Patient is experiencing fatigue. Depression (initial): Treatment-resistant depression defined as diagnosis of major depressive disorder (MDD) or bipolar depression, AND trial and failure, contraindication, or intolerance to at least two antidepressants from different classes (eg, SSRIs, SNRIs, bupropion). Used as adjunctive therapy. Idiopathic Hypersomnia (Initial): Diagnosis of idiopathic hypersomnia as confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible).
Age Restrictions	N/A

Prescriber Restrictions	N/A
Coverage Duration	Narcolepsy: Init, Reauth: 12 mo. All other indications: Init, Reauth: 6 mo.
Other Criteria	OSA, Narcolepsy, Idiopathic Hypersomnia (Reauth): Documentation of positive clinical response to modafinil therapy. SWD (Reauth): Documentation of positive clinical response to modafinil therapy. MS Fatigue (reauth): Patient is experiencing relief of fatigue with modafinil therapy. Depression (reauth): Documentation of positive clinical response to modafinil therapy. Used as adjunctive therapy.

### **PYRUKYND (S)**

#### **Products Affected**

• Pyrukynd

#### **PA** Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A Exclusion N/A Criteria Required Initial: Diagnosis of hemolytic anemia confirmed by the presence of Medical chronic hemolysis (e.g., increased indirect bilirubin, elevated lactated Information dehydrogenase [LDH], decreased haptoglobin, increased reticulocyte count). Diagnosis of pyruvate kinase deficiency confirmed by molecular testing of ALL the following mutations on the PKLR gene: a) Presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least 1 was a missense variant AND b) Patients is not homozygous for the c.1436G to A (p.R479H) variant AND c) Patient does not have 2 non-missense variants (without the presence of another missense variant) in the PKLR gene. Hemoglobin is less than or equal to 10g/dL. Patient has symptomatic anemia or is transfusion dependent. Exclusion of other causes of hemolytic anemias (e. g., infections, toxins, drugs). **Age Restrictions** N/A Prescriber Initial, Reauth: Prescribed by or in consultation with a hematologist. Restrictions Coverage Initial: 6 months. Reauth: 12 months. Duration **Other Criteria** Reauth: Documentation of positive clinical response to therapy.

Pyrukynd Taper Pack

# QINLOCK (S)

### **Products Affected**

• Qinlock

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Gastrointestinal Stromal Tumor (GIST): Diagnosis of gastrointestinal stromal tumor (GIST). Disease is advanced. Patient has received prior treatment with three or more kinase inhibitors (e.g., sunitinib, regorafenib), one of which must include imatinib.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# QUALAQUIN (S)

#### **Products Affected**

#### • Quinine Sulfate CAPS 324MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Excluded if used solely for the treatment or prevention of nocturnal leg cramps.
Required Medical Information	Malaria: Diagnosis of uncomplicated malaria. One of the following: 1) Treatment in areas of chloroquine-sensitive malaria, and trial and failure, contraindication, or intolerance to chloroquine or hydroxychloroquine, OR 2) Treatment in areas of chloroquine-resistant malaria.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	7 days
Other Criteria	N/A

### **REPATHA (S)**

#### **Products Affected**

• Repatha

- Repatha Pushtronex System
- Repatha Sureclick

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	HeFH/ASCVD/Primary HLD (init): One of the following dx: A)HeFH as confirmed by one of the following: 1)Both of the following: a)Untreated/pre-treatment LDL greater than 190 mg/dL in an adult, AND b)One of the following: i) Family hx of tendinous xanthomas and/or arcus cornealis in 1st degree relative, or 2nd degree relative, ii)Hx of myocardial infarction (MI) in 1st-degree relative less than 60 years of age, iii)Family hx of MI in 2nd-degree relative less than 50 years of age, iiv)Family hx of LDL-C greater than 190 mg/dL in 1st- or 2nd-degree relative, v)Family hx of FH in 1st- or 2nd-degree relative, or 2)Untreated/pre-treatment LDL-C greater than 190 mg/dL in an adult AND one of the following: presence of tendinous xanthoma in pt, arcus cornealis before age 45, or functional mutation in the LDL receptor, ApoB, or PCSK9 gene. OR B)ASCVD as confirmed by ACS, hx of MI, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA, or peripheral arterial disease presumed to be of atherosclerotic origin. OR C)Primary hyperlipidemia (HLD). HoFH (init): Dx of HoFH as confirmed by one of the following: 1)Gen confirmation of 2 mutations in LDL receptor, ApoB, PCSK9, or LDLRAP1 or ARH, or 2)either untreated LDL greater than 500 or treated LDL greater than 300, AND either xanthoma before 10 yo or evidence of HeFH in both parents. HeFH/ASCVD/Primary HLD (init): One of the following: set A)Both of the following: a)One of the following LDL values while on max tolerated lipid lowering regimen w/in the last 120 days: 1)LDL greater than or equal to 100 mg/dL w/ASCVD, or 2)LDL greater than or equal to 130 mg/dL w/o ASCVD. AND b)One of the following: 1)Pt has been receiving at least 12 wks of one high-intensity (HI) statin therapy (tx) and will continue to receive a HI statin [ie, atorvastatin 40-80 mg, rosuvastatin 20-40 mg] at max tolerated dose.
Age Restrictions	N/A

Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Reauth: 12 months

Other Criteria	Set A (cont, initial): OR (2) Both of the following: A) Pt unable to tolerate HI statin as evidenced by intolerable and persistent (ie, more than 2 wks) myalgia (muscle symptoms w/o CK elevations) or myositis (muscle symptoms w/ CK elevations less than 10 times ULN) AND B) One of the following: a) Pt has been receiving at least 12 wks of one moderate- intensity (MI) or low-intensity (LI) statin tx and will continue to receive a MI or LI statin [ie, atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 10-40 mg, pravastatin 10-80 mg, lovastatin 20-40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1-4 mg] at max tolerated dose, OR b) Pt is unable to tolerate MI or LI statin as evidenced by intolerable and persistent (ie, more than 2 weeks) myalgia (muscle symptoms w/o CK elevations) or myositis (muscle symptoms w/ CK elevations less than 10 times ULN), OR (3) Pt has a labeled contraindication to all statins, OR (4) Pt has experienced rhabdomyolysis or muscle symptoms w/ statin treatment w/ CK elevations greater than 10 times ULN on one statin tx. OR set B) Both of the following: a) One of the following LDL values while on max tolerated lipid lowering tx w/in the last 120 days: (1) LDL b/t 70 and 99 mg/dL w/ ASCVD. (2) LDL b/t 100 and 129 mg/dL w/o ASCVD. AND b) Both of the following: (1) One of the following: i) Pt has been receiving at least 12 wks of one max-tolerated statin tx and will continue to receive a statin at max tolerated dose, ii) pt is unable to tolerate statin tx as evidenced by intolerable and persistent (ie, more than 2 wks) myalgia (muscle symptoms w/ CK elevations) or myositis (muscle symptoms w/ CK elevations less than 10 times ULN, iii) Patient has a labeled contraindication to all statins, or iv) Pt has experienced rhabdomyolysis or muscle symptoms w/ statin tx w/ CK elevations greater than 10 times ULN on one statin tx and (2) Pt has been receiving at least 12 weeks of ezetimibe (Zetia) tx as adjunct to max tolerated statin tx OR Pt has a hx of contr
	HoFH (reauth): One of the following: 1)Pt continues to receive other

# **RETEVMO (S)**

#### **Products Affected**

• Retevmo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Lung Cancer: Diagnosis of metastatic non-small cell lung cancer (NSCLC). Disease has presence of RET gene fusion-positive tumor(s). Medullary Thyroid Cancer (MTC): Diagnosis of medullary thyroid cancer (MTC). Disease is advanced or metastatic. Disease has presence of RET gene mutation tumor(s). Disease requires treatment with systemic therapy. Thyroid Cancer: Diagnosis of thyroid cancer. Disease is advanced or metastatic. Disease has presence of RET gene fusion-positive tumor(s). Disease requires treatment with systemic therapy. Patient is radioactive iodine-refractory or radioactive iodine therapy is not appropriate.
Age Restrictions	N/A
Prescriber Restrictions	Lung Cancer, MTC: Prescribed by or in consultation with an oncologist. Thyroid Cancer: Prescribed by or in consultation with an endocrinologist or an oncologist.
Coverage Duration	Lung Cancer, MTC, Thyroid Cancer: 12 months
Other Criteria	Approve for continuation of prior therapy.

### **REVATIO (S)**

### **Products Affected**

• Sildenafil Citrate TABS 20MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
Age Restrictions	N/A
Prescriber Restrictions	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: Initial: 6 months. Reauth: 12 months.
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.

# **REVCOVI (S)**

### **Products Affected**

• Revcovi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of adenosine deaminase deficiency (ADA) with severe combined immunodeficiency (SCID).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

# **REVLIMID (S)**

### **Products Affected**

• Revlimid

• Lenalidomide

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple myeloma (MM): Diagnosis of MM. Either used as 1) combination therapy with dexamethasone, or 2) maintenance therapy following autologous hematopoietic stem cell transplantation (auto- HSCT). Myelodysplastic syndromes (MDS): Diagnosis of transfusion- dependent anemia due to low- or intermediate-1-risk MDS associated with a deletion 5q. Mantle cell lymphoma (MCL): Diagnosis of MCL. Disease has relapsed after, is refractory to, or progressed after at least one prior therapy (eg, bortezomib, bendamustine, cladribine, rituximab). Follicular Lymphoma (FL): Diagnosis of FL that has been previously treated. Used in combination with a rituximab product. Marginal Zone Lymphoma (MZL): Diagnosis of MZL that has been previously treated. Used in combination with a rituximab product.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## **REZUROCK (S)**

#### **Products Affected**

• Rezurock

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic graft versus host disease (cGVHD) (initial): Diagnosis of cGVHD. Trial and failure of two or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.).
Age Restrictions	N/A
Prescriber Restrictions	cGVHD (initial): Prescribed by or in consultation with one of the following: hematologist, oncologist, or physician experienced in the management of transplant patients.
Coverage Duration	cGVHD (initial, reauth): 12 months
Other Criteria	cGVHD (reauth): Patient does not show evidence of progressive disease while on therapy.

# **RILUTEK (S)**

### **Products Affected**

• Riluzole

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Amyotrophic lateral sclerosis (ALS): Diagnosis of amyotrophic lateral sclerosis (ALS).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	ALS: 12 months
Other Criteria	N/A

### **RINVOQ (S)**

#### **Products Affected**

• Rinvoq

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid arthritis (RA) (initial - 15 mg): Diagnosis of moderately to severely active RA. One of the following: Trial and failure, contraindication, or intolerance (TF/C/I) to one disease modifying antirheumatic drug (DMARD) [eg, methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)], OR for continuation of prior therapy. Psoriatic arthritis (PsA) (initial - 15 mg): Diagnosis of active PsA. Ankylosing spondylitis (AS) (initial - 15 mg): Diagnosis of active AS. RA, PsA, AS (initial - 15 mg): Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, Enbrel, Humira). Not used in combination with a potent immunosuppressant (e.g., azathioprine, cyclosporine). Atopic dermatitis (AD) (initial - 15 mg and 30 mg): Diagnosis of moderate to severe AD. TF/C/I to at least one of the following: a) Medium or higher potency topical corticosteroid, b) Pimecrolimus cream, c) Tacrolimus ointment, or d) Eucrisa (crisaborole) ointment. One of the following: 1) Trial and failure of a minimum 12- week supply of at least one systemic drug product for the treatment of AD (examples include, but are not limited to, Adbry [tralokinumab-ldrm], Dupixent [dupilumab], etc.), OR 2) Patient has a contraindication, intolerance, or treatment is inadvisable with both of the following FDA- approved AD therapies: Adbry (tralokinumab-ldrm) and Dupixent (dupilumab). Not used in combination with biologic immunomodulators (eg, Dupixent, Adbry) or other immunosuppressants (eg, azathioprine, cyclosporine). Ulcerative colitis (UC) (initial): Diagnosis of moderately to severely active UC. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, aminosalicylate (eg, mesalamine, olsalazine, sulfasalazine), azathioprine, or corticosteroids (eg, prednisone). Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, Humira). Not used in combination with a potent immunosuppressant (eg, azathioprine, cyclosporine)
Age Restrictions	N/A

Prescriber Restrictions	RA, AS (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. AD (initial): Prescribed by or in consultation with a dermatologist or allergist/immunologist. UC (initial): Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	RA, PsA, AS, UC, AD (initial, reauth): 12 months.
Other Criteria	RA, PsA, AS, UC (reauth): Documentation of positive clinical response to therapy. Not used in combination with a potent immunosuppressant (e.g., azathioprine, cyclosporine). AD (reauth): Documentation of a positive clinical response to therapy (eg, reduction in body surface area involvement, reduction in pruritus severity). Not used in combination with biologic immunomodulators (eg, Dupixent, Adbry) or other immunosuppressants (eg, azathioprine, cyclosporine).

### **ROZLYTREK (S)**

#### **Products Affected**

• Rozlytrek

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of metastatic non-small cell lung cancer (NSCLC). Patient has ROS1 rearrangement positive tumor(s). Solid Tumors: Patient has solid tumors with a neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, TPR-NTRK1, etc.). Disease is without a known acquired resistance mutation (e.g., TRKA G595R, TRKA G667C or TRKC G623R substitutions). Disease is one of the following: metastatic or unresectable (including cases where surgical resection is likely to result in severe morbidity). One of the following: disease has progressed following previous treatment (e.g., surgery, radiation therapy, or systemic therapy) or disease has no satisfactory alternative treatments.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## RUBRACA (S)

#### **Products Affected**

• Rubraca

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Ovarian cancer: Diagnosis of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. Both of the following: 1) Disease is recurrent, and 2) Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin). Prostate cancer: Diagnosis of metastatic castration- resistant prostate cancer. Presence of deleterious BRCA mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has received previous treatment with both of the following: 1) Androgen receptor-directed therapy [e.g., Erleada (apalutamide), Xtandi (enzalutamide), Zytiga (abiraterone)], AND 2) A taxane-based chemotherapy [e.g., docetaxel, Jevtana (cabazitaxel)].
Age Restrictions	N/A
Prescriber Restrictions	Ovarian cancer: Prescribed by or in consultation with an oncologist. Prostate cancer: Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

# **RUXIENCE (S)**

### **Products Affected**

• Ruxience

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-Hodgkin's Lymphoma (NHL): One of the following: 1) Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma. Used as first-line treatment in combination with chemotherapy, 2) Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma. Patient achieved a complete or partial response to a rituximab product in combination with chemotherapy. Used as monotherapy for maintenance therapy, 3) Diagnosis of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma. One of the following: a) Patient has stable disease following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy or, b) Patient achieved a partial or complete response following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy or, b) Diagnosis of diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma. Used as first-line treatment in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens. Chronic Lymphocytic Leukemia (CLL): Diagnosis of chronic lymphocytic leukemia. Used in combination with fludarabine and cyclophosphamide. Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA): Diagnosis of WG or MPA. Patient is concurrently on glucocorticoids (eg, prednisone).
Age Restrictions	N/A
Prescriber Restrictions	NHL, CLL: Prescribed by or in consultation with a hematologist/oncologist. WG, MPA: Prescribed by or in consultation with a nephrologist, pulmonologist, or rheumatologist.
Coverage Duration	NHL, CLL: 12 months. WG, MPA: 3 months.

Other Criteria	Approve for continuation of prior therapy.
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### RYDAPT (S)

### **Products Affected**

• Rydapt

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acute Myeloid Leukemia (AML): Newly diagnosed acute myeloid leukemia (AML), FMS-like tyrosine kinase 3 (FLT3) mutation-positive as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA), used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation. Aggressive Systemic Mastocytosis (ASM), Systemic Mastocytosis with Associated Hematological Neoplasm (SM-AHN), Mast Cell Leukemia (MCL): Diagnosis of one of the following: aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL).
Age Restrictions	N/A
Prescriber Restrictions	All uses: Prescribed by or in consultation with a hematologist or oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### **Products Affected**

• Vigabatrin

• Vigadrone

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Complex Partial Seizures (CPS): For use as adjunctive therapy. Failure, contraindication, or intolerance to two formulary anticonvulsants [eg, Lamictal (lamotrigine), Depakene (valproic acid), Dilantin (phenytoin)]. Infantile Spasms (IS): Diagnosis of infantile spasms.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### SANDOSTATIN (S)

### **Products Affected**

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

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acromegaly (initial): Diagnosis of acromegaly. One of the following: A) Inadequate response to surgical resection and/or pituitary irradiation OR B) Patient is not a candidate for surgical resection or pituitary irradiation. Trial and failure, contraindication or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses. Carcinoid tumor (initial): Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea or flushing episodes. Vasoactive intestinal peptide tumor (initial): Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All uses (initial, reauth): 12 months
Other Criteria	Acromegaly (reauth): Documentation of positive clinical response to therapy (e.g., reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size). Carcinoid tumor (reauth): Patient has improvement in number of diarrhea or flushing episodes. Vasoactive intestinal peptide tumor (reauth): Patient has improvement in number of diarrhea episodes.

### SARCLISA (S)

#### **Products Affected**

• Sarclisa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of multiple myeloma. Patient has received at least two prior treatment regimens which included lenalidomide and a proteasome inhibitor (e.g., bortezomib, carfilzomib). Used in combination with pomalidomide and dexamethasone.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist/hematologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# **SCEMBLIX (S)**

#### **Products Affected**

• Scemblix

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of chronic myelogenous/myeloid leukemia (CML). Disease is Philadelphia chromosome-positive (Ph+). Disease is in chronic phase. One of the following: 1) Patient has been previously treated with two or more alternative tyrosine kinase inhibitors (TKI) [e.g., Bosulif (bosutinib), imatinib, Sprycel (dasatinib), Tasigna (nilotinib), Iclusig (ponatinib)], OR 2) Disease is T315I mutation positive.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### SCIG (S)

### **Products Affected**

• Cuvitru

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	All uses (initial, reauth): Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication).
Required Medical Information	Initial: Immune globulin will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. Medication is being used subcutaneously. Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) OR one of the following FDA- approved or literature supported diagnoses: 1) Common variable immunodeficiency (CVID), OR 2) Congenital agammaglobulinemia (X- linked or autosomal recessive), OR 3) Severe combined immunodeficiencies (SCID), OR 4) Wiskott-Aldrich syndrome, OR 5) Other primary immunodeficiency with an immunologic evaluation including IgG levels below the normal laboratory value for the patient's age at the time of diagnosis and the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine).
Age Restrictions	N/A
Prescriber Restrictions	All uses (initial, reauth): Prescribed by or in consultation with a physician who has specialized expertise in managing patients on SCIG therapy (e.g., immunologist, hematologist, neurologist).
Coverage Duration	Initial, reauth: 12 months
Other Criteria	Subject to Part B vs. Part D review. All uses (reauth): Patient has experienced an objective improvement on immune globulin therapy and the immune globulin will be administered at the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both strategies) for maintenance therapy.

### **SECUADO (S)**

#### **Products Affected**

• Secuado

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of schizophrenia. Both of the following: 1) Trial and failure of Saphris (asenapine) and 2) Trial and failure, contraindication, or intolerance to one of the following generic formulary atypical antipsychotic agents: aripiprazole, olanzapine, paliperidone, quetiapine, risperidone, or ziprasidone.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## **SIGNIFOR (S)**

### **Products Affected**

• Signifor

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cushing's disease (initial): Diagnosis of Cushing's disease. One of the following: a) Pituitary surgery has not been curative for the patient or b) Patient is not a candidate for pituitary surgery.
Age Restrictions	N/A
Prescriber Restrictions	Cushing's disease (initial): Prescribed by or in consultation with an endocrinologist.
Coverage Duration	Cushing's disease (initial, reauth): 12 months
Other Criteria	Cushing's disease (reauth): Documentation of positive clinical response to therapy (e.g., a clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs or symptoms of the disease).

### SKYRIZI (S)

#### **Products Affected**

• Skyrizi Pen

• Skyrizi INJ 150MG/ML, 360MG/2.4ML, 75MG/0.83ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. Psoriatic arthritis (PsA) (Initial): Diagnosis of active PsA. Crohn's disease (CD) (Initial): Diagnosis of moderately to severely active CD. Will be used as a maintenance dose following the intravenous induction doses.
Age Restrictions	N/A
Prescriber Restrictions	Plaque psoriasis (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. CD (Initial): Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	Plaque psoriasis, PsA, CD (Initial, reauth): 12 months
Other Criteria	Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. PsA, CD (Reauth): Documentation of positive clinical response to therapy.

### **SOMATULINE DEPOT (S)**

#### **Products Affected**

• Somatuline Depot

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acromegaly: Diagnosis of acromegaly. One of the following: A) Inadequate response to one of the following: surgery or radiotherapy, OR B) Not a candidate for one of the following: surgery or radiotherapy. Gastroenteropancreatic neuroendocrine tumors (GEP-NETs) (120mg/0.5mL strength only): Diagnosis of GEP-NETs. Disease is one of the following: (a) unresectable, locally advanced or (b) metastatic. Carcinoid syndrome (120mg/0.5mL strength only): Diagnosis of carcinoid syndrome. Used to reduce the frequency of short-acting somatostatin analog rescue therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All uses: 12 months
Other Criteria	All Indications: Approve for continuation of prior therapy.

### **SOMAVERT (S)**

#### **Products Affected**

• Somavert

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acromegaly (initial): Diagnosis of acromegaly AND Failure to surgery and/or radiation therapy and/or other medical therapies (such as dopamine agonists [e.g., bromocriptine, cabergoline]) unless patient is not a candidate for these treatment options AND trial and failure or intolerance to generic octreotide (a somatostatin analogue)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	Initial and reauth: 12 months
Other Criteria	Acromegaly (reauth): Patient has experienced a positive clinical response to therapy (biochemical control, decrease or normalization of IGF-1 levels).

#### **Products Affected**

• Itraconazole SOLN

• Itraconazole CAPS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	One of the following: 1) patient has a systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis), OR 2) all of the following: a) patient has a diagnosis of onychomycosis confirmed by one of the following (CAPSULE ONLY): i) positive potassium hydroxide (KOH) preparation, OR ii) fungal culture, OR iii) nail biopsy, AND b) patient has had a trial and failure, contraindication, or intolerance to oral terbinafine, OR 3) both of the following (ORAL SOLUTION ONLY): a) patient has a diagnosis of candidiasis (esophageal or oropharyngeal), AND b) one of the following: i) candidiasis is refractory or resistant to treatment with fluconazole OR ii) trial and failure, contraindication, or intolerance to fluconazole.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Systemic fungal infxn:6mo.Candidiasis:1mo.Fingernail onycho:5wks.Toenail onycho, other:3mo.
Other Criteria	N/A

### **SPRAVATO (S)**

#### **Products Affected**

• Spravato 84mg Dose

• Spravato 56mg Dose

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	One of the following: A) Both of the following: 1) Diagnosis of major depressive disorder (treatment-resistant) and 2) Patient has not experienced a clinical meaningful improvement after treatment with at least two antidepressants from different classes for an adequate duration (at least 4 weeks each) in the current depressive episode OR B) Both of the following: 1) Diagnosis of major depressive disorder and 2) Patient has both of the following: a) depressive symptoms and b) acute suicidal ideation or behavior. Used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a psychiatrist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## **SPRYCEL (S)**

### **Products Affected**

• Sprycel

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Philadelphia chromosome positive (Ph+)/BCR ABL chronic myelogenous leukemia (CML): Diagnosis of Ph+/BCR ABL CML. Ph+/BCR ABL acute lymphoblastic leukemia (ALL): Diagnosis of Ph+/BCR ABL ALL.
Age Restrictions	N/A
Prescriber Restrictions	All Uses: Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	All Uses: 12 months
Other Criteria	All Uses: Approve for continuation of prior therapy.

## STELARA (IV) (S)

#### **Products Affected**

• Stelara INJ 130MG/26ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Crohn's Disease (CD): Diagnosis of moderately to severely active CD. Both of the following: trial and failure, contraindication, or intolerance to Humira (adalimumab), and trial and failure, contraindication, or intolerance to one of the following conventional therapies: 6- mercaptopurine, Imuran (azathioprine), methotrexate, corticosteroid (eg, prednisone, methylprednisolone). Ulcerative Colitis (UC): Diagnosis of moderately to severely active UC. Trial and failure, contraindication, or intolerance to both Humira (adalimumab) and Xeljanz/Xeljanz XR (tofacitinib).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	One time
Other Criteria	Stelara is to be administered as an intravenous induction dose. Stelara induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for Crohn's Disease/ulcerative colitis: 260 mg for patients weighing 55 kg or less, 390 mg for patients weighing more than 55 kg to 85 kg, or 520 mg for patients weighing more than 85 kg.

### **STELARA (S)**

### **Products Affected**

• Stelara INJ 45MG/0.5ML, 90MG/ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Plaque psoriasis (Initial - 45mg/0.5mL): Diagnosis of moderate to severe plaque psoriasis. Plaque psoriasis (Initial - 90mg/1mL): Diagnosis of moderate to severe plaque psoriasis. Patient's weight is greater than 100 kg (220 lbs). Plaque psoriasis (Initial): Trial and failure, contraindication (eg, safety concerns, not indicated for patient's age/weight), or intolerance to two of the following: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab), Cosentyx (secukinumab), OR for continuation of prior therapy. Psoriatic arthritis (PsA) (Initial - 45mg/0.5mL): Diagnosis of active PsA. PsA (Initial - 90mg/1mL): Diagnosis of active PsA. Patient's weight is greater than 100 kg (220 lbs). Diagnosis of co-existent moderate to severe psoriasis. PsA (Initial): Trial and failure, contraindication, or intolerance (TF/C/I) to two of the following, or attestation demonstrating a trial may be inappropriate: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib/ER), OR for continuation of prior therapy. Crohn's disease (CD) (Initial): Diagnosis of moderately to severely active Crohn's disease. Both of the following: a) TF/C/I to one of the following: Humira or Skyrizi, and b) TF/C/I to treatment with at least one immunomodulator or corticosteroid [e.g., Purinethol (6- mercaptopurine), Imuran (azathioprine), Sandimmune (cyclosporine A), Prograf (tacrolimus), MTX (methotrexate), prednisone, methylprednisolone], OR for continuation of prior therapy. Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. TF/C/I to two of the following, or attestation demonstrating a trial may be inappropriate: Humira (adalimumab), Rinvoq (upadacitinib), or Xeljanz/Xeljanz XR (tofacitinb), OR for continuation of prior therapy.
Age Restrictions	N/A

Prescriber Restrictions	Plaque psoriasis (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. CD and UC (initial): Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	All uses (Initial, reauth): 12 months
Other Criteria	Reauth (PsA, CD, UC): Documentation of positive clinical response to therapy. Reauth (plaque psoriasis): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline.

## STIVARGA (S)

#### **Products Affected**

• Stivarga

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Metastatic colorectal cancer (mCRC): All of the following: 1) diagnosis of mCRC, AND 2) trial and failure, contraindication or intolerance to fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI), AND 3) trial and failure, contraindication or intolerance to an anti-VEGF therapy (e.g., bevacizumab), AND 4) one of the following: a) RAS mutation, OR b) both of the following: RAS wild-type (RAS mutation negative tumor) and trial and failure, contraindication or intolerance to an anti-EGFR therapy [e.g., Vectibix (panitumumab), Erbitux (cetuximab)]. Gastrointestinal stromal tumor (GIST): All of the following: 1) diagnosis of locally advanced, unresectable or metastatic GIST, AND 2) trial and failure, contraindication or intolerance to both of the following: a) Gleevec (imatinib mesylate), AND b) Sutent (sunitinib malate). Hepatocellular Carcinoma (HCC): Diagnosis of HCC. Trial and failure or intolerance to Nexavar (sorafenib tosylate).
Age Restrictions	N/A
Prescriber Restrictions	mCRC, GIST: Prescribed by or in consultation with an oncologist. HCC: Prescribed by or in consultation with an oncologist, hepatologist, or gastroenterologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### **STRENSIQ (S)**

### **Products Affected**

• Strensiq

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Hypophosphatasia: Diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia AND for patients requesting the 80 mg/0.8 mL vial only: Patient's weight is greater than or equal to 40 kg.
Age Restrictions	N/A
Prescriber Restrictions	Hypophosphatasia: Prescribed by or in consultation with a specialist experienced in the treatment of inborn errors of metabolism or endocrinologist
Coverage Duration	Hypophosphatasia: 12 months
Other Criteria	N/A

## **SUPPRELIN LA (S)**

#### **Products Affected**

• Supprelin La

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Central Precocious Puberty (CPP) (initial): Diagnosis of CPP (idiopathic or neurogenic). Early onset of secondary sexual characteristics in females less than age 8 or males less than age 9. Advanced bone age of at least one year compared with chronologic age. One of the following: a) patient has undergone gonadotropin-releasing hormone agonist (GnRHa) testing AND Peak luteinizing hormone (LH) level above pre-pubertal range, or b) patient has a random LH level in the pubertal range.
Age Restrictions	N/A
Prescriber Restrictions	CPP (initial, reauth): Prescribed by or in consultation with a pediatric endocrinologist.
Coverage Duration	CPP (init, reauth): 12 months
Other Criteria	CPP (reauthorization): LH levels have been suppressed to pre-pubertal levels.

## **SUTENT (S)**

### **Products Affected**

• Sunitinib Malate

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Renal cell carcinoma: Diagnosis of advanced or metastatic renal cell carcinoma. Gastrointestinal stromal tumor (GIST): Diagnosis of GIST after disease progression on, or contraindication or intolerance to Gleevec (imatinib). Pancreatic neuroendocrine tumors: Diagnosis of progressive, well-differentiated pancreatic neuroendocrine tumor that is unresectable locally advanced or metastatic disease. Adjuvant treatment of renal cell carcinoma: Diagnosis of renal cell carcinoma (RCC). Used as adjuvant therapy. Patient is at high risk of recurrent RCC following nephrectomy.
Age Restrictions	N/A
Prescriber Restrictions	All uses: Prescribed by or in consultation with an oncologist
Coverage Duration	All uses: 12 months
Other Criteria	All Indications: Approve for continuation of prior therapy.

• Sutent

### **SYLATRON (S)**

#### **Products Affected**

• Sylatron

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Melanoma: Diagnosis of melanoma with microscopic or gross nodal involvement AND The prescribed medication will be used as adjuvant therapy within 84 days of definitive surgical resection, including complete lymphadenectomy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### SYNAGIS (S)

### **Products Affected**

• Synagis INJ 100MG/ML, 50MG/0.5ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Patient will use palivizumab for immunoprophylaxis of respiratory syncytial virus (RSV) during the peak months of infection in the patient's geographic region AND Patient meets one of the following criteria: 1) Infants born at 28 weeks, six days gestation or earlier and who are younger than 12 months of age at the start of the RSV season OR 2) Diagnosis of chronic lung disease of prematurity, born before 32 weeks, 0 days gestation, received greater than 21% oxygen for at least the first 28 days after birth, and one of the following: a) 12 months of age or younger at the start of the RSV season OR b) greater than 12 months of age to 24 months of age at the start of the RSV season and received medical support (i.e., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) within 6 months before the start of the second RSV season. OR 3) Patient is 12 months of age or younger at the start of the RSV season and has one of the following: a) acyanotic heart failure that will require a cardiac surgical procedure and the patient is receiving medication to control congestive heart failure, OR b) moderate to severe pulmonary hypertension OR c) cyanotic heart defect. OR 4) patient is younger than 24 months of age and will or has undergone a cardiac transplantation during the RSV season. OR 5) Patient is 12 months of age or younger at the start of the RSV season with a congenital abnormality or neuromuscular disorder and has an impaired ability to clear secretions from the upper airway due to an ineffective cough. OR 6) Patient is younger than 24 months of age with a lymphocyte count below the normal range for patient's age and has received or will receive a solid organ transplant, hematopoietic stem cell transplant recipient, or chemotherapy during the RSV season.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pediatric specialist (i.e., pulmonologist, neonatologist, neurologist, cardiologist, pediatric intensivist, or infectious disease specialist).

Coverage Duration	5 months (5 doses) during RSV season.
Other Criteria	N/A

# SYNRIBO (S)

### **Products Affected**

• Synribo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic myelogenous leukemia (CML): Diagnosis of CML in the chronic or accelerated phase AND Patient has tried and has had resistance, relapse, inadequate response, intolerance or is contraindicated to TWO tyrosine kinase inhibitors (i.e., Gleevec [imatinib], Sprycel, Tasigna, and Bosulif, Iclusig).
Age Restrictions	N/A
Prescriber Restrictions	CML: Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

#### **Products Affected**

• Clovique

**PA** Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A N/A Exclusion Criteria Required Initial: Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration). Trial and failure, contraindication, or intolerance to a penicillamine Medical Information product (e.g., Depen, Cuprimine) N/A **Age Restrictions** Prescriber N/A Restrictions Coverage 12 months **Duration Other Criteria** Reauth: Documentation of a positive clinical response to therapy

• Trientine Hydrochloride

# TABRECTA (S)

### **Products Affected**

• Tabrecta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of non-small cell lung cancer (NSCLC). Disease is one of the following: recurrent, advanced, metastatic. Presence of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# **TAFAMIDIS (S)**

### **Products Affected**

• Vyndaqel

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM) (initial): Diagnosis of transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM). One of the following: 1) Patient has a transthyretin (TTR) mutation (e.g., V122I), 2) Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of TTR amyloid deposits, OR 3) All of the following: i) echocardiogram or cardiac magnetic resonance imaging suggestive of amyloidosis, ii) scintigraphy scan suggestive of cardiac TTR amyloidosis, and iii) absence of light- chain amyloidosis. One of the following: 1) History of heart failure (HF), with at least one prior hospitalization for HF, OR 2) Presence of clinical signs and symptoms of HF (e.g., dyspnea, edema). Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure.
Age Restrictions	N/A
Prescriber Restrictions	ATTR-CM (initial, reauth): Prescribed by or in consultation with a cardiologist
Coverage Duration	ATTR-CM (initial, reauth): 12 months
Other Criteria	ATTR-CM (reauth): Documentation of positive clinical response to therapy. Patient continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure.

# TAFINLAR (S)

### **Products Affected**

• Tafinlar

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Melanoma: Diagnosis of unresectable or metastatic melanoma AND cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) OR both of the following: cancer is BRAF V600E or V600K mutant type as detected by an FDA- approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) and medication is used in combination with Mekinist (trametinib). Adjuvant Treatment for Melanoma: Diagnosis of melanoma. Cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Involvement of lymph nodes following complete resection. Used as adjunctive therapy. Medication is used in combination with Mekinist (trametinib). Non-small Cell Lung Cancer (NSCLC): Diagnosis of metastatic non-small cell lung cancer AND cancer is BRAF V600E mutant type as detected by an FDA- approved test (THxID-BRAF Kit) or a test performed at a facility approved test (THxID-BRAF Kit) or a test performed at a facility approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) AND medication is used in combination with Mekinist (trametinib). Anaplastic Thyroid Cancer (ATC): Diagnosis of locally advanced or metastatic anaplastic thyroid cancer. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Cancer may not be treated with standard locoregional treatment options. Medication is used in combination with Mekinist (trametinib).
Age Restrictions	Solid tumors: Patient is 6 years of age or older.
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.

Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy. Solid tumors: Diagnosis of solid tumors. Disease is unresectable or metastatic. Patient has progressed on or following prior treatment and have no satisfactory alternative treatment options. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Medication is used in combination with Mekinist (trametinib).

# TAGRISSO (S)

### **Products Affected**

• Tagrisso

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): One of the following: A) All of the following: Diagnosis of metastatic NSCLC. One of the following: 1) Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA), OR 2) Both of the following: a) Patient has known active EGFR T790M mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved test or a test performed at a facility approved test or a test performed at a facility approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) and b) Patient has experienced disease progression on or after one of the following EGFR Tyrosine Kinase Inhibitors (TKIs): Gilotrif (afatinib), Iressa (gefitinib), Tarceva (erlotinib), or Vizimpro (dacomitinib). OR B) All of the following: Diagnosis of NSCLC. Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Both of the following: 1) Patient is receiving as adjuvant therapy, and 2) Patient has had a complete surgical resection of the primary NSCLC tumor.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# TALZENNA (S)

### **Products Affected**

• Talzenna

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Breast cancer: Diagnosis of breast cancer. Disease is one of the following: a) locally advanced or b) metastatic. Presence of a deleterious or suspected deleterious germline BRCA-mutation (gBRCAm) as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Disease is human epidermal growth factor receptor 2 (HER2)-negative.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# TARCEVA (S)

### **Products Affected**

• Erlotinib Hydrochloride

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of locally advanced or metastatic (Stage III or IV) NSCLC AND Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Pancreatic Cancer: Diagnosis of locally advanced, unresectable, or metastatic pancreatic cancer AND erlotinib will be used in combination with gemcitabine.
Age Restrictions	N/A
Prescriber Restrictions	All uses: Prescribed by or in consultation with an oncologist
Coverage Duration	All uses: 12 months
Other Criteria	All Indications: Approve for continuation of prior therapy.

# TARGRETIN (S)

#### **Products Affected**

• Bexarotene

**Criteria Details PA** Criteria Indications All Medically-accepted Indications. **Off-Label Uses** N/A Exclusion N/A Criteria Required Cutaneous T-Cell Lymphoma (CTCL): Diagnosis of CTCL. Trial and Medical failure, contraindication, or intolerance to at least one prior therapy Information (including skin-directed therapies [eg, corticosteroids {ie, clobetasol, diflorasone, halobetasol, augmented betamethasone dipropionate}] or systemic therapies [eg, interferons]). **Age Restrictions** N/A Prescriber Prescribed by or in consultation with an oncologist or dermatologist Restrictions 12 months Coverage Duration **Other Criteria** Approve for continuation of prior therapy.

• Targretin GEL

# TARPEYO (S)

### **Products Affected**

• Tarpeyo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of primary immunoglobulin A nephropathy (IgAN). Patient is at risk of rapid disease progression [e.g., generally a urine protein-to- creatinine ratio (UPCR) greater than or equal to 1.5 g/g, or by other criteria such as clinical risk scoring using the International IgAN Prediction Tool]. Used to reduce proteinuria. Estimated glomerular filtration rate (eGFR) greater than or equal to 35 mL/min/1.73 m2. One of the following: 1) Patient has been on a minimum 90-day trial of a maximally tolerated dose and will continue to receive therapy with one of the following: a) an angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril), or b) an angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan), OR 2) Patient has a contraindication or intolerance to both ACE inhibitors and ARBs. Trial and failure, contraindication, or intolerance to another glucocorticoid (e.g., methylprednisolone, prednisone).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist.
Coverage Duration	9 months.
Other Criteria	N/A

# TASIGNA (S)

### **Products Affected**

• Tasigna

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic myelogenous leukemia (CML): Diagnosis of Ph+/BCR ABL CML
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# TAVALISSE (S)

### **Products Affected**

• Tavalisse

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic Idiopathic Thrombocytopenic Purpura (ITP) (initial): Diagnosis of chronic immune ITP or relapsed/refractory ITP. Baseline platelet count is less than 30,000/mcL. Trial and failure, contraindication, or intolerance to at least one of the following: corticosteroids (e.g., prednisone, methylprednisolone), immunoglobulins [e.g., Gammagard, immune globulin (human)], splenectomy, thrombopoietin receptor agonists (e.g., Nplate, Promacta), or Rituxan (rituximab). Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding.
Age Restrictions	N/A
Prescriber Restrictions	ITP (initial): Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	ITP (initial, reauth): 12 months
Other Criteria	ITP (reauth): Documentation of positive clinical response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding.

# TAVNEOS (S)

### **Products Affected**

• Tavneos

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Diagnosis of one of the following types of severe active anti- neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis: a) Granulomatosis with polyangiitis (GPA) OR b) Microscopic polyangiitis (MPA). Diagnosis is confirmed by one of the following: a) ANCA test positive for proteinase 3 (PR3) antigen, b) ANCA test positive for myeloperoxidase (MPO) antigen, OR c) Tissue biopsy. Patient is receiving concurrent immunosuppressant therapy with one of the following: a) cyclophosphamide OR b) rituximab. One of the following: a) Patient is concurrently on glucocorticoids (e.g., prednisone) OR b) History of contraindication or intolerance to glucocorticoids (e.g., prednisone).
Age Restrictions	N/A
Prescriber Restrictions	Initial, Reauth: Prescribed by or in consultation with a nephrologist, pulmonologist, or rheumatologist
Coverage Duration	Initial, Reauth: 12 months
Other Criteria	Reauth: Patient does not show evidence of progressive disease while on therapy. Patient is receiving concurrent immunosuppressant therapy (e.g., azathioprine, cyclophosphamide, methotrexate, rituximab).

# TAZVERIK (S)

### **Products Affected**

• Tazverik

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Epithelioid sarcoma: Diagnosis of epithelioid sarcoma. Disease is one of the following: metastatic or locally advanced. Patient is not eligible for complete resection. Follicular lymphoma: Diagnosis of follicular lymphoma. Disease is one of the following: relapsed or refractory.
Age Restrictions	N/A
Prescriber Restrictions	Epithelioid sarcoma: Prescribed by or in consultation with an oncologist. Follicular lymphoma: Prescribed by or in consultation with an oncologist or hematologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# **TECFIDERA (S)**

#### **Products Affected**

• Dimethyl Fumarate Starterpack MISC 0

• Dimethyl Fumarate CPDR

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS) (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions).
Age Restrictions	N/A
Prescriber Restrictions	MS (initial, reauth): Prescribed by or in consultation with a neurologist
Coverage Duration	MS (initial, reauth): 12 months
Other Criteria	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).

# **TEGSEDI (S)**

### **Products Affected**

• Tegsedi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) (initial): Diagnosis of hATTR amyloidosis with polyneuropathy. Patient has a transthyretin (TTR) mutation (e.g., V30M). One of the following: 1) Patient has a baseline polyneuropathy disability (PND) score less than or equal to IIIb, 2) Patient has baseline familial amyloidotic polyneuropathy (FAP) stage of 1 or 2, OR 3) Patient has a baseline neuropathy impairment score (NIS) between 10 and 130. Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy).
Age Restrictions	N/A
Prescriber Restrictions	hATTR amyloidosis (initial): Prescribed by or in consultation with a neurologist
Coverage Duration	hATTR amyloidosis (initial, reauth): 12 months
Other Criteria	hATTR amyloidosis (reauth): Patient has demonstrated a benefit from therapy (e.g., improved neurologic impairment, slowing of disease progression, quality of life assessment). One of the following: 1) Patient continues to have a PND score less than or equal to IIIb, 2) Patient continues to have a FAP stage of 1 or 2, OR 3) Patient continues to have a NIS between 10 and 130.

# **TEPMETKO (S)**

### **Products Affected**

• Tepmetko

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is metastatic. Presence of mesenchymal-epithelial transition (MET) exon 14 skipping alterations.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## **TERIPARATIDE (S)**

#### **Products Affected**

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• Teriparatide

• Forteo INJ 600MCG/2.4ML

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Postmenopausal osteoporosis or osteopenia or men with primary or hypogonadal osteoporosis or osteopenia (initial): Diagnosis of one of the following: a) postmenopausal osteoporosis or osteopenia or b) primary or hypogonadal osteoporosis or osteopenia. One of the following: Set I) Both of the following: A) Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) One of the following: 1) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) trial and failure, contraindication, or intolerance (TF/C/I) to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]), or Set II) Both of the following: A) BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) One of the following: 1) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) both of the following: i) TF/C/I to one osteoporosis treatment (e.g., alendronate, zoledronic acid, Prolia [denosumab]) and ii) One of the following FRAX 10-year probabilities: a) Major osteoporotic fracture at 20% or more in the U.S., or the country- specific threshold in other countries or regions, or b) Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions. Glucocorticoid-Induced Osteoporosis: See Other Criteria section.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All uses (initial): 24 months. All uses (reauth): 12 months.

following fractures resulting from minimal trauma: vertebral compression fx, fx of the hip, fx of the distal radius, fx of the pelvis, or fx of the proximal humerus. TF/C/I to one bisphosphonate (e.g., alendronate). All uses (initial, reauth): One of the following: 1) Treatment duration of parathyroid hormones [e.g., teriparatide, Tymlos (abaloparatide)] has not exceeded a total of 24 months during the patient's lifetime, or 2) Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones [e.g., teriparatide, Tymlos (abaloparatide)].
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### **TESTOSTERONE (S)**

#### **Products Affected**

- Androderm PT24 2MG/24HR, 4MG/24HR
- Testosterone GEL 25MG/2.5GM, 50MG/5GM
- Testosterone Cypionate INJ 100MG/ML, 200MG/ML
- Testosterone Pump

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than 300 ng/dL (10.4 nmol/L) or less than the reference range for the lab, OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome), OR 4) Both of the following: a) Patient is continuing testosterone therapy, and b) One of the following: i) Follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is within or below the normal limits of the reporting lab, or ii) follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted. Gender Dysphoria (GD)/Gender Incongruence (off-label): Dx of GD/Gender Incongruence.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	HG(init): (New to T tx:6 mo. New to plan and cont T tx:12 mo), (reauth): 12 mo. GD: 12 mo.

Other Criteria	HG (Reauth): 1) Follow-up total serum T level within or below the
	normal limits of the reporting lab, or 2) Follow-up total serum T level
	outside of upper limits of normal for the reporting lab and the dose is
	adjusted, OR 3) Has a condition that may cause altered SHBG (eg,
	thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one
	of the following: Follow-up calculated free or bioavailable T level within
	or below the normal limits of the reporting lab, or follow-up calculated
	free or bioavailable T level outside of upper limits of normal for the
	reporting lab and the dose is adjusted.

## **TESTOSTERONE ENANTHATE (S)**

#### **Products Affected**

• Testosterone Enanthate INJ

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than 300 ng/dL (10.4 nmol/L) or less than the reference range for the lab, OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome), OR 4) Both of the following: a) Patient is continuing testosterone therapy, and b) One of the following: i) Follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is within or below the normal limits of the reporting lab, or ii) follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted. Delayed puberty (DP): Dx of DP AND male patient at birth. Breast cancer (BC): Dx of inoperable BC AND used for palliative treatment AND female patient at birth. Gender Dysphoria (GD)/Gender Incongruence (off-label): Dx of GD/Gender Incongruence.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	HG(init): (New to T tx:6 mo. Cont T tx:12 mo), (reauth): 12 mo. BC, GD: 12 mo. DP: 6 mo.

Other Criteria	HG (Reauth): 1) Follow-up total serum T level within or below the
	normal limits of the reporting lab, or 2) Follow-up total serum T level
	outside of upper limits of normal for the reporting lab and the dose is adjusted OP 3) Has a condition that may cause altered SHPC (ag
	adjusted, OR 3) Has a condition that may cause altered SHBG (eg,
	thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one
	of the following: Follow-up calculated free or bioavailable T level within
	or below the normal limits of the reporting lab, or follow-up calculated
	free or bioavailable T level outside of upper limits of normal for the
	reporting lab and the dose is adjusted.

# **THALOMID (S)**

### **Products Affected**

• Thalomid

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple myeloma (MM): Diagnosis of MM. Used in combination with dexamethasone, unless the patient has an intolerance to steroids. Erythema nodosum leprosum (ENL): Diagnosis of moderate to severe ENL with cutaneous manifestations. Thalomid is not used as monotherapy if moderate to severe neuritis is present.
Age Restrictions	N/A
Prescriber Restrictions	MM: Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# TIBSOVO (S)

### **Products Affected**

• Tibsovo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Relapsed or refractory Acute Myeloid Leukemia (AML): Diagnosis of AML. Disease is relapsed or refractory. Newly-Diagnosed AML: Diagnosis of newly-diagnosed AML. One of the following: 1) patient is greater than or equal to 75 years old OR 2) patient has comorbidities that preclude use of intensive induction chemotherapy. Locally Advanced or Metastatic Cholangiocarcinoma: Diagnosis of cholangiocarcinoma. Disease is locally advanced or metastatic. Patient has been previously treated. All indications: Patient has an isocitrate dehydrogenase-1 (IDH1) mutation as detected by a U.S. Food and Drug Administration (FDA)- approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	N/A
Prescriber Restrictions	Relapsed or refractory AML, Newly-Diagnosed AML: Prescribed by or in consultation with a hematologist/oncologist. Locally Advanced or Metastatic Cholangiocarcinoma: Prescribed by or in consultation with a hepatologist, gastroenterologist, or oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# **TOPICAL RETINOID (S)**

#### **Products Affected**

• Tretinoin CREA 0.025%, 0.05%

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acne vulgaris: Diagnosis of acne vulgaris (i.e., acne).
Age Restrictions	PA applies to members 26 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

# TRAZIMERA (S)

### **Products Affected**

• Trazimera

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Breast cancer: Diagnosis of human epidermal growth factor receptor 2 (HER2)-overexpressing breast cancer. One of the following treatment regimens: a) As adjuvant treatment, b) metastatic disease and one of the following: 1) used in combination with a taxane (eg, docetaxel, paclitaxel), or 2) used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease, or c) used in combination with Perjeta (pertuzumab). Gastric Cancer: Diagnosis of HER2-overexpressing gastric or gastroesophageal junction adenocarcinoma (locally advanced, recurrent, or metastatic). Used in combination with one of the following treatment regimens: a) Platinol (cisplatin) and Adrucil (5-fluorouracil), or b) Platinol (cisplatin) and Xeloda (capecitabine).
Age Restrictions	N/A
Prescriber Restrictions	All uses: Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# **TRELSTAR (S)**

### **Products Affected**

• Trelstar Mixject INJ 11.25MG, 22.5MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prostate Cancer: Diagnosis of advanced or metastatic prostate cancer. Trial and failure, contraindication, or intolerance to any brand Lupron formulation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# TRIKAFTA (S)

### **Products Affected**

• Trikafta TBPK 50MG; 0; 25MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cystic Fibrosis (CF) (initial): Diagnosis of CF. Patient has at least one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected by an FDA-cleared cystic fibrosis mutation test or a test performed at a Clinical Laboratory Improvement Amendments (CLIA)-approved facility: F508del mutation OR a mutation in the CFTR gene that is responsive based on in vitro data.
Age Restrictions	CF (initial): 6 years of age or older.
Prescriber Restrictions	CF (initial): Prescribed by or in consultation with a pulmonologist or specialist affiliated with a CF care center.
Coverage Duration	CF (initial, reauth): 12 months
Other Criteria	CF (reauth): Documentation of positive clinical response to therapy (e.g., improvement in lung function [percent predicted forced expiratory volume in one second {PPFEV1}] or decreased number of pulmonary exacerbations).

# **TRIPTODUR (S)**

### **Products Affected**

• Triptodur

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Central Precocious Puberty (CPP) (initial): Diagnosis of CPP (idiopathic or neurogenic). Early onset of secondary sexual characteristics in females less than age 8 or males less than age 9. Advanced bone age of at least one year compared with chronologic age. One of the following: a) patient has undergone gonadotropin-releasing hormone agonist (GnRHa) testing AND Peak luteinizing hormone (LH) level above pre-pubertal range, or b) patient has a random LH level in the pubertal range. Trial and failure or intolerance to Lupron Depot-Ped.
Age Restrictions	N/A
Prescriber Restrictions	CPP (initial, reauth): Prescribed by or in consultation with a pediatric endocrinologist.
Coverage Duration	CPP (Initial, reauth): 12 months
Other Criteria	CPP (reauthorization): LH levels have been suppressed to pre-pubertal levels.

# **TRODELVY (S)**

### **Products Affected**

• Trodelvy

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Triple Negative Breast Cancer (TNBC): Diagnosis of TNBC. Disease is metastatic. Patient has received at least two prior therapies for metastatic disease (e.g., carboplatin, cisplatin, gemcitabine, paclitaxel, docetaxel, capecitabine, etc.).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# **TRUSELTIQ (S)**

### **Products Affected**

• Truseltiq

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of cholangiocarcinoma. Disease is one of the following: a) unresectable locally advanced or b) metastatic. Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has been previously treated.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hepatologist, gastroenterologist, or oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# TUKYSA (S)

### **Products Affected**

• Tukysa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Breast cancer: Diagnosis of breast cancer. Disease is one of the following: a) advanced unresectable or b) metastatic. Disease is human epidermal growth factor receptor 2 (HER2)-positive. Used in combination with trastuzumab and capecitabine. Patient has received one or more prior anti- HER2 based regimens (e.g., trastuzumab, pertuzumab, ado-trastuzumab emtansine).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# **TURALIO (S)**

### **Products Affected**

• Turalio

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Tenosynovial Giant Cell Tumor (TGCT): Diagnosis of TGCT. Patient is symptomatic. Patient is not a candidate for surgery due to worsening functional limitation or severe morbidity with surgical removal.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# TYKERB (S)

### **Products Affected**

• Lapatinib Ditosylate

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Breast Cancer: Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive metastatic or recurrent breast cancer. Used in combination with one of the following: Trastuzumab, Xeloda (capecitabine), or aromatase inhibitors [eg, Aromasin (exemestane), Femara (letrozole), Arimidex (anastrozole)].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### TYMLOS (S)

### **Products Affected**

• Tymlos

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of postmenopausal osteoporosis or osteopenia. One of the following: Set I) Both of the following: A) Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) One of the following: 1) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) trial and failure, contraindication, or intolerance (TF/C/I) to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]), or Set II) Both of the following: A) BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) One of the following: 1) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) both of the following: i) TF/C/I to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]) and ii) one of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities: a) major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions, or b) hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions. Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	24 months (max 24 months of therapy per lifetime)
Other Criteria	N/A

### TYSABRI (S)

### **Products Affected**

• Tysabri

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS) (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following disease-modifying therapies for MS: A) Aubagio (teriflunomide), B) Lemtrada (alemtuzumab), C) Mavenclad (cladribine), D) Plegridy (peginterferon beta-1a), E) Any one of the inteferon beta-1a injections (eg, Avonex), F) Any one of the interferon beta-1b injections (eg, Betaseron, Extavia), G) Any one of the glatiramer acetate injections (eg, Copaxone, Glatopa, generic glatiramer acetate), H) Any one of the oral fumarates (eg, brand Tecfidera, generic dimethyl fumarate), I) Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (eg, Gilenya, Mayzent, Zeposia), J) Any one of the B-cell targeted therapies (eg, Ocrevus, Kesimpta), 2) Patient is not a candidate for any of the drugs listed as prerequisites due to the severity of their MS, or 3) for continuation of prior therapy. MS (init, reauth): Not used in combination with another disease-modifying therapy for MS. Crohn's Disease (CD) (initial): Diagnosis of moderately to severely active CD with evidence of inflammation (eg, elevated C-reactive protein [CRP], elevated erythrocyte sedimentation rate, presence of fecal leukocytes). TF/C/I to one of the following conventional therapies: corticosteroids (eg, prednisone, methylprednisolone), 6-mercaptopurine (6MP [Purinethol], azathioprine (Imuran), methotrexate (Rheumatrex, Trexall), aminosalicylates (eg, sulfasalazine, mesalamine, olsalazine). TF/C/I to a TNF-inhibitor (eg, Enbrel [etanercept], Humira [adalimumab], or infliximab).
Age Restrictions	N/A

Prescriber Restrictions	MS (init, reauth): Prescribed by or in consultation with a neurologist. CD (initial): Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	MS (init, reauth): 12mo. CD (Init): 3 mo. CD (Reauth): 6 mo if not on steroids. Otherwise, 3 mo.
Other Criteria	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression). CD (reauth): Documentation of positive clinical response (eg, improved disease activity index) to therapy.

# **UBRELVY (S)**

### **Products Affected**

• Ubrelvy

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Diagnosis of migraine with or without aura. Will be used for the acute treatment of migraine. Will not be used for preventive treatment of migraine. Patient has fewer than 15 headache days per month. Trial and failure or intolerance to one triptan (e.g., eletriptan, rizatriptan, sumatriptan) or a contraindication to all triptans. Medication will not be used in combination with another oral CGRP inhibitor.
Age Restrictions	Initial: 18 years of age or older.
Prescriber Restrictions	Initial, Reauth: Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.
Coverage Duration	Initial: 3 months. Reauth: 12 months.
Other Criteria	Reauth: Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea). Will not be used for preventive treatment of migraine. Medication will not be used in combination with another oral CGRP inhibitor.

### UDENYCA (S)

### **Products Affected**

• Udenyca

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Febrile neutropenia (FN) prophylaxis: Patient will be receiving prophylaxis for FN due to one of the following: 1) Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown, 3) patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN, 4) both of the following: a) patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN, AND b) patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia, OR 5) Both of the following: a) patient is receiving myelosuppressive anticancer drugs associated with neutropenia, AND b) patient has a history of FN or dose- limiting event during a previous course of chemotherapy (secondary prophylaxis). Treatment of FN (off-label): Patient has received or is receiving myelosuppressive anticancer drugs associated complications. Acute radiation syndrome (ARS) (off-label): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS).
Age Restrictions	N/A
Prescriber Restrictions	All uses: Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	ARS: 1 mo. FN (prophylaxis, treatment): 3 mo or duration of tx.
Other Criteria	N/A

# UKONIQ (S)

### **Products Affected**

• Ukoniq

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Marginal zone lymphoma (MZL): Diagnosis of MZL. Disease is one of the following: relapsed or refractory. Patent has received at least one prior anti-CD20-based regimen (e.g., bendamustine + rituximab, bendamustine + obinutuzumab, etc.). Follicular lymphoma (FL): Diagnosis of FL. Disease is one of the following: relapsed or refractory. Patient has received at least three prior lines of systemic therapy (e.g., bendamustine + rituximab, bendamustine + obinutuzumab, etc.).
Age Restrictions	N/A
Prescriber Restrictions	MZL/FL: Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# VALCHLOR (S)

### **Products Affected**

• Valchlor

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL) (initial): All of the following: 1) diagnosis of Stage IA MF-CTCL, OR diagnosis of Stage IB MF-CTCL, AND 2) patient has received at least one prior skin-directed therapy [e.g., topical corticosteroids, bexarotene topical gel (Targretin topical gel), etc.].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# VARIZIG (S)

### **Products Affected**

• Varizig INJ 125UNIT/1.2ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Presence of contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication).
Required Medical Information	Immune globulin is being used intramuscularly. The immune globulin is being used for passive immunization or post exposure-prophylaxis of varicella. Patient is considered a high risk individual (i.e., immune compromised, pregnant woman, newborn of mother with varicella, premature infant, and infant less than 1 year old).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months (approve one dose only)
Other Criteria	N/A

# VASCEPA (S)

### **Products Affected**

• Icosapent Ethyl

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Severe Hypertriglyceridemia (init): Diagnosis (dx) of hypertriglyceridemia and patient has a pre-treatment triglyceride (TG) level greater than or equal to 500 mg/dL. Prevention of CV Events (init): Dx of hypertriglyceridemia and patient has a pre-treatment TG level of 150 to 499 mg/dL. One of the following: 1) Patient has established cardiovascular disease (CVD) (e.g., coronary artery disease, cerebrovascular or carotid disease, peripheral artery disease, etc.) OR 2) Both of the following: a) Dx of diabetes mellitus AND b) Patient has two or more risk factors for developing CVD. Medication will be used as an adjunct to maximally tolerated statin therapy unless there is a contraindication or intolerance to statin therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial/Reauth: 12 months
Other Criteria	Severe Hypertriglyceridemia (reauth):Documentation of positive clinical response to therapy. Prevention of CV Events (Reauth): Documentation of positive clinical response to therapy. Medication continues to be used as an adjunct to maximally tolerated statin therapy unless there is a contraindication or intolerance to statin therapy.

### VENCLEXTA (S)

#### **Products Affected**

• Venclexta

**PA** Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A Exclusion N/A Criteria Required Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma Medical (SLL): Diagnosis of CLL or SLL. Acute Myeloid Leukemia (AML): Information Diagnosis of newly diagnosed AML. Used in combination with azacitidine, or decitabine, or low-dose cytarabine. One of the following: 1) age 75 years or older OR 2) comorbidities that preclude use of intensive induction chemotherapy. N/A **Age Restrictions** Prescriber Prescribed by or in consultation with a hematologist or oncologist Restrictions Coverage 12 months Duration **Other Criteria** Approve for continuation of prior therapy.

• Venclexta Starting Pack

# VENTAVIS (S)

### **Products Affected**

• Ventavis

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
Age Restrictions	N/A
Prescriber Restrictions	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH (Initial): 6 months. (Reauth): 12 months
Other Criteria	Subject to Part B vs D review. PAH (Reauth): Documentation of positive clinical response to therapy.

# VERZENIO (S)

### **Products Affected**

• Verzenio

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Advanced or Metastatic Breast Cancer: Diagnosis of advanced or metastatic breast cancer. Disease is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative. One of the following: a) used in combination with an aromatase inhibitor (e.g., Arimidex [anastrozole], Aromasin [exemestane], Femara [letrozole]) and patient is male or a postmenopausal woman, OR b) used in combination with Faslodex (fulvestrant) and disease has progressed following endocrine therapy, OR c) used as monotherapy and disease has progressed following endocrine therapy and patient has already received at least one prior chemotherapy regimen. Early Breast Cancer: Diagnosis of early breast cancer at high risk of recurrence. Disease is hormone receptor (HR)-positive. Disease is node-positive. Used as adjunctive therapy. Used in combination with one of the following endocrine therapies: 1) tamoxifen or 2) aromatase inhibitor (e.g., anastrozole, letrozole, exemestane). Patient has a Ki-67 score of greater than or equal to 20% as determined by an FDA approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# VIMIZIM (S)

### **Products Affected**

• Vimizim

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Mucopolysaccharidosis (initial): Diagnosis of Mucopolysaccharidosis type IVA (MPS IVA, Morquio A syndrome) confirmed by both of the following: a) documented clinical signs and symptoms of the disease (e.g., kyphoscoliosis, genu valgum, pectus carinatum, gait disturbance, growth deficiency, etc.) and b) documented reduced fibroblast or leukocyte GALNS enzyme activity or molecular genetic testing of GALNS.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial, reauth: 12 months
Other Criteria	Reauth: Documentation of positive clinical response to therapy.

# VITRAKVI (S)

### **Products Affected**

• Vitrakvi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Presence of solid tumors (e.g., salivary gland, soft tissue sarcoma, infantile fibrosarcoma, thyroid cancer, lung, melanoma, colon, etc.). Disease is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion (e.g. ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.). Disease is without a known acquired resistance mutation [e.g., TRKA G595R substitution, TRKA G667C substitution, or other recurrent kinase domain (solvent front and xDFG) mutations]. Disease is one of the following: metastatic or unresectable (including cases where surgical resection is likely to result in severe morbidity). One of the following: Disease has progressed on previous treatment (e.g., surgery, radiotherapy, or systemic therapy) OR Disease has no satisfactory alternative treatments.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# VIZIMPRO (S)

### **Products Affected**

• Vizimpro

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is metastatic. Disease is positive for one of the following epidermal growth factor receptor (EGFR) mutations: exon 19 deletion or exon 21 L858R substitution.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### VONJO (S)

### **Products Affected**

• Vonjo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of ONE of the following: a) Primary myelofibrosis, b) Post- polycythemia vera myelofibrosis, OR c) Post-essential thrombocythemia myelofibrosis. Disease is intermediate or high risk. Pre-treatment platelet count below 50 x 10^9/L.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### **VORICONAZOLE INJECTION (S)**

#### **Products Affected**

• Voriconazole INJ

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Invasive aspergillosis: Diagnosis of invasive aspergillosis (IA). Candidemia: Diagnosis of candidemia. One of the following: (1) patient is non-neutropenic or (2) infection is located in skin, abdomen, kidney, bladder wall, or wounds. Esophageal Candidiasis: Diagnosis of esophageal candidiasis. Mycosis: Diagnosis of fungal infection caused by Scedosporium apiospermum (asexual form of Pseudallescheria boydii) or Fusarium spp. including Fusarium solani. For fusariosis: Patient is intolerant of, or refractory to, other therapy (e.g., liposomal amphotericin B, amphotericin B lipid complex).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 weeks
Other Criteria	N/A

# **VOSEVI (S)**

### **Products Affected**

• Vosevi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Criteria will be applied consistent with current AASLD/IDSA guideline. All patients: Diagnosis of chronic hepatitis C, patient is without decompensated liver disease (defined as Child-Pugh Class B or C), and not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni, Zepatier].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine.
Coverage Duration	12 to 24 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.
Other Criteria	N/A

# **VOTRIENT (S)**

### **Products Affected**

• Votrient

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Renal cell carcinoma (RCC): Diagnosis of advanced/metastatic RCC. Soft tissue sarcoma: Diagnosis of advanced soft tissue sarcoma and patient received at least one prior chemotherapy (e.g., ifosfamide, doxorubicin, cisplatin, dacarbazine, docetaxel, oxaliplatin, etc.).
Age Restrictions	N/A
Prescriber Restrictions	All uses: Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### WELIREG (S)

### **Products Affected**

• Welireg

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of von Hippel-Lindau (VHL) disease. Patient requires therapy for one of the following: a) renal cell carcinoma (RCC), b) central nervous system (CNS) hemangioblastoma, or c) pancreatic neuroendocrine tumor (pNET). Patient does not require immediate surgery.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# XALKORI (S)

### **Products Affected**

• Xalkori

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of advanced or metastatic NSCLC AND One of the following: A) Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) or B) Patient has MET amplification- or ROS1 rearrangement-positive tumor as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Anaplastic Large Cell Lymphoma (ALCL): Diagnosis of systemic ALCL. Disease is relapsed or refractory. Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Inflammatory Myofibroblastic Tumor (IMT): Diagnosis of IMT. Disease is one of the following: a) unresectable, b) recurrent, or c) refractory. Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Inflammatory Myofibroblastic Tumor (IMT):
Age Restrictions	IMT: Patient is 1 year of age or older.
Prescriber Restrictions	NSCLC, IMT: Prescribed by or in consultation with an oncologist. ALCL: Prescribed by or in consultation with an oncologist or hematologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# XCOPRI (S)

### **Products Affected**

• Xcopri

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of partial onset seizures.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### **Products Affected**

• Xeljanz Xr

• Xeljanz

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Xeljanz tab/Xeljanz XR tab: Rheumatoid arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Trial and failure, contraindication, or intolerance (TF/C/I) to one disease modifying antirheumatic drug (DMARD) [eg, methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)]. Psoriatic arthritis (PsA) (Initial): Diagnosis of active PsA. RA, PsA, AS (Initial): Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, Enbrel, Humira). Ankylosing spondylitis (AS) (Initial): Diagnosis of active AS. Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. Trial and failure, contraindication or intolerance to one of the following conventional therapies: 6-mercaptopurine (Purinethol), aminosalicylate [e.g., mesalamine (Asacol, Pentasa, Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine, Sulfazine)], azathioprine (Imuran), or corticosteroids (e.g., prednisone, methylprednisolone). Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, Humira). All indications: Patient is not receiving tofacitinib in combination with a potent immunosuppressant (eg, azathioprine, cyclosporine).
Age Restrictions	N/A
Prescriber Restrictions	RA, PJIA, AS (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. UC (initial): Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	RA/PJIA/PsA/AS (initial, reauth): 12 months. UC (init): 4 mo. UC (reauth): 12 mo.

Other Criteria	Xeljanz: Polyarticular course juvenile idiopathic arthritis (PJIA) (Initial): Diagnosis of active polyarticular course juvenile idiopathic arthritis. One of the following: TF/C/I to Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29/F40.2 for specific phobia diagnostic criteria), OR for continuation of prior therapy. All Indications (Reauth): Documentation of positive clinical response to therapy. Patient is not receiving tofacitinib in combination with a potent immunosuppressant (eg, azathioprine,
	cyclosporine).

## XENAZINE (S)

### **Products Affected**

• Tetrabenazine

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chorea associated with Huntington's Disease (HD) (Initial): Diagnosis of chorea in patients with Huntington's disease. Tardive dyskinesia (Initial): Diagnosis of tardive dyskinesia. One of the following: 1) Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication, OR 2) Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication. Tourette's syndrome (Initial): Patient has tics associated with Tourette's syndrome. Trial and failure, contraindication, or intolerance to Haldol (haloperidol).
Age Restrictions	N/A
Prescriber Restrictions	HD (Initial): Prescribed by or in consultation with a neurologist. Tardive dyskinesia, Tourette's syndrome (Initial): Prescribed by or in consultation with neurologist or psychiatrist.
Coverage Duration	All uses: (initial) 3 months. (Reauth) 12 months.
Other Criteria	All indications (Reauth): Documentation of clinical response and benefit from therapy.

# XERMELO (S)

## **Products Affected**

• Xermelo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Carcinoid syndrome diarrhea (Initial): Diagnosis of carcinoid syndrome diarrhea AND diarrhea is inadequately controlled by a stable dose of somatostatin analog (SSA) therapy (e.g., octreotide [Sandostatin, Sandostatin LAR], lanreotide [Somatuline Depot]) for at least 3 months AND used in combination with SSA therapy.
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist
Coverage Duration	Initial: 6 months. Reauth: 12 months
Other Criteria	Carcinoid syndrome diarrhea (Reauthorization): Documentation of a positive clinical response to therapy AND drug will continue to be used in combination with SSA therapy.

## XGEVA (S)

### **Products Affected**

• Xgeva

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Myeloma (MM)/Bone metastasis from solid tumors (BMST): One of the following: 1) Both of the following: a) Diagnosis of multiple myeloma and b) Trial and failure, intolerance, or contraindication to one bisphosphonate (eg, zoledronic acid), OR 2) Both of the following: a) Diagnosis of solid tumors (eg, breast cancer, kidney cancer, lung cancer, prostate cancer, thyroid cancer) and b) Documented evidence of one or more metastatic bone lesions. Giant cell tumor of bone (GCTB): Both of the following: 1) Diagnosis of giant cell tumor of bone AND 2) One of the following: a) tumor is unresectable, OR b) surgical resection is likely to result in severe morbidity. Hypercalcemia of malignancy (HCM): Both of the following: 1) Diagnosis of hypercalcemia of malignancy, AND 2) Trial and failure, contraindication, or intolerance to one intravenous bisphosphonate (eg, pamidronate, Zometa (zoledronic acid).
Age Restrictions	N/A
Prescriber Restrictions	GCTB, HCM: Prescribed by or in consultation with an oncologist
Coverage Duration	MM/BMST, GCTB: 12 mo. HCM: 2 mo.
Other Criteria	Approve for continuation of prior therapy.

## XIFAXAN (S)

## **Products Affected**

• Xifaxan

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Travelers' diarrhea (TD) (200 mg strength only): Diagnosis of travelers' diarrhea, AND one of the following: a) Trial and failure, contraindication, or intolerance to one of the following: Cipro (ciprofloxacin), Levaquin (levofloxacin), ofloxacin, Zithromax (azithromycin) OR b) resistance to all of the following: Cipro (ciprofloxacin), Levaquin (levofloxacin), ofloxacin, Zithromax (azithromycin). Prophylaxis of hepatic encephalopathy (HE) recurrence (550mg strength only): Used for the prophylaxis of hepatic encephalopathy recurrence, AND trial and failure, contraindication or intolerance to lactulose. Treatment of HE: Used for the treatment of HE. Trial and failure, contraindication, or intolerance to lactulose. Irritable bowel syndrome with diarrhea (IBS-D) (550mg strength only) (initial): Diagnosis of IBS-D, AND trial and failure, contraindication or intolerance to an antidiarrheal agent [eg, loperamide].
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	TD: 14 days. HE (prophylaxis, treatment): 12 months. IBS-D (initial, reauth): 2 weeks.
Other Criteria	IBS-D (reauth): Patient experiences IBS-D symptom recurrence.

## XOLAIR (S)

### **Products Affected**

• Xolair

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Asthma (init): Diagnosis of moderate to severe persistent allergic asthma. Positive skin test or in vitro reactivity to a perennial aeroallergen. Pretreatment serum immunoglobulin (Ig)E level between 30 to 700 IU/mL for patients 12 years of age and older OR 30 to 1300 IU/mL for patients 6 years to less than 12 years of age. Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) High-dose inhaled corticosteroid (ICS) [e.g., greater than 500 mcg fluticasone propionate equivalent/day] and ii) additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta- 2 agonist [LABA] [e.g., salmeterol], tiotropium), OR b) One maximally- dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone/vilanterol)]. Chronic Idiopathic Urticaria (CIU) (init): Diagnosis of CIU. Persistent symptoms (itching and hives) for at least 4 consecutive weeks despite titrating to an optimal dose with a second generation H1 antihistamine (e.g., cetirizine, fexofenadine), unless there is a contraindication or intolerance to H1 antihistamines. Patient has tried and had an inadequate response or intolerance or contraindication to at least one of the following additional therapies: H2 antagonist (e.g., famotidine, cimetidine), leukotriene receptor antagonist (e.g., montelukast), H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamine, hydroxyzine, doxepin. Used concurrently with an H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamine, Nasal polyps (NP) (init): Diagnosis of NP. Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone). Used i
Age Restrictions	N/A

Prescriber Restrictions	Asthma (init/reauth): Prescribed by or in consultation with an allergist/immunologist, or pulmonologist. CIU (init): Prescribed by or in consultation with an allergist/immunologist, or dermatologist. NP (init/reauth): Prescribed by or in consultation with an allergist/immunologist, otolaryngologist, or pulmonologist.
Coverage Duration	Asthma, init: 6 mo, reauth: 12 mo. CIU, init: 3 mo, reauth: 6 mo. NP, init/reauth: 12 mo.
Other Criteria	Asthma (reauth): Documentation of positive clinical response to therapy (e.g., Reduction in asthma exacerbations, improvement in forced expiratory volume in 1 second (FEV1), decreased use of rescue medications). Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications. CIU (reauth): Patient's disease status has been re- evaluated since the last authorization to confirm the patient's condition warrants continued treatment. Patient has experienced one or both of the following: Reduction in itching severity from baseline or Reduction in the number of hives from baseline. NP (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS: 0- 8 scale], improvement in nasal congestion/obstruction score [NCS: 0-3 scale]). Used in combination with another agent for nasal polyps.

## XOSPATA (S)

## **Products Affected**

• Xospata

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of acute myeloid leukemia (AML). Disease is relapsed or refractory. Patient has a FMS-like tyrosine kinase (FLT3) mutation as determined by a U.S. Food and Drug Administration (FDA)-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## XPOVIO (S)

#### **Products Affected**

- Xpovio
- Xpovio 100 Mg Once Weekly
- Xpovio 40 Mg Once Weekly
- Xpovio 40 Mg Twice Weekly

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

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Myeloma (MM): Diagnosis of multiple myeloma. Patient has received at least one prior therapy (e.g., lenalidomide, bortezomib, daratumumab, pomalidomide). Used in combination with bortezomib and dexamethasone. Relapsed/Refractory Multiple Myeloma (RRMM): Diagnosis of relapsed or refractory multiple myeloma (RRMM). Patient has received at least four prior therapies (e.g., lenalidomide, bortezomib, daratumumab, pomalidomide). Disease is refractory to all of the following: 1) Two proteasome inhibitors (e.g., bortezomib, carfilzomib), 2) Two immunomodulatory agents (e.g., lenalidomide, thalidomide), and 3) An anti-CD38 monoclonal antibody (e.g. daratumumab). Used in combination with dexamethasone. Diffuse large B-cell lymphoma (DLBCL): Diagnosis of one of the following: 1) Relapsed or refractory DLBCL not otherwise specified OR 2) Relapsed or refractory DLBCL arising from follicular lymphoma. Patient has previously received at least two lines of systemic therapy (e.g., CHOP: cyclophosphamide, doxorubicin, vincristine, and prednisone plus rituximab).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## XTANDI (S)

## **Products Affected**

• Xtandi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Castration-resistant or castration-recurrent prostate cancer (CRPC): Diagnosis of castration-resistant (chemical or surgical) or recurrent prostate cancer. Metastatic castration-sensitive prostate cancer (M-CSPC): Diagnosis of metastatic castration-sensitive prostate cancer.
Age Restrictions	N/A
Prescriber Restrictions	CRPC, M-CSPC: Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# XYREM (S)

## **Products Affected**

• Xyrem

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Narcolepsy with cataplexy (Narcolepsy Type 1)(initial): Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), AND symptoms of cataplexy are present, AND symptoms of excessive daytime sleepiness (eg, irrepressible need to sleep or daytime lapses into sleep) are present. Narcolepsy without cataplexy (Narcolepsy Type 2)(initial): Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), AND symptoms of cataplexy are absent, AND symptoms of excessive daytime sleepiness (eg, irrepressible need to sleep or daytime lapses into sleep) are present, AND trial and failure, contraindication, or intolerance to one of the following: 1) amphetamine-based stimulant (eg, amphetamine, dextroamphetamine), OR 2) methylphenidate-based stimulant.
Age Restrictions	N/A
Prescriber Restrictions	All uses (initial): Prescribed by or in consultation with one of the following: neurologist, psychiatrist, or sleep medicine specialist.
Coverage Duration	All uses (initial): 6 months. All uses (reauth): 12 months
Other Criteria	Narcolepsy Type 1 (reauth): Documentation demonstrating a reduction in the frequency of cataplexy attacks associated with therapy, OR documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy. Narcolepsy Type 2 (reauth): Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy.

## ZAVESCA (S)

## **Products Affected**

• Miglustat

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Gaucher disease: Diagnosis of mild to moderate type 1 Gaucher disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Gaucher disease: 12 months
Other Criteria	N/A

## ZEJULA (S)

## **Products Affected**

• Zejula

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: advanced epithelial ovarian cancer, advanced fallopian tube cancer, or advanced primary peritoneal cancer. Used for maintenance treatment in patients who are in a complete or partial response to first-line platinum-based chemotherapy (e.g., cisplatin, carboplatin). Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: recurrent epithelial ovarian cancer, recurrent fallopian tube cancer, or recurrent primary peritoneal cancer. Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## ZELBORAF (S)

### **Products Affected**

• Zelboraf

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma. Cancer is BRAFV600 mutant type (MT) as detected by a U.S. Food and Drug Administration (FDA)-approved test (eg, cobas 4600 BRAFV600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Erdheim-Chester Disease: Diagnosis of Erdheim-Chester disease AND Disease is BRAFV600 mutant type (MT).
Age Restrictions	N/A
Prescriber Restrictions	Melanoma: Prescribed by or in consultation with an oncologist. Erdheim- Chester Disease: Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	All indications: Approve for continuation of therapy.

## ZEPZELCA (S)

### **Products Affected**

• Zepzelca

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of metastatic small cell lung cancer (SCLC). Disease has progressed on or after platinum-based chemotherapy (e.g., carboplatin, cisplatin, oxaliplatin).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## ZIRABEV (S)

### **Products Affected**

• Zirabev

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Non-Small Cell Lung Cancer: Excluded if squamous cell histology.
Required Medical Information	Colorectal Cancer: Diagnosis of metastatic colorectal cancer. One of the following: 1) Both of the following: a) used as first- or second-line treatment and b) used in combination with an intravenous 5-fluorouracil-based chemotherapy, OR 2) All of the following: a) used as second-line treatment, b) used in combination with fluoropyrimidine-irinotecan-based chemotherapy or fluoropyrimidine-oxaliplatin-based chemotherapy, and c) patient has progressed on a first-line bevacizumab-containing regimen. Non-Small Cell Lung Cancer (NSCLC): Diagnosis of NSCLC. Disease is unresectable, locally advanced, recurrent, or metastatic. Used as first-line treatment. Used in combination with paclitaxel and carboplatin. Renal Cell Cancer: Diagnosis of metastatic renal cell cancer. Used in combination with paclitaxel and carboplatin. Renal Cell Cancer: Diagnosis of metastatic renal cell cancer. Used in combination with one of the following: a) paclitaxel and cisplatin or b) paclitaxel and topotecan. Glioblastoma: Diagnosis of recurrent glioblastoma. Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer: Diagnosis of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. One of the following: 1) All of the following: a) disease is stage 3 or 4, b) patient has been treated with bevacizumab as a single agent, c) treatment is following surgical resection, and d) used in combination with carboplatin and paclitaxel, OR 2) All of the following: a) disease is platinum-resistant recurrent, b) patient has perceived no more than 2 prior chemotherapy regimens, and c) used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, OR 3) All of the following: a) disease is platinum-sensitive recurrent, b) patient has been treated with bevacizumab as a single agent, and c) used in combination with one of the following: i) carboplatin and paclitaxel or ii) carboplatin and gencitabine.
Age Restrictions	N/A

Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Hepatocellular Carcinoma (HCC): Diagnosis of hepatocellular carcinoma. Disease is unresectable or metastatic. Used in combination with Tecentriq (atezolizumab). Patient has not received prior systemic therapy. Approve for continuation of prior therapy.

# ZOKINVY (S)

## **Products Affected**

• Zokinvy

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	One of the following: 1) Diagnosis of Hutchinson-Gilford Progeria Syndrome, OR 2) For treatment of processing-deficient Progeroid Laminopathies with one of the following: i) Heterozygous LMNA mutation with progerin-like protein accumulation OR ii) Homozygous or compound heterozygous ZMPSTE24 mutations. Patient has a body surface area of 0.39 m <sup>2</sup> and above.
Age Restrictions	Patient is 12 months of age or older.
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

## ZOLADEX (S)

## **Products Affected**

• Zoladex INJ 3.6MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prostate Cancer: Diagnosis of advanced or metastatic prostate cancer. Trial and failure, contraindication, or intolerance to any brand Lupron formulation. Endometriosis [Zoladex (3.6 mg strength)]: Treatment of endometriosis. Trial and failure to Lupron Depot (3.75 mg or 11.25 mg). Advanced Breast Cancer [Zoladex (3.6 mg strength)]: For the palliative treatment of advanced breast cancer. Endometrial thinning [Zoladex (3.6 mg strength)] For the treatment of dysfunctional uterine bleeding. Used as an endometrial thinning agent prior to endometrial ablation.
Age Restrictions	Endometriosis: 18 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# ZOLINZA (S)

## **Products Affected**

• Zolinza

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cutaneous T-cell lymphoma (CTCL): Diagnosis of CTCL. Progressive, persistent or recurrent disease on or contraindication or intolerance to two systemic therapies (e.g., bexarotene, romidepsin, etc.).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# ZYDELIG (S)

## **Products Affected**

• Zydelig

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic lymphocytic leukemia (CLL): Diagnosis of CLL. Used in combination with Rituxan (rituximab). The patient has relapsed on at least one prior therapy (eg, purine analogues [fludarabine, pentostatin, cladribine], alkylating agents [chlorambucil, cyclophosphamide], or monoclonal antibodies [rituximab]). Patient is a candidate for Rituxan (rituximab) monotherapy due to presence of other comorbidities (eg, coronary artery disease, peripheral vascular disease, diabetes mellitus, pulmonary disease [COPD]).
Age Restrictions	N/A
Prescriber Restrictions	CLL: Prescribed by or in consultation with an oncologist/hematologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## ZYKADIA (S)

## **Products Affected**

• Zykadia

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC that is metastatic or recurrent. Tumor is anaplastic lymphoma kinase (ALK)- positive as detected by a U.S. Food and Drug Administration (FDA)- approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## ZYTIGA (PREFERRED) (S)

### **Products Affected**

• Abiraterone Acetate

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Metastatic Castration-Resistant Prostate Cancer (mCRPC): Diagnosis of metastatic castration-resistant (chemical or surgical) or recurrent prostate cancer. Used in combination with prednisone. Metastatic Castration- Sensitive Prostate Cancer (mCSPC): Diagnosis of metastatic high-risk castration-sensitive prostate cancer. Used in combination with prednisone.
Age Restrictions	N/A
Prescriber Restrictions	mCRPC, mCSPC: Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	mCRPC, mCSPC: 12 months
Other Criteria	Approve for continuation of prior therapy

## PART B VERSUS PART D

#### **Products Affected**

- Abelcet
- Acetylcysteine SOLN
- Acyclovir Sodium INJ 50MG/ML
- Akynzeo CAPS
- Albuterol Sulfate NEBU 0.083%, 2.5MG/0.5ML
- Ambisome
- 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; 447MG/100ML; 1083MG/100ML; 795MG/100ML; 50MEQ/L; 600MG/100ML; 300MG/100ML; 405MG/100ML; 750MG/100ML
- Amphotericin B INJ
- Amphotericin B Liposome
- Aprepitant CAPS
- Azathioprine TABS
- Budesonide SUSP
- Clinisol Sf 15%
- Cromolyn Sodium NEBU
- Cyclophosphamide CAPS
- Cyclosporine CAPS
- Cyclosporine Modified
- Engerix-b
- Epoprostenol Sodium INJ 0.5MG
- Everolimus TABS 0.25MG, 0.5MG, 0.75MG, 1MG
- Formoterol Fumarate NEBU
- Ganciclovir INJ 500MG, 500MG/10ML
- Gengraf CAPS 100MG, 25MG
- Gengraf SOLN
- Hyperhep B
- Hyperrab

- Imovax Rabies (h.d.c.v.)
- Ipratropium Bromide INHALATION SOLN 0.02%
- Ipratropium Bromide/albuterol Sulfate
- Mycophenolate Mofetil CAPS
- Mycophenolate Mofetil SUSR
- Mycophenolate Mofetil TABS
- Mycophenolic Acid Dr
- Nabi-hb INJ 312UNIT/ML
- Nutrilipid
- Ondansetron Hcl SOLN
- Ondansetron Hydrochloride TABS
- Ondansetron Odt
- Pentamidine Isethionate INHALATION SOLR
- Perforomist
- 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
- Prehevbrio
- Prograf PACK
- Rabavert
- Recombivax Hb
- Sandimmune SOLN
- Sirolimus SOLN
- Sirolimus TABS
- Tacrolimus CAPS
- Tobramycin NEBU
- Zortress TABS 1MG

Formulary ID 22323 Version 21 Last Updated: November 2022

#### 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.

## INDEX

#### A

Abelcet
Abiraterone Acetate
Acetylcysteine
Actemra 1
Actemra Actpen1
Actemra Sc (s)1
Actimmune
Actimmune (s)
Acyclovir Sodium
Adcirca (s) 4
Adempas
Adempas (s) 5
Afinitor
Afinitor (s)
Afinitor Disperz7
Afinitor Disperz (s)7
Aimovig
Aimovig (s)
Akynzeo
Albuterol Sulfate
Aldurazyme 10
Aldurazyme (s) 10
Alecensa 11
Alecensa (s) 11
Alosetron Hydrochloride133
Alpha-1 Proteinase Inhibitor, Non-preferred (s). 12
Alpha-1 Proteinase Inhibitor, Prolastin (s) 13
Alunbrig 14
Alunbrig (s) 14
Alyq4
Ambisome
Ambrisentan 127
Aminosyn II
Amnesteem
Amphotericin B
Amphotericin B Liposome

Formulary ID 22323 Version 21 Last Updated: November 2022

Ampyra (s)	15
Androderm	
Aprepitant	
Aralast Np	
Arcalyst	16
Arcalyst (s)	16
Armodafinil	
Auryxia	
Auryxia (s)	17
Austedo	
Austedo (s)	
Ayvakit	19
Ayvakit (s)	19
Azathioprine	

#### B

Bafiertam	20
Bafiertam (s)	20
Balversa	21
Balversa (s)	21
Benlysta	22
Benlysta (s)	
Besremi	23
Besremi (s)	23
Betaseron	148
Bexarotene	239
Bivigam	111
Bosulif	24
Bosulif (s)	24
Braftovi	25
Braftovi (s)	25
Briviact	
Briviact (s)	26
Brukinsa	
Brukinsa (s)	27
Budesonide	

#### С

Cabiry (s)	Cablivi
Cabometyx       29         Cabometyx (s)       29         Calquence       30         Calquence (s)       30         Caprelsa       31         Caprelsa (s)       31         Cayston       32         Cayston (s)       32         Cardelga (s)       33         Cholbam       34         Cholbam (s)       34         Ciclodan       35         Ciclopirox (s)       35         Ciclopirox (s)       35         Ciclopirox Nail Lacquer       36         Chiryze (s)       36         Claravis       107         Clinisol Sf 15%       312         Clovique       231         Cometriq       37         Copiktra       38         Corlanor (s)       39         Cosentyx       40         Cosentyx Sensoready Pen       40         Cotellic (s)       42         Cromolyn Sodium       312         Cyclosporine       312         Cyclosporine       312         Cyclosporine       312         Cyclosporine       312         Cyclosporine       312          <	
Cabometyx (s)       29         Calquence       30         Calquence (s)       30         Caprelsa       31         Caprelsa (s)       31         Cayston       32         Cayston (s)       32         Cardelga (s)       33         Cholbam       34         Cholbam (s)       34         Ciclodan       35         Ciclopirox (s)       35         Ciclopirox (s)       35         Ciclopirox (s)       35         Ciclopirox Nail Lacquer       36         Claravis       107         Clinisol Sf 15%       312         Clovique       231         Cometriq       37         Copiktra       38         Corlanor (s)       39         Cosentyx (s)       40         Cosentyx Sensoready Pen       40         Cotellic (s)       42         Cromolyn Sodium       312         Cyclophosphamide       312         Cyclosporine       312	
Calquence       30         Calquence (s)       30         Caprelsa       31         Caprelsa (s)       31         Cayston       32         Cayston (s)       32         Cerdelga       33         Cerdelga (s)       33         Cholbam       34         Cholbam (s)       34         Ciclodan       35         Ciclopirox (s)       35         Ciclopirox (s)       35         Ciclopirox (s)       36         Cinryze       36         Cinryze (s)       36         Claravis       107         Clinisol Sf 15%       312         Clovique       231         Cometriq       37         Copiktra       38         Copiktra (s)       38         Corlanor (s)       39         Cosentyx (s)       40         Cosentyx Sensoready Pen       40         Cotellic (s)       42         Cromolyn Sodium       312         Cyclosporine       312         Cyclosporine       312         Cyclosporine       312         Cyclosporine       312	
Calquence (s)	
Caprelsa       31         Caprelsa (s)       31         Cayston       32         Cayston (s)       32         Cerdelga       33         Cerdelga (s)       33         Cholbam       34         Cholbam (s)       34         Ciclodan       35         Ciclopirox (s)       35         Ciclopirox (s)       35         Ciclopirox (s)       36         Claravis       107         Clinisol Sf 15%       312         Clowetriq       37         Cometriq (s)       37         Copiktra       38         Corlanor       39         Corlanor (s)       39         Cosentyx       40         Cosentyx (s)       40         Cosentyx (s)       40         Cotellic (s)       42         Cromolyn Sodium       312         Cyclophosphamide       312         Cyclosporine       312         Cyclosporine       312         Cyclosporine       312	-
Caprelsa (s)	
Cayston       32         Cayston (s)       32         Cerdelga       33         Cerdelga (s)       33         Cholbam       34         Cholbam (s)       34         Ciclopirox (s)       35         Ciclopirox Nail Lacquer       35         Cinryze       36         Cinryze (s)       36         Claravis       107         Clinisol Sf 15%       312         Clovique       231         Cometriq (s)       37         Copiktra       38         Corlanor       39         Cosentyx (s)       40         Cosentyx Sensoready Pen       40         Cotellic       42         Cromolyn Sodium       312         Cuvitru       211         Cyclosporine       312         Cy	•
Cayston (s)       32         Cerdelga       33         Cerdelga (s)       33         Cholbam       34         Cholbam (s)       34         Ciclodan       35         Ciclopirox (s)       35         Ciclopirox Nail Lacquer       35         Cinryze       36         Cinryze (s)       36         Claravis       107         Clinisol Sf 15%       312         Clovique       231         Cometriq.       37         Copiktra       38         Corlanor.       39         Corlanor (s)       39         Cosentyx       40         Cosentyx Sensoready Pen       40         Cotellic       42         Cromolyn Sodium       312         Cuvitru       211         Cyclosporine       312         Cyclosporine       312         Cyclosporine Modified       312         Cystaran       43	
Cerdelga       33         Cerdelga (s)       33         Cholbam       34         Cholbam (s)       34         Ciclodan       35         Ciclopirox (s)       35         Ciclopirox Nail Lacquer       35         Cinryze       36         Cinryze (s)       36         Claravis       107         Clinisol Sf 15%       312         Clovique       231         Cometriq       37         Copiktra       38         Corpiktra (s)       38         Corlanor       39         Cosentyx       40         Cosentyx (s)       40         Cosentyx Sensoready Pen       40         Cotellic       42         Cromolyn Sodium       312         Cuvitru       211         Cyclosporine       312         Cyclosporine       312         Cyclosporine       312         Cyclosporine       312         Cyclosporine       312	
Cerdelga (s)       33         Cholbam       34         Cholbam (s)       34         Ciclodan       35         Ciclopirox (s)       35         Ciclopirox Nail Lacquer       35         Cinryze       36         Cinryze (s)       36         Claravis       107         Clinisol Sf 15%       312         Clovique       231         Cometriq       37         Cometriq (s)       37         Copiktra       38         Corlanor       39         Corlanor (s)       39         Cosentyx       40         Cosentyx Sensoready Pen       40         Cotellic       42         Cromolyn Sodium       312         Cyclosporine       312         Cystaran       43	•
Cholbam       34         Cholbam (s)       34         Ciclodan       35         Ciclopirox (s)       35         Ciclopirox Nail Lacquer       35         Cinryze       36         Cinryze (s)       36         Claravis       107         Clinisol Sf 15%       312         Clovique       231         Cometriq       37         Cometriq (s)       37         Copiktra       38         Corlanor.       39         Corlanor (s)       39         Cosentyx       40         Cosentyx Sensoready Pen       40         Cotellic       42         Cromolyn Sodium       312         Cuvitru       211         Cyclosporine       312         Cystaran       43	-
Ciclodan       35         Ciclopirox (s)       35         Ciclopirox Nail Lacquer       35         Cinryze       36         Cinryze (s)       36         Claravis       107         Clinisol Sf 15%       312         Clovique       231         Cometriq       37         Cometriq (s)       37         Copiktra       38         Corlanor       39         Corlanor (s)       39         Cosentyx       40         Cosentyx Sensoready Pen       40         Cotellic       42         Cromolyn Sodium       312         Cuvitru       211         Cyclosporine       312         Cyclosporine       312         Cyclosporine       312	
Ciclodan       35         Ciclopirox (s)       35         Ciclopirox Nail Lacquer       35         Cinryze       36         Cinryze (s)       36         Claravis       107         Clinisol Sf 15%       312         Clovique       231         Cometriq       37         Cometriq (s)       37         Copiktra       38         Corlanor       39         Corlanor (s)       39         Cosentyx       40         Cosentyx Sensoready Pen       40         Cotellic       42         Cromolyn Sodium       312         Cuvitru       211         Cyclosporine       312         Cyclosporine       312         Cyclosporine       312	Cholbam (s)
Ciclopirox (s)	
Ciclopirox Nail Lacquer	
Cinryze       36         Cinryze (s)       36         Claravis       107         Clinisol Sf 15%       312         Clovique       231         Cometriq       37         Cometriq (s)       37         Copiktra       38         Corlanor       39         Corlanor (s)       39         Cosentyx       40         Cosentyx (s)       40         Cotellic       42         Cotellic (s)       42         Coromolyn Sodium       312         Cyclosporine       312         Cystaran       43	
Cinryze (s)       36         Claravis       107         Clinisol Sf 15%       312         Clovique       231         Cometriq       37         Cometriq (s)       37         Copiktra       38         Copiktra (s)       38         Corlanor.       39         Corlanor (s)       39         Cosentyx       40         Cosentyx Sensoready Pen       40         Cotellic       42         Cotellic (s)       42         Cromolyn Sodium       312         Cyclosporine       312         Cyclosporine       312         Cyclosporine       312         Cyclosporine       312         Cyclosporine       312         Cystaran       43	
Claravis	-
Clovique       231         Cometriq       37         Cometriq (s)       37         Copiktra       38         Copiktra (s)       38         Corlanor       39         Corlanor (s)       39         Cosentyx       40         Cosentyx (s)       40         Cosentyx Sensoready Pen       40         Cotellic       42         Cotellic (s)       42         Cromolyn Sodium       312         Cyclosporine       312         Cyclosporine Modified       312         Cystaran       43	
Cometriq	Clinisol Sf 15%
Cometriq (s)	Clovique
Copiktra       38         Copiktra (s)       38         Corlanor.       39         Corlanor (s)       39         Cosentyx.       40         Cosentyx (s)       40         Cosentyx Sensoready Pen       40         Cotellic       42         Cotellic (s)       42         Cotromolyn Sodium       312         Cuvitru.       211         Cyclosporine       312         Cyclosporine Modified       312         Cystaran.       43	Cometriq
Copiktra (s)	Cometriq (s)
Corlanor.39Corlanor (s)39Cosentyx.40Cosentyx (s)40Cosentyx Sensoready Pen40Cotellic42Cotellic (s)42Cromolyn Sodium312Cuvitru.211Cyclophosphamide312Cyclosporine312Cyclosporine Modified312Cystaran.43	Copiktra
Corlanor (s)39Cosentyx40Cosentyx (s)40Cosentyx Sensoready Pen40Cotellic42Cotellic (s)42Cromolyn Sodium312Cuvitru211Cyclophosphamide312Cyclosporine312Cyclosporine Modified312Cystaran43	Copiktra (s)
Cosentyx40Cosentyx (s)40Cosentyx Sensoready Pen40Cotellic42Cotellic (s)42Cromolyn Sodium312Cuvitru211Cyclophosphamide312Cyclosporine312Cyclosporine Modified312Cystaran43	Corlanor
Cosentyx (s)40Cosentyx Sensoready Pen40Cotellic42Cotellic (s)42Cromolyn Sodium312Cuvitru211Cyclophosphamide312Cyclosporine312Cyclosporine Modified312Cystaran43	Corlanor (s)
Cosentyx Sensoready Pen40Cotellic42Cotellic (s)42Cromolyn Sodium312Cuvitru211Cyclophosphamide312Cyclosporine312Cyclosporine Modified312Cystaran43	Cosentyx
Cotellic42Cotellic (s)42Cromolyn Sodium312Cuvitru211Cyclophosphamide312Cyclosporine312Cyclosporine Modified312Cystaran43	Cosentyx (s) 40
Cotellic (s)42Cromolyn Sodium312Cuvitru211Cyclophosphamide312Cyclosporine312Cyclosporine Modified312Cystaran43	Cosentyx Sensoready Pen 40
Cromolyn Sodium312Cuvitru211Cyclophosphamide312Cyclosporine312Cyclosporine Modified312Cystaran43	Cotellic
Cuvitru	Cotellic (s)
Cyclophosphamide312Cyclosporine312Cyclosporine Modified312Cystaran43	Cromolyn Sodium
Cyclosporine	Cuvitru
Cyclosporine Modified	Cyclophosphamide
Cystaran	Cyclosporine
	Cyclosporine Modified
Cystaran (s) 43	Cystaran
	Cystaran (s) 43

D.h.e. 45 (s)	44
Dalfampridine Er	
Daliresp	
Daliresp (s)	45
Danyelza	46
Danyelza (s)	46
Daraprim (s)	47
Darzalex Faspro	48
Darzalex Faspro (s)	48
Daurismo	50
Daurismo (s)	50
Deferasirox	51
Deferasirox (s)	51
Deferiprone	76
Diacomit	52
Diacomit (s)	52
Diclofenac Sodium	178
Dihydroergotamine Mesylate	44, 146
Dimethyl Fumarate	245
Dimethyl Fumarate Starterpack	245
Dronabinol	141
Droxidopa	158
Dupixent	53
Dupixent (s)	

#### E

Elaprase	
Elaprase (s)	
Emgality	57
Emgality (s)	
Enbrel	59
Enbrel (s)	59
Enbrel Mini	59
Enbrel Sureclick	59
Engerix-b	
Enspryng	60
Enspryng (s)	60
Epclusa Preferred (s)	61
Epidiolex	62
Epidiolex (s)	62
Epoetin Alfa (s)	63
Epoprostenol Sodium	

Erivedge	
Erivedge (s)	
Erleada	
Erleada (s)	
Erlotinib Hydrochloride	
Esbriet	
Esbriet (s)	
Eucrisa	
Eucrisa (s)	
Everolimus	
Evrysdi	69
Evrysdi (s)	
Exkivity	
Exkivity (s)	
• • •	

#### F

Farydak	72
-	
Farydak (s)	72
Fasenra	73
Fasenra (s)	73
Fasenra Pen	73
Fentanyl (s)	75
Fentanyl Citrate Oral Transmucosal	75
Ferriprox (s)	
Fingolimod	
Fintepla	77
Fintepla (s)	77
Firazyr (s)	
Firmagon	
Firmagon (s)	79
Formoterol Fumarate	
Forteo	
Fotivda	
Fotivda (s)	

## G

Galafold	
Galafold (s)	
Gamastan	
Gamastan S/d (s)	
Gammagard S/d Iga Less Than 1mcg/m1 111	
Ganciclovir	
Gavreto	
Gavreto (s)	

Formulary ID 22323 Version 21 Last Updated: November 2022

Gengraf	312
Genotropin	88
Genotropin Miniquick	88
Gilenya	84
Gilenya (s)	84
Gilotrif	85
Gilotrif (s)	85
Glatiramer Acetate	86
Glatiramer Acetate (s)	86
Gleevec (s)	87
Glydo	128
Growth Hormone, Preferred (s)	88

#### H

Herzuma	91
Herzuma (s)	91
Hrm - Megestrol Suspension	92
Hrm - Megestrol Tablet	93
Humira	94
Humira (s)	94
Humira Pediatric Crohns Disease Starter Pack	s94
Humira Pen	94
Humira Pen-cd/uc/hs Starter	94
Humira Pen-pediatric Uc Starter Pack	94
Humira Pen-ps/uv Starter	
Hyperhep B	
Hyperrab	
• •	

#### Ι

Ibrance	96
Ibrance (s)	96
Icatibant Acetate	
Iclusig	
Iclusig (s)	
Icosapent Ethyl	
Idhifa	
Idhifa (s)	
Ilumya	
Ilumya (s)	
Imatinib Mesylate	
Imbruvica	
Imbruvica (s)	
Imovax Rabies (h.d.c.v.)	
Increlex	
	-

Increlex (s) 1	01
Inlyta 1	02
Inlyta (s) 1	02
Inqovi 1	.03
Inqovi (s) 1	.03
Inrebic 1	.04
Inrebic (s) 1	04
Intron A 1	05
Intron A (s) 1	05
Ipratropium Bromide 3	512
Ipratropium Bromide/albuterol Sulfate 3	512
Iressa1	06
Iressa (s) 1	06
Isotretinoin 1	07
Isotretinoin (s) 1	07
Istodax (s) 1	08
Isturisa 1	.09
Isturisa (s) 1	.09
Itraconazole 2	217
Ivermectin 1	10
Ivermectin (s) 1	10
Ivig (s) 1	11

#### $\boldsymbol{J}$

## K

Kalydeco	
Kalydeco (s)	
Kanjinti	
Kanjinti (s)	
Kanuma	
Kanuma (s)	
Kesimpta	
Kesimpta (s)	
Kisqali	
Kisqali (s)	
Kisqali Femara 200 Dose	
Kisqali Femara 400 Dose	
Kisqali Femara 600 Dose	
Kisqali-femara Pack (s)	

Formulary ID 22323 Version 21 Last Updated: November 2022

Korlym	121
Korlym (s)	121
Koselugo	
Koselugo (s)	
Kuvan (s)	123
Kynmobi	124
Kynmobi (s)	
Kynmobi Titration Kit	

#### L

Lapatinib Ditosylate	
Lemtrada	125
Lemtrada (s)	125
Lenalidomide	197
Lenvima (s)	126
Lenvima 10 Mg Daily Dose	126
Lenvima 12mg Daily Dose	126
Lenvima 14 Mg Daily Dose	126
Lenvima 18 Mg Daily Dose	126
Lenvima 20 Mg Daily Dose	126
Lenvima 24 Mg Daily Dose	126
Lenvima 4 Mg Daily Dose	126
Lenvima 8 Mg Daily Dose	126
Letairis (s)	127
Leuprolide Acetate	
Lidocaine	.128, 129
Lidocaine Hcl	128
Lidocaine Hcl Jelly	128
Lidocaine Topical (s)	128
Lidocaine/prilocaine	128
Lidocaine-prilocaine-cream Base	
Lidoderm (s)	129
Livmarli	130
Livmarli (s)	130
Lonsurf	131
Lonsurf (s)	131
Lorbrena	132
Lorbrena (s)	132
Lotronex (s)	
Lumakras	134
Lumakras (s)	134
Lumizyme	135
Lumizyme (s)	
Lupron (s)	136

### M

Makena	
Makena (s)	
Marinol (s)	
Mavyret	
Mavyret (s)	
Megestrol Acetate	
Mekinist	
Mekinist (s)	
Mektovi	
Mektovi (s)	
Miglustat	
Migranal (s)	
Modafinil	
Monjuvi	
Monjuvi (s)	
Ms Interferons (preferred) (s)	
Mvasi	
Mvasi (s)	
Myalept	151
Myalept (s)	151
Mycophenolate Mofetil	
Mycophenolic Acid Dr	
Myorisan	

## N

Nabi-hb	312
Naglazyme	152
Naglazyme (s)	152
Natpara	153
Natpara (s)	153
Nerlynx	154
Nerlynx (s)	154
Neulasta	155
Neulasta (s)	155
Neulasta Onpro Kit	155

Formulary ID 22323 Version 21 Last Updated: November 2022

Nexavar	156
Nexavar (s)	156
Ninlaro	157
Ninlaro (s)	157
Northera (s)	158
Noxafil	183
Nubeqa	159
Nubeqa (s)	159
Nuedexta	160
Nuedexta (s)	160
Nuplazid	161
Nuplazid (s)	161
Nutrilipid	312
Nuvigil (s)	162

#### 0

Octreotide Acetate	208
Odomzo	163
Odomzo (s)	163
Ofev	164
Ofev (s)	164
Ondansetron Hcl	
Ondansetron Hydrochloride	
Ondansetron Odt	
Onureg	166
Onureg (s)	166
Opsumit	167
Opsumit (s)	167
Orencia	168, 169
Orencia Clickject	169
Orencia IV (s)	168
Orencia Sc (s)	
Orgovyx	
Orgovyx (s)	170
Orkambi	
Orkambi (s)	
Orkambi Granules (s)	172
Osphena	
Osphena (s)	173
Oxandrin (s)	
Oxandrolone	174
Oxbryta	175
Oxbryta (s)	

#### P

Part B Versus Part D
Pegasys176
Pegasys (s)176
Pegasys Proclick176
Pemazyre
Pemazyre (s)
Pennsaid (s) 178
Pentamidine Isethionate
Perforomist
Phesgo
Phesgo (s)
Piqray (s)
Piqray 200mg Daily Dose
Piqray 250mg Daily Dose
Piqray 300mg Daily Dose
Pirfenidone
Plenamine
Polivy
Polivy (s)
Pomalyst182
Pomalyst (s)182
Posaconazole (s)
Posaconazole Dr
Prehevbrio
Premium Lidocaine
Procrit
Prograf
Prolastin-c13
Promacta184
Promacta (s)184
Provigil (s)
Pyrimethamine
Pyrukynd
Pyrukynd (s)
Pyrukynd Taper Pack

## Q

Qinlock	189
Qinlock (s)	189
Qualaquin (s)	190
Quinine Sulfate	190

#### R

Rabavert	312
Recombivax Hb	312
Repatha	191
Repatha (s)	191
Repatha Pushtronex System	191
Repatha Sureclick	191
Retevmo	194
Retevmo (s)	194
Revatio (s)	195
Revcovi	196
Revcovi (s)	196
Revlimid	197
Revlimid (s)	197
Rezurock	198
Rezurock (s)	198
Rilutek (s)	199
Riluzole	199
Rinvoq	200
Rinvoq (s)	200
Roflumilast	45
Romidepsin	108
Rozlytrek	202
Rozlytrek (s)	202
Rubraca	203
Rubraca (s)	203
Ruxience	204
Ruxience (s)	204
Rydapt	206
Rydapt (s)	206

#### S

Sabril (s)	207
Sajazir	78
Sandimmune	
Sandostatin (s)	208
Sapropterin Dihydrochloride	123
Sarclisa	209
Sarclisa (s)	209
Scemblix	210
Scemblix (s)	210
Scig (s)	211
Secuado	212

Secuado (s)       212         Signifor       213         Signifor (s)       213         Sildenafil Citrate       195         Sirolimus       312         Skyrizi       214         Skyrizi (s)       214         Skyrizi (s)       214         Skyrizi Pen       214         Sofosbuvir/velpatasvir       61         Somatuline Depot       215         Somatuline Depot (s)       216         Sorafenib       156         Sorafenib       156         Sorafenib       156         Sorafenib       156         Spravato (s)       218         Spravato (s)       218         Spravato 56mg Dose       218         Spravato 56mg Dose       218         Sprycel       219         Sprycel (s)       220         Stelara       220, 221         Stelara (s)       221         Stivarga       223         Stivarga (s)       224         Strensiq.       224         Strensiq.       224         Strensiq.       224         Stivarga (s)       223         Stivarga (s)       224 <th></th> <th></th>		
Signifor (s)       213         Sildenafil Citrate       195         Sirolimus       312         Skyrizi       214         Skyrizi (s)       214         Skyrizi (s)       214         Sofosbuvir/velpatasvir       61         Somatuline Depot       215         Somatuline Depot (s)       215         Somavert.       216         Sorafenib       156         Sorafenib       156         Sorafenib Tosylate.       156         Sporanox (s)       217         Spravato (s)       218         Spravato 56mg Dose       218         Spravato 56mg Dose       218         Sprycel.       219         Sprycel (s)       219         Stelara       220, 221         Stelara (iv) (s)       220         Stelara (iv) (s)       223         Stivarga (s)       223         Stivarga (s)       224         Supprelin La       225         Supprelin La       226         Suparelin La (s)       226         Synagis (s)       227         Synagis (s)       228         Synagis (s)       226         Syna	Secuado (s)	. 212
Sildenafil Citrate       195         Sirolimus       312         Skyrizi       214         Skyrizi (s)       214         Skyrizi (s)       214         Sofosbuvir/velpatasvir       61         Somatuline Depot       215         Somatuline Depot (s)       215         Somavert       216         Sorafenib       156         Sorafenib       156         Sorafenib       156         Sorafenib Tosylate       156         Sporanox (s)       217         Spravato (s)       218         Spravato (s)       218         Spravato 56mg Dose       218         Spravato 84mg Dose       218         Sprycel       219         Stelara       220, 221         Stelara       220, 221         Stelara (iv) (s)       220         Stelara (s)       221         Stivarga (s)       223         Strensiq       224         Strensiq (s)       224         Sunitinib Malate       226         Supprelin La       225         Superlin La (s)       226         Synagis (s)       227         Synagis (s) </td <td>Signifor</td> <td>. 213</td>	Signifor	. 213
Sirolimus       312         Skyrizi       214         Skyrizi (s)       214         Skyrizi Pen       214         Sofosbuvir/velpatasvir       61         Somatuline Depot       215         Somatuline Depot (s)       215         Somavert.       216         Sorafenib       156         Sorafenib       156         Sorafenib       156         Sorafenib Tosylate.       156         Sporanox (s)       217         Spravato (s)       218         Spravato 56mg Dose       218         Spravato 56mg Dose       218         Sprycel.       219         Sprycel (s)       219         Stelara       220, 221         Stelara (iv) (s)       220         Stelara (s)       221         Stivarga (s)       223         Strensiq (s)       224         Sunitinib Malate       226         Supprelin La       225         Superlin La (s)       226         Sylatron       227         Synagis (s)       228         Synagis (s)       227         Synagis (s)       228         Synribo (s)	Signifor (s)	. 213
Skyrizi       214         Skyrizi (s)       214         Skyrizi Pen       214         Sofosbuvir/velpatasvir       61         Somatuline Depot       215         Somatuline Depot (s)       215         Somavert       216         Somavert (s)       216         Sorafenib       156         Sorafenib Tosylate       156         Sporanox (s)       217         Spravato (s)       218         Spravato 56mg Dose       218         Spravato 56mg Dose       218         Sprycel       219         Sprycel (s)       219         Stelara       220, 221         Stelara (iv) (s)       220         Stelara (iv) (s)       220         Stelara (iv) (s)       223         Strensiq       224         Strensiq       224         Supprelin La       225         Supprelin La (s)       226         Sylatron       227         Sylatron       227         Synagis (s)       228         Synibo       230         Synribo (s)       230         Synribo (s)       231	Sildenafil Citrate	. 195
Skyrizi (s)       214         Skyrizi Pen       214         Sofosbuvir/velpatasvir       61         Somatuline Depot       215         Somatuline Depot (s)       215         Somavert       216         Somavert       216         Somavert (s)       216         Sorafenib       156         Sorafenib Tosylate       156         Sporanox (s)       217         Spravato (s)       218         Spravato (s)       218         Spravato 56mg Dose       218         Spravato 56mg Dose       218         Sprycel       219         Stelara       220, 221         Stelara (iv) (s)       220         Stelara (iv) (s)       220         Stelara (s)       221         Stivarga (s)       223         Strensiq       224         Strensiq (s)       224         Suprelin La (s)       225         Suprelin La (s)       226         Sylatron       227         Sylatron (s)       227         Synagis (s)       228         Synribo (s)       230         Synribo (s)       230         Synribo (s)<	Sirolimus	. 312
Skyrizi Pen       214         Sofosbuvir/velpatasvir       61         Somatuline Depot       215         Somatuline Depot (s)       215         Somavert       216         Somavert       216         Somavert (s)       216         Sorafenib       156         Sorafenib Tosylate       156         Sorafenib Tosylate       156         Sporanox (s)       217         Spravato (s)       218         Spravato 56mg Dose       218         Spravato 56mg Dose       218         Sprycel       219         Sprycel       219         Sprycel (s)       219         Stelara       220, 221         Stelara (iv) (s)       220         Stelara (s)       221         Stivarga (s)       223         Strensiq       224         Strensiq (s)       224         Sunitinib Malate       226         Suprelin La (s)       225         Superlin La (s)       226         Sylatron       227         Sylatron (s)       227         Synagis (s)       228         Synagis (s)       228         Synribo <td>Skyrizi</td> <td>. 214</td>	Skyrizi	. 214
Sofosbuvir/velpatasvir.       61         Somatuline Depot.       215         Somatuline Depot (s).       215         Somavert.       216         Somavert.       216         Somavert.       216         Sorafenib       156         Sorafenib       156         Sorafenib Tosylate.       156         Sporanox (s)       217         Spravato (s)       218         Spravato 56mg Dose       218         Spravato 56mg Dose       218         Sprycel.       219         Sprycel (s)       219         Stelara       220, 221         Stelara (iv) (s)       220         Stelara (iv) (s)       220         Stelara (iv) (s)       223         Strivarga (s)       223         Strensiq       224         Strensiq (s)       224         Suprelin La (s)       225         Supprelin La (s)       226         Sylatron       227         Sylatron (s)       227         Synagis (s)       228         Synagis (s)       228         Synribo       230         Synribo (s)       230         Synribo	Skyrizi (s)	. 214
Somatuline Depot       215         Somavert.       216         Somavert (s)       216         Sorafenib       156         Sorafenib Tosylate       156         Sporanox (s)       217         Spravato (s)       218         Spravato 56mg Dose       218         Spravato 56mg Dose       218         Sprycel.       219         Sprycel.       219         Stelara (iv) (s)       220         Stelara (iv) (s)       220         Stelara (s)       221         Stivarga.       223         Strensiq       224         Strensiq (s)       224         Supprelin La       225         Supprelin La (s)       226         Sylatron (s)       227         Sylatron (s)       227         Synagis (s)       228         Synagis (s)       228         Synagis (s)       228         Synribo (s)       230         Synribo (s)       230         Synribo (s)       230	Skyrizi Pen	. 214
Somatuline Depot (s)       215         Somavert.       216         Somavert (s)       216         Sorafenib       156         Sorafenib Tosylate.       156         Sporanox (s)       217         Spravato (s)       218         Spravato 56mg Dose       218         Spravato 56mg Dose       218         Spravato 84mg Dose       219         Sprycel       219         Sprycel (s)       219         Stelara       220, 221         Stelara (iv) (s)       220         Stelara (s)       221         Stivarga.       223         Stivarga (s)       223         Stivarga (s)       224         Supprelin La       226         Supprelin La (s)       226         Supprelin La (s)       225         Sutent (s)       226         Sylatron       227         Sylatron       227         Sylatron (s)       227         Synagis (s)       228         Synnibo (s)       230         Synribo (s)       230         Synribo (s)       230         Synribo (s)       231	Sofosbuvir/velpatasvir	61
Somavert.       216         Sorafenib       156         Sorafenib Tosylate.       156         Sporanox (s)       217         Spravato (s)       218         Spravato 56mg Dose       218         Spravato 56mg Dose       218         Spravato 84mg Dose       219         Sprycel.       219         Sprycel (s)       219         Stelara       220, 221         Stelara (iv) (s)       220         Stelara (iv) (s)       223         Stivarga (s)       223         Strensiq       224         Sunitinib Malate       226         Supprelin La       225         Supprelin La (s)       225         Superlin La (s)       226         Sylatron       227         Sylatron       227         Sylatron       227         Synagis (s)       228         Synagis (s)       228         Synribo (s)       230         Synribo (s)       230         Synribo (s)       230	Somatuline Depot	. 215
Somavert.       216         Sorafenib       156         Sorafenib Tosylate.       156         Sporanox (s)       217         Spravato (s)       218         Spravato 56mg Dose       218         Spravato 56mg Dose       218         Spravato 84mg Dose       219         Sprycel.       219         Sprycel (s)       219         Stelara       220, 221         Stelara (iv) (s)       220         Stelara (iv) (s)       223         Stivarga (s)       223         Strensiq       224         Sunitinib Malate       226         Supprelin La       225         Supprelin La (s)       225         Superlin La (s)       226         Sylatron       227         Sylatron       227         Sylatron       227         Synagis (s)       228         Synagis (s)       228         Synribo (s)       230         Synribo (s)       230         Synribo (s)       230	Somatuline Depot (s)	. 215
Sorafenib       156         Sorafenib       Tosylate       156         Sporanox (s)       217         Spravato (s)       218         Spravato 56mg Dose       218         Spravato 84mg Dose       218         Sprycel       219         Sprycel       219         Sprycel (s)       219         Stelara       220, 221         Stelara (iv) (s)       220         Stelara (s)       221         Stivarga       223         Strensiq       224         Strensiq       224         Sunitinib       Malate         226       225         Supprelin La       226         Superelin La (s)       226         Sutent       226         Sylatron       227         Sylatron       227         Sylatron (s)       227         Synagis (s)       228         Synribo       230         Synribo (s)       230         Synribo (s)       230         Synribo (s)       231		
Sorafenib Tosylate	Somavert (s)	. 216
Sporanox (s)       217         Spravato (s)       218         Spravato 56mg Dose       218         Spravato 84mg Dose       218         Spravato 84mg Dose       219         Sprycel.       219         Stelara       220, 221         Stelara (iv) (s)       220         Stelara (s)       221         Stivarga       223         Strensiq       224         Strensiq (s)       224         Supprelin La       225         Supprelin La (s)       226         Supprelin La (s)       225         Sutent       226         Sylatron       227         Sylatron (s)       227         Synagis (s)       228         Synribo       230         Synribo (s)       230         Syprine (s)       231	Sorafenib	. 156
Spravato (s)       218         Spravato 56mg Dose       218         Spravato 84mg Dose       218         Spravato 84mg Dose       219         Sprycel.       219         Sprycel (s)       219         Stelara       220, 221         Stelara (iv) (s)       220         Stelara (s)       221         Stivarga       223         Stivarga (s)       223         Strensiq       224         Strensiq (s)       224         Supprelin La       226         Supprelin La (s)       225         Supprelin La (s)       226         Sylatron       227         Sylatron (s)       227         Synagis (s)       228         Synagis (s)       228         Synribo       230         Synribo (s)       230         Sypribo (s)       230         Sypribo (s)       231	Sorafenib Tosylate	. 156
Spravato 56mg Dose       218         Spravato 84mg Dose       218         Sprycel       219         Sprycel (s)       219         Stelara       220, 221         Stelara (iv) (s)       220         Stelara (s)       221         Stivarga       223         Stivarga (s)       223         Strensiq       224         Strensiq       224         Sunitinib Malate       226         Supprelin La       225         Supprelin La (s)       225         Sutent       226         Sylatron       227         Sylatron (s)       227         Synagis (s)       228         Synribo       230         Synribo (s)       230         Syprine (s)       231	-	
Spravato 84mg Dose       218         Sprycel       219         Sprycel (s)       219         Stelara       220, 221         Stelara (iv) (s)       220         Stelara (s)       221         Stivarga       223         Stivarga (s)       223         Strensiq       224         Strensiq (s)       224         Sunitinib Malate       226         Supprelin La       225         Supprelin La (s)       226         Sutent       226         Sylatron       227         Synagis       228         Synagis (s)       228         Synribo       230         Synribo (s)       230         Synribo (s)       231	Spravato (s)	. 218
Spravato 84mg Dose       218         Sprycel       219         Sprycel (s)       219         Stelara       220, 221         Stelara (iv) (s)       220         Stelara (s)       221         Stivarga       223         Stivarga (s)       223         Strensiq       224         Strensiq (s)       224         Sunitinib Malate       226         Supprelin La       225         Supprelin La (s)       226         Sutent       226         Sylatron       227         Synagis       228         Synagis (s)       228         Synribo       230         Synribo (s)       230         Synribo (s)       231	Spravato 56mg Dose	. 218
Sprycel       219         Sprycel (s)       219         Stelara       220, 221         Stelara (iv) (s)       220         Stelara (s)       221         Stivarga       223         Stivarga (s)       223         Strensiq       224         Strensiq (s)       224         Sunitinib Malate       226         Supprelin La       225         Supprelin La (s)       226         Sutent       226         Sylatron       227         Synagis       227         Synagis (s)       228         Synribo       230         Synribo (s)       230         Synribo (s)       230         Synribo (s)       231		
Stelara       220, 221         Stelara (iv) (s)       220         Stelara (s)       221         Stivarga       223         Stivarga (s)       223         Strensiq       224         Strensiq (s)       224         Sunitinib Malate       226         Supprelin La       225         Supprelin La (s)       226         Sutent (s)       226         Sylatron       227         Synagis       228         Synagis (s)       228         Synribo       230         Synribo (s)       230         Syprine (s)       231		
Stelara (iv) (s)	Sprycel (s)	. 219
Stelara (s)	· · · · · · · · · · · · · · · · · · ·	
Stivarga       223         Stivarga (s)       223         Strensiq (s)       224         Strensiq (s)       224         Sunitinib Malate       226         Supprelin La       225         Supprelin La (s)       226         Sutent       226         Sutent (s)       226         Sylatron       227         Sylatron (s)       227         Synagis (s)       228         Synribo       230         Synribo (s)       230         Syprine (s)       231	Stelara (iv) (s)	. 220
Stivarga (s)       223         Strensiq       224         Strensiq (s)       224         Sunitinib Malate       226         Supprelin La       225         Supprelin La (s)       226         Sutent.       226         Sutent (s)       226         Sylatron       227         Synagis       228         Synagis (s)       228         Synribo       230         Synribo (s)       230         Syprine (s)       231		
Stivarga (s)       223         Strensiq       224         Strensiq (s)       224         Sunitinib Malate       226         Supprelin La       225         Supprelin La (s)       226         Sutent.       226         Sutent (s)       226         Sylatron       227         Synagis       228         Synagis (s)       228         Synribo       230         Synribo (s)       230         Syprine (s)       231		
Strensiq.       224         Strensiq (s)       224         Sunitinib Malate       226         Supprelin La       225         Supprelin La (s)       225         Sutent.       226         Sutent (s)       226         Sylatron       227         Sylatron (s)       227         Synagis       228         Synagis (s)       228         Synribo       230         Synribo (s)       230         Syprine (s)       231	-	
Sunitinib Malate       226         Supprelin La       225         Supprelin La (s)       225         Sutent       226         Sutent (s)       226         Sylatron       227         Sylatron (s)       227         Synagis       228         Synagis (s)       228         Synribo       230         Synribo (s)       230         Syprine (s)       231		
Supprelin La       225         Supprelin La (s)       225         Sutent       226         Sutent (s)       226         Sylatron       227         Sylatron (s)       227         Synagis       228         Synagis (s)       228         Synribo       230         Synribo (s)       230         Syprine (s)       231	-	
Supprelin La (s)	Sunitinib Malate	. 226
Supprelin La (s)	Supprelin La	. 225
Sutent.       226         Sutent (s)       226         Sylatron       227         Sylatron (s)       227         Synagis       228         Synagis (s)       228         Synribo       230         Syprine (s)       231		
Sutent (s)       226         Sylatron       227         Sylatron (s)       227         Synagis       228         Synagis (s)       228         Synribo       230         Synribo (s)       230         Syprine (s)       231		
Sylatron (s)       227         Synagis       228         Synagis (s)       228         Synribo       230         Synribo (s)       230         Syprine (s)       231		
Synagis       228         Synagis (s)       228         Synribo       230         Synribo (s)       230         Syprine (s)       231	Sylatron	. 227
Synagis (s)       228         Synribo       230         Synribo (s)       230         Syprine (s)       231	Sylatron (s)	. 227
Synribo         230           Synribo (s)         230           Syprine (s)         231	Synagis	. 228
Synribo         230           Synribo (s)         230           Syprine (s)         231	Synagis (s)	. 228
Synribo (s)		
Syprine (s)		
	• • • • • •	
	Τ	

Tabrecta	. 232
Tabrecta (s)	. 232
Formulary ID 22323 Version 21	
Last Updated: November 2022	

Tacrolimus	312
Tadalafil	4
Tafamidis (s)	233
Tafinlar	234
Tafinlar (s)	234
Tagrisso	236
Tagrisso (s)	236
Talzenna	237
Talzenna (s)	237
Tarceva (s)	238
Targretin	239
Targretin (s)	239
Tarpeyo	240
Tarpeyo (s)	240
Tasigna	241
Tasigna (s)	241
Tavalisse	242
Tavalisse (s)	242
Tavneos	
Tavneos (s)	243
Tazverik	244
Tazverik (s)	244
Tecfidera (s)	245
Tegsedi	246
Tegsedi (s)	
Tepmetko	
Tepmetko (s)	247
Teriparatide	248
Teriparatide (s)	248
Testosterone	
Testosterone (s)	250
Testosterone Cypionate	250
Testosterone Enanthate	
Testosterone Enanthate (s)	252
Testosterone Pump	
Tetrabenazine	
Thalomid	254
Thalomid (s)	254
Tibsovo	
Tibsovo (s)	255
Tobramycin	
Topical Retinoid (s)	
Trazimera	

Trazimera (s)	257
Trelstar (s)	
Trelstar Mixject	
Tretinoin	256
Trientine Hydrochloride	231
Trikafta	259
Trikafta (s)	259
Triptodur	260
Triptodur (s)	260
Trodelvy	261
Trodelvy (s)	261
Truseltiq	262
Truseltiq (s)	262
Tukysa	263
Tukysa (s)	263
Turalio	
Turalio (s)	264
Tykerb (s)	265
Tymlos	266
Tymlos (s)	266
Tysabri	267
Tysabri (s)	267

#### U

Ubrelvy	59
Ubrelvy (s)	59
Udenyca	70
Udenyca (s)	70
Ukoniq2'	71
Ukoniq (s)2	71

### V

272
272
273
273
274
275
275
275
276
276
277
277

Formulary ID 22323 Version 21 Last Updated: November 2022

Vigabatrin	207
Vigadrone	207
Vimizim	
Vimizim (s)	
Vitrakvi	
Vitrakvi (s)	
Vizimpro	
Vizimpro (s)	
Vonjo	
Vonjo (s)	
Voriconazole	
Voriconazole Injection (s)	
Vosevi	
Vosevi (s)	
Votrient	
Votrient (s)	
Vyndaqel	

#### W

Welireg	.285
Welireg (s)	.285

#### X

Xalkori	
Xalkori (s)	
Xcopri	
Xcopri (s)	
Xeljanz	
Xeljanz (s)	
Xeljanz Xr	
Xenazine (s)	
Xermelo	
Xermelo (s)	
Xgeva	
Xgeva (s)	
Xifaxan	
Xifaxan (s)	
Xolair	
Xolair (s)	
Xospata	
Xospata (s)	
Xpovio	
Xpovio (s)	
Xpovio 100 Mg Once Weekly	
· · ·	

Veryin 10 Ma Orea Washly	207
Xpovio 40 Mg Once Weekly	297
Xpovio 40 Mg Twice Weekly	297
Xpovio 60 Mg Once Weekly	297
Xpovio 60 Mg Twice Weekly	297
Xpovio 80 Mg Once Weekly	297
Xpovio 80 Mg Twice Weekly	297
Xtandi	298
Xtandi (s)	298
Xyrem	299
Xyrem (s)	299

## Z

Zavesca (s)	
Zejula	
Zejula (s)	
Zelboraf	
Zelboraf (s)	
Zemaira	

Zenatane	107
Zepzelca	
Zepzelca (s)	
Zirabev	
Zirabev (s)	
Zokinvy	
Zokinvy (s)	
Zoladex	
Zoladex (s)	
Zolinza	
Zolinza (s)	
Zortress	
Zydelig	
Zydelig (s)	
Zykadia	
Zykadia (s)	
Zytiga (preferred) (s)	