

# ACTEMRA SC (s)

## Products Affected

- ACTEMRA ACTPEN
- ACTEMRA SUBCUTANEOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	RA, GC, SJIA, PJIA, SSc-ILD (initial, reauth): 12 months
<b>Other Criteria</b>	RA, GC, SJIA, PJIA, SSc-ILD (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.

Formulary ID 22333 Version 17 Effective Date: 09/01/2022

Last Updated: August 2022

PA Criteria	Criteria Details
Off Label Uses	

# Actimmune (s)

---

**Products Affected**

- ACTIMMUNE

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

# Adbry (s)

## Products Affected

- ADBRY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial: Diagnosis of moderate to severe atopic dermatitis. One of the following: a) Involvement of at least 10% body surface area (BSA), or b) SCORing Atopic Dermatitis (SCORAD) index value of at least 25. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least two of the following: a) Medium or higher potency topical corticosteroid, b) Pimecrolimus cream, c) Tacrolimus ointment, or d) Eucrisa (crisaborole) ointment.
<b>Age Restrictions</b>	Initial: Patient is 18 years of age or older.
<b>Prescriber Restrictions</b>	Initial: Prescribed by or in consultation with a dermatologist or allergist/immunologist.
<b>Coverage Duration</b>	Initial: 6 months. Reauth: 12 months.
<b>Other Criteria</b>	Reauth: Documentation of a positive clinical response to therapy as evidenced by at least one of the following: a) Reduction in BSA involvement from baseline, or b) Reduction in SCORAD index value from baseline.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ADCIRCA (s)

## Products Affected

- *alyq*
- *tadalafil (pah)*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
<b>Coverage Duration</b>	PAH: Initial: 6 months. Reauth: 12 months.
<b>Other Criteria</b>	PAH (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ADEMPAS (s)

## Products Affected

- ADEMPAS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PAH, CTEPH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
<b>Coverage Duration</b>	PAH, CTEPH: Initial: 6 months. Reauth: 12 months.
<b>Other Criteria</b>	PAH, CTEPH (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# AFINITOR (s)

## Products Affected

- AFINITOR ORAL TABLET 10 MG
- *everolimus oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses: Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	All uses: 12 months
<b>Other Criteria</b>	All Indications: Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# AFINITOR DISPERZ (s)

## Products Affected

- AFINITOR DISPERZ
- *everolimus oral tablet soluble*

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



# Aimovig (s)

## Products Affected

- AIMOVIG SUBCUTANEOUS SOLUTION  
AUTO-INJECTOR 140 MG/ML, 70 MG/ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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.</p> <p>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.</p> <p>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.</p>
<b>Age Restrictions</b>	EM, CM (initial): 18 years of age or older.
<b>Prescriber Restrictions</b>	EM, CM (initial, reauth): Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.
<b>Coverage Duration</b>	EM, CM (initial): 6 months. EM, CM (reauth): 12 months.
<b>Other Criteria</b>	<p>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.</p> <p>CM (reauth): Patient continues to be monitored for medication overuse headache.</p>

Formulary ID 22333 Version 17 Effective Date: 09/01/2022

Last Updated: August 2022

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Aldurazyme (s)

---

**Products Affected**

- ALDURAZYME

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Alecensa (s)

## Products Affected

- ALECENSA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ALPHA-1 PROTEINASE INHIBITOR, NON-PREFERRED (s)

## Products Affected

- ARALAST NP
- ZEMAIRA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 µM/L [e.g., Pi(Malton, Malton), Pi(SZ)]. One of the following: Circulating pre-treatment serum AAT level less than 11 µM/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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ALPHA-1 PROTEINASE INHIBITOR, PROLASTIN (s)

## Products Affected

- PROLASTIN-C INTRAVENOUS SOLUTION RECONSTITUTED

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 µM/L [e.g., Pi(Malton, Malton), Pi(SZ)]. Circulating pre-treatment serum AAT level less than 11 µM/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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ALUNBRIG (s)

## Products Affected

- ALUNBRIG ORAL TABLET 180 MG, 30 MG, 90 MG
- ALUNBRIG ORAL TABLET THERAPY PACK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# AMPYRA (s)

## Products Affected

- *dalfampridine er*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	MS (initial): Prescribed by or in consultation with a neurologist.
<b>Coverage Duration</b>	MS (Initial): 6 months. (Reauth): 12 months.
<b>Other Criteria</b>	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).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# ANADROL-50 (s)

## Products Affected

- ANADROL-50 ORAL TABLET 50 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Anemia (initial): Diagnosis of anemia caused by deficient red cell production AND trial and failure or intolerance to two standard therapies for anemia (i.e., erythropoiesis-stimulating agents, immunosuppressants) AND Treatment will not replace other supportive measures (e.g., transfusion, correction of iron, folic acid, vitamin B12 or pyridoxine deficiency, antibacterial therapy, corticosteroids).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial, reauth: 12 months
<b>Other Criteria</b>	Anemia (reauth): Documentation of a positive clinical response to therapy as evidenced by an improvement in anemia (e.g., increased hemoglobin, increased reticulocyte count, reduction/elimination for need of blood transfusions).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Arcalyst (s)

## Products Affected

- ARCALYST

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	CAPS, Recurrent Pericarditis (initial, reauth): 12 months. DIRA: 12 months.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# AUBAGIO (s)

---

## Products Affected

- AUBAGIO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	MS (initial, reauth): Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	MS (initial, reauth): 12 months
<b>Other Criteria</b>	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Auryxia (s)

---

## Products Affected

- AURYXIA

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

# Austedo (s)

## Products Affected

- AUSTEDO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Huntington's disease chorea (initial): Prescribed by a neurologist. Tardive dyskinesia (initial): Prescribed by or in consultation with a neurologist or psychiatrist.
<b>Coverage Duration</b>	Initial: 3 months. Reauth: 12 months
<b>Other Criteria</b>	All indications (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Ayvakit (s)

## Products Affected

- AYWAKIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	GIST: Prescribed by or in consultation with an oncologist. AdvSM: Prescribed by or in consultation with an oncologist/hematologist, allergist, or immunologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Bafiertam (s)

## Products Affected

- BAFIERTAM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	MS (initial, reauth): Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	MS (initial, reauth): 12 months
<b>Other Criteria</b>	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Balversa (s)

## Products Affected

- BALVERSA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Benlysta (s)

## Products Affected

- BENLYSTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	SLE (init): Prescribed by or in consultation with a rheumatologist. Lupus Nephritis (init): Prescribed by or in consultation with a nephrologist or rheumatologist.
<b>Coverage Duration</b>	SLE, Lupus Nephritis (init, reauth): 6 months
<b>Other Criteria</b>	SLE, Lupus Nephritis (reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Besremi (s)

## Products Affected

- BESREMI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Bosulif (s)

---

## Products Affected

- BOSULIF

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

# Braftovi (s)

## Products Affected

- BRAFTOVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# BRIVIACT (s)

---

## Products Affected

- BRIVIACT ORAL

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

# Brukina (s)

## Products Affected

- BRUKINSA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist/hematologist.
<b>Coverage Duration</b>	12 months.
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# CABLIVI (s)

## Products Affected

- CABLIVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist.
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Cabometyx (s)

## Products Affected

- CABOMETYX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Calquence (s)

## Products Affected

- CALQUENCE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Camzyos (s)

## Products Affected

- CAMZYOS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial: Diagnosis of obstructive hypertrophic cardiomyopathy (HCM). Patient has New York Heart Association (NYHA) Class II or III symptoms (e.g., shortness of breath, chest pain). Patient has a left ventricular ejection fraction of greater than or equal to 55%. Patient has valsalva left ventricular outflow tract (LVOT) peak gradient greater than or equal to 50 mmHg at rest or with provocation. Trial and failure, contraindication, or intolerance to both of the following at a maximally tolerated dose: a) non-vasodilating beta blocker (e.g., bisoprolol, propranolol) and b) calcium channel blocker (e.g., verapamil, diltiazem).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Initial, Reauth: Prescribed by or in consultation with a cardiologist.
<b>Coverage Duration</b>	Initial: 16 weeks, Reauth: 12 months
<b>Other Criteria</b>	Reauthorization: Documentation of positive clinical response to therapy (e.g., improved symptom relief). Patient has a left ventricular ejection fraction of greater than or equal to 50%.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# CAPRELSA (s)

---

## Products Affected

- CAPRELSA ORAL TABLET 100 MG, 300 MG

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

# CARISOPRODOL (s)

## Products Affected

- *carisoprodol oral tablet 350 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The drug is being prescribed for an FDA-approved indication. If the patient is 65 years of age or older, 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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Cayston (s)

## Products Affected

- CAYSTON

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Cystic fibrosis (CF) (Initial, Reauth): Diagnosis of CF AND Patient has evidence of Pseudomonas aeruginosa in the lungs.
<b>Age Restrictions</b>	CF (Initial): 7 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	CF (Initial, reauth): 12 months
<b>Other Criteria</b>	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).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Cerdelga (s)

## Products Affected

- CERDELGA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Gaucher disease (initial): 18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Gaucher disease (initial, reauth): 12 months
<b>Other Criteria</b>	Gaucher disease (Reauth): Patient continues to need requested medication.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Cholbam (s)

## Products Affected

- CHOLBAM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses (initial): Prescribed by a hepatologist, medical geneticist, pediatric gastroenterologist, OR other specialist that treats inborn errors of metabolism.
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months
<b>Other Criteria</b>	All uses (reauth): documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# CIALIS (s)

## Products Affected

- *tadalafil oral tablet 2.5 mg, 5 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use of nitrates.
<b>Required Medical Information</b>	Diagnosis of benign prostatic hyperplasia (BPH). Trial and failure, contraindication, or intolerance to an alpha-blocker (e.g., doxazosin, prazosin, tamsulosin) or a 5-alpha reductase inhibitor (e.g., dutasteride, finasteride).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Cibinqo (s)

## Products Affected

- CIBINQO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial: Diagnosis of atopic dermatitis. Disease is considered moderate to severe based on one of the following: a) Involvement of at least 10% body surface area (BSA), or b) A validated clinical scale (eg, SCORing Atopic Dermatitis [SCORAD] index value of at least 25, Investigator's Global Assessment [IGA] of at least 3). Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least one of the following: a) Medium or higher potency topical corticosteroid, b) Pimecrolimus cream, c) Tacrolimus ointment, or d) Eucria (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 atopic dermatitis (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 atopic dermatitis therapies: Adbry (tralokinumab-ldrm) and Dupixent (dupilumab). Not used in combination with biologic immunomodulators (eg, Dupixent, Adbry) or other immunosuppressants (eg, azathioprine, cyclosporine).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Initial: Prescribed by or in consultation with a dermatologist or allergist/immunologist.
<b>Coverage Duration</b>	Initial: 6 months. Reauth: 12 months.
<b>Other Criteria</b>	Reauth: Documentation of a positive clinical response to therapy as evidenced by at least one of the following: a) Reduction in BSA involvement from baseline, or b) A validated clinical scale shows improvement from baseline (eg, SCORAD index, IGA). Not used in combination with biologic immunomodulators (eg, Dupixent, Adbry) or other immunosuppressants (eg, azathioprine, cyclosporine).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# CICLOPIROX (s)

## Products Affected

- *ciclodan*
- *ciclopirox external solution*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	48 weeks.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# CIMZIA (s)

## Products Affected

- CIMZIA PREFILLED KIT
- CIMZIA STARTER KIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Rheumatoid Arthritis (RA, initial): Diagnosis (dx) 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. Crohn's Disease (CD, initial): Dx of moderately to severely active CD. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine (Purinethol), Azathioprine (Imuran), Corticosteroid (eg, prednisone, methylprednisolone), Methotrexate (Rheumatrex, Trexall). TF/C/I to Humira OR for continuation of prior therapy. Psoriatic Arthritis (PsA, initial): Dx of active PsA. One of the following: a) Either a TF/C/I 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): Dx of active AS. TF/C/I to two of the following: Enbrel, Humira, Rinvoq, Xeljanz/Xeljanz XR, or attestation demonstrating a trial may be inappropriate, OR for continuation of prior therapy. Plaque Psoriasis (initial): Dx of moderate to severe plaque psoriasis. TF/C/I to two of the following: Humira, Enbrel, Skyrizi (risankizumab), Cosentyx (secukinumab) OR for continuation of prior therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	CD (init): Prescribed by or in consultation with a gastroenterologist. RA, AS, nr-axSpA (init): Prescribed by or in consultation with a rheumatologist. PsA (init): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque psoriasis (init): Prescribed by or in consultation with a dermatologist.
<b>Coverage Duration</b>	RA, PsA, AS, Plaque psoriasis, nr-axSpA (init, reauth): 12 mos. CD (init): 16 wks. (reauth): 12 mos.
<b>Other Criteria</b>	Non-radiographic axial spondyloarthritis (nr-axSpA, initial): Dx of 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

Formulary ID 22333 Version 17 Effective Date: 09/01/2022

Last Updated: August 2022

PA Criteria	Criteria Details
	definitive radiographic evidence of structural damage on sacroiliac joints.) TF/C/I to two non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., diclofenac, ibuprofen, meloxicam, naproxen). Reauth (RA, CD, PsA, AS, nr-axSpA): 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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Cinryze (s)

## Products Affected

- CINRYZE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	HAE (prophylaxis): Prescribed by or in consultation with an immunologist or an allergist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Cometriq (s)

---

**Products Affected**

- COMETRIQ

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

# Copiktra (s)

## Products Affected

- COPIKTRA

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

# CORLANOR (s)

## Products Affected

- CORLANOR ORAL SOLUTION
- CORLANOR ORAL TABLET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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. One of the following: patient is on a beta-blocker (e.g., bisoprolol, carvedilol, metoprolol succinate extended release) at a maximally tolerated dose, or patient has a contraindication or intolerance to beta-blocker therapy. Patient has been hospitalized for worsening HF in the previous 12 months. Trial and failure, contraindication, or intolerance to maximally tolerated doses of an ACE inhibitor (e.g., captopril, enalapril, lisinopril) or ARB (e.g., candesartan, losartan, valsartan). 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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	CHF, DCM (initial): Prescribed by or in consultation with a cardiologist
<b>Coverage Duration</b>	CHF, DCM (initial, reauth): 12 months
<b>Other Criteria</b>	CHF, DCM (reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# COSENTYX (s)

## Products Affected

- COSENTYX (300 MG DOSE)
- COSENTYX 150 MG/ML
- COSENTYX SENSOREADY (300 MG)
- COSENTYX SENSOREADY PEN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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).</p>
<b>Age Restrictions</b>	ERA (initial): Patient is 4 years of age or older.
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months

PA Criteria	Criteria Details
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Cotellic (s)

## Products Affected

- COTELLIC

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# CYSTARAN (s)

## Products Affected

- CYSTARAN

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

## D.H.E. 45 (s)

### Products Affected

- *dihydroergotamine mesylate injection*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Initial, Reauth: Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.
<b>Coverage Duration</b>	Migraines, CH (initial): 3 months. Migraines, CH (reauth): 12 months.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Daliresp (s)

## Products Affected

- DALIRESP

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

# Danyelza (s)

## Products Affected

- DANYELZA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Neuroblastoma: Patient is 1 year of age or older.
<b>Prescriber Restrictions</b>	Neuroblastoma: Prescribed by or in consultation with an oncologist or hematologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# DARAPRIM (s)

## Products Affected

- *pyrimethamine oral*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an infectious disease specialist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Toxoplasmosis only: Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Darzalex Faspro (s)

## Products Affected

- DARZALEX FASPRO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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, thalidomide, and dexamethasone. Light Chain (AL) Amyloidosis: Newly diagnosed light chain (AL) amyloidosis. Used in combination with all of the following: bortezomib, cyclophosphamide, and dexamethasone. 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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	MM: Prescribed by or in consultation with an oncologist/hematologist. Light Chain (AL) Amyloidosis: Prescribed by or in consultation with a hematologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy
<b>Indications</b>	All Medically-accepted Indications.

Formulary ID 22333 Version 17 Effective Date: 09/01/2022

Last Updated: August 2022

PA Criteria	Criteria Details
Off Label Uses	

# Daurismo (s)

## Products Affected

- DAURISMO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# DEFERASIROX (s)

## Products Affected

- *deferasirox granules*
- *deferasirox oral tablet*
- *deferasirox oral tablet soluble*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Iron Overload Due to Blood Transfusions (initial): 2 years of age or older. NTDT (initial): 10 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Iron Overload Due to Blood Transfusions, MDS (initial, reauth): 12 mo. NTDT (initial, reauth): 6mo.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Diacomit (s)

## Products Affected

- DIACOMIT

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

# DUPIXENT (s)

## Products Affected

- DUPIXENT SUBCUTANEOUS SOLUTION PEN-INJECTOR 200 MG/1.14ML, 300 MG/2ML
- DUPIXENT SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 100 MG/0.67ML, 200 MG/1.14ML, 300 MG/2ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 Fasentra (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].
<b>Age Restrictions</b>	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.
<b>Prescriber Restrictions</b>	Atopic dermatitis (Initial): Prescribed by or in consultation with one of the following: dermatologist, allergist/immunologist. Asthma (initial, reauth):

PA Criteria	Criteria Details
	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.
<b>Coverage Duration</b>	AD, CRSwNP, EoE (Init/Reauth): 12 months. Asthma (Init): 6 mo. Asthma (reauth): 12 mo.
<b>Other Criteria</b>	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 eosinophils 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 pruritus 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 with another agent for CRSwNP. EoE (reauth): Documentation of a positive clinical response to therapy as evidenced by improvement of at least one of the following from baseline: symptoms (eg, dysphagia, food impaction, chest pain, heartburn), histologic measures (eg, esophageal intraepithelial eosinophil count), or endoscopic measures (eg, edema, furrows, exudates, rings, strictures).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Elaprase (s)

---

## Products Affected

- ELAPRASE

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



# ELIGARD (s)

---

## Products Affected

- ELIGARD SUBCUTANEOUS KIT 22.5 MG, 30 MG, 45 MG, 7.5 MG

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# Elyxyb (s)

---

## Products Affected

- ELYXYB

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of migraine with or without aura. Trial and failure, contraindication, or intolerance to two generic nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# Emgality (s)

## Products Affected

- EMGALITY SUBCUTANEOUS SOLUTION AUTO-INJECTOR 120 MG/ML
- EMGALITY SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 100 MG/ML, 120 MG/ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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.</p> <p>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.</p> <p>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.</p>
<b>Age Restrictions</b>	EM, CM, ECH (initial): 18 years of age or older.
<b>Prescriber Restrictions</b>	EM, CM, ECH (initial, reauth): Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.
<b>Coverage Duration</b>	EM, CM (initial): 6 months. ECH (initial): 3 months. EM, CM, ECH (reauth): 12 months.
<b>Other Criteria</b>	EM, CM (120 mg/mL strength only) (reauth): Patient has experienced a positive response to therapy, demonstrated by a reduction in headache

Formulary ID 22333 Version 17 Effective Date: 09/01/2022

Last Updated: August 2022

PA Criteria	Criteria Details
	<p>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.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Enbrel (s)

## Products Affected

- ENBREL
- ENBREL MINI
- ENBREL SUBCUTANEOUS SOLUTION RECONSTITUTED
- ENBREL SURECLICK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Enspryng (s)

## Products Affected

- ENSPRYNG

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

# ENTYVIO (s)

## Products Affected

- ENTYVIO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Ulcerative Colitis (UC) (init): Diagnosis (Dx) of moderately to severely active UC. Trial and failure, contraindication, or intolerance (F/C/I) to one of the following conventional therapies: 6-mercaptopurine (Purinethol), aminosalicylates [eg, mesalamine (Asacol, Pentasa, Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine, Sulfazine)], azathioprine (Imuran), corticosteroids (eg, prednisone, methylprednisolone). One of the following: F/C/I to one tumor necrosis factor (TNF) inhibitor [eg, Humira (adalimumab), infliximab], OR for continuation of prior Entyvio therapy. Crohn's Disease (CD) (init): Dx of moderately to severely active CD. F/C/I to one of the following medications: 6-mercaptopurine (Purinethol), azathioprine (Imuran), corticosteroids (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex, Trexall). One of the following: F/C/I to one TNF inhibitor [eg, Humira (adalimumab), infliximab], OR for continuation of prior Entyvio therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	UC, CD (init): Prescribed by or in consultation with a gastroenterologist
<b>Coverage Duration</b>	UC, CD (init): 14 weeks. UC, CD (reauth): 12 months.
<b>Other Criteria</b>	UC, CD (reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## EPCLUSA preferred (s)

### Products Affected

- *sofosbuvir-velpatasvir*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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)].
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	12 to 24 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Epidiolex (s)

## Products Affected

- EPIDIOLEX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	LGS, DS, TSC: Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# EPOETIN ALFA (s)

## Products Affected

- PROCRIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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. Patient is receiving ribavirin and one of the following: interferon alfa or peginterferon alfa. Anemia with HIV (Initial): Anemia by lab values (Hgb less than 12 g/dL or Hct less than 36%) 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.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	<p>CKD,HIV(Init):6mo. CKD,HIV(reauth):12mo. Chemo,HCV(all):3mo. MDS:(init) 3mo,(reauth)12mo. Preop:1mo.</p>
<b>Other Criteria</b>	<p>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</p>

Formulary ID 22333 Version 17 Effective Date: 09/01/2022

Last Updated: August 2022

PA Criteria	Criteria Details
	<p>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. Off-label uses (except MDS, HCV): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%. CKD (init, reauth), HIV (init), Chemo (init), Preop, MDS (init), HCV (init): Verify iron evaluation for adequate iron stores.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Erivedge (s)

## Products Affected

- ERIVEDGE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or dermatologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Erleada (s)

## Products Affected

- ERLEADA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	NM-CRPC, M-CSPC: Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Esbriet (s)

## Products Affected

- ESBRIET
- *pirfenidone*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	IPF (initial): Prescribed by or in consultation with a pulmonologist
<b>Coverage Duration</b>	initial, reauth: 12 months
<b>Other Criteria</b>	IPF (reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# EUCRISA (s)

## Products Affected

- EUCRISA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Reauth: Documentation of a positive clinical response to therapy (e.g., reduction in body surface area involvement, reduction in pruritus severity).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Evrysdi (s)

## Products Affected

- EVRYSDI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 (HINE) (infant to early childhood), Hammersmith Functional Motor Scale Expanded (HFMSSE), Upper Limb Module (ULM) Test (Non ambulatory), or Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND), or Motor Function Measure 32 (MFM-32) Scale. 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 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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	SMA (Initial, Reauth): Prescribed by or in consultation with a neurologist with expertise in the diagnosis and treatment of SMA
<b>Coverage Duration</b>	Initial, Reauth: 12 months
<b>Other Criteria</b>	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

Formulary ID 22333 Version 17 Effective Date: 09/01/2022

Last Updated: August 2022



PA Criteria	Criteria Details
	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).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## Exkivity (s)

### Products Affected

- EXKIVITY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Exservan (s)

## Products Affected

- EXSERVAN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Amyotrophic Lateral Sclerosis (ALS): Diagnosis of ALS. Trial and failure or intolerance to generic riluzole tablets.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# Fabrazyme (s)

---

## Products Affected

- FABRAZYME

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Fabry Disease: Diagnosis of Fabry disease. Fabrazyme will not be used in combination with Galafold (migalastat).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Fabry Disease: 12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# FARYDAK (s)

## Products Affected

- FARYDAK ORAL CAPSULE 10 MG, 15 MG, 20 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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)].
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist/hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Fasenra (s)

## Products Affected

- FASENRA
- FASENRA PEN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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)].
<b>Age Restrictions</b>	Asthma (Initial): Patient is 12 years of age or older
<b>Prescriber Restrictions</b>	Asthma (Initial/Reauth): Prescribed by or in consultation with a pulmonologist or allergist/immunologist
<b>Coverage Duration</b>	Asthma (init): 6 months. Asthma (reauth): 12 months
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Fensolvi (s)

## Products Affected

- FENSOLVI (6 MONTH)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	CPP (initial, reauth): Prescribed by or in consultation with a pediatric endocrinologist.
<b>Coverage Duration</b>	CPP (Initial, reauth): 12 months
<b>Other Criteria</b>	CPP (reauthorization): LH levels have been suppressed to pre-pubertal levels.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# FENTANYL (s)

## Products Affected

- *fentanyl citrate buccal lozenge on a handle*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 µg/hr, Oxycodone at a dose of greater than or equal to 30 mg/day, Oral hydromorphone at a dose of greater than or equal to 8 mg/day, Oral oxymorphone 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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with one of the following: Pain specialist, Oncologist, Hematologist, Hospice care specialist, or Palliative care specialist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Ferriprox (s)

## Products Affected

- *deferiprone*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 $1.5 \times 10^9/L$ . 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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	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 $1.5 \times 10^9/L$ .
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Fintepla (s)

## Products Affected

- FINTEPLA

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

# Firazyr (s)

## Products Affected

- *icatibant acetate*
- *sajazir*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	HAE: Prescribed by or in consultation with an immunologist or an allergist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# FIRMAGON (s)

## Products Affected

- FIRMAGON
- FIRMAGON (240 MG DOSE)

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

# Fotivda (s)

## Products Affected

- FOTIVDA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist, nephrologist, or urologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Galafold (s)

## Products Affected

- GALAFOLD

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	FD (initial, reauth): 12 months.
<b>Other Criteria</b>	FD (reauthorization): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## Gamastan S/D (s)

### Products Affected

- GAMASTAN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication).
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 months (Approve one dose only)
<b>Other Criteria</b>	Subject to Part B vs D review.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## Gattex (s)

### Products Affected

- GATTEX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Short Bowel Syndrome (SBS) (Initial): Diagnosis of SBS. Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient is dependent on parenteral nutrition/intravenous (PN/IV) support for at least 12 months.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	SBS (Init, reauth): Prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	SBS (Init): 6 months. SBS (Reauth): 12 months.
<b>Other Criteria</b>	SBS (Reauth): Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has had a reduction in weekly parenteral nutrition/intravenous (PN/IV) support from baseline while on therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Gavreto (s)

## Products Affected

- GAVRETO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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. One of the following: patient is radioactive iodine-refractory or radioactive iodine therapy is not appropriate.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	NSCLC, MTC: Prescribed by or in consultation with an oncologist. Thyroid Cancer: Prescribed by or in consultation with an endocrinologist or an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# GILENYA (s)

## Products Affected

- GILENYA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	MS (initial, reauth): Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	MS (initial, reauth): 12 months
<b>Other Criteria</b>	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# GILOTRIF (s)

## Products Affected

- GILOTRIF

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# GLATIRAMER ACETATE (s)

## Products Affected

- *glatiramer acetate subcutaneous solution*  
*prefilled syringe 20 mg/ml, 40 mg/ml*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	MS (initial, reauth): Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	MS (initial, reauth): 12 months
<b>Other Criteria</b>	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Gleevec (s)

## Products Affected

- *imatinib mesylate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 re-arrangements OR G) Aggressive systemic mastocytosis without the D816V c-KIT mutation or with c-KIT mutational status unknown.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Hypereosinophilic syndrome or chronic eosinophilic leukemia, Aggressive systemic mastocytosis: Prescribed by or in consultation with an oncologist, hematologist, allergist, or immunologist. All other uses: Prescribed by or in consultation with an oncologist or hematologist.
<b>Coverage Duration</b>	All uses: 12 months
<b>Other Criteria</b>	All uses: Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# GROWTH HORMONE, PREFERRED (s)

## Products Affected

- GENOTROPIN
- GENOTROPIN MINIQUICK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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 2.25SD 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) and ht remains at or below 3rd percentile (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):ISS 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.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist. GFCRI: prescribed by endocrinologist or nephrologist
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>AGHD(initial):dx of AGHD with clin records supporting dx of childhood-onset GHD, or adult-onset GHD w/clin records doc 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 ng/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 nrml range as provided by physicians lab.</p> <p>AGHD,IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level. TransitionPhaseAdolescent Pts(TPAP)(initial): attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t 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 nrml 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 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 ng/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 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 ng/mL 30, 45, 60 and 90 mins after admin]. TPAP(reauth): evidence of positive response to therapy (eg,incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3).</p> <p>IGHDA(initial):doc GHD after 2 GH stim tests(ITT,L-ARG,glucagon,macimorelin), w/ 2 corresponding peak GH values [ITT at or below 5mcg/L],[Arg at or below 5mcg/L],[glucagon at or below 3mcg/L],[macimorelin less than 2.8 ng/mL 30,45,60,90 mins after admin].</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# HRM - Megestrol Suspension

## Products Affected

- *megestrol acetate oral suspension 40 mg/ml, 625 mg/5ml*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	PA applies to patients 65 years or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# HRM - Megestrol Tablet

---

## Products Affected

- *megestrol acetate oral tablet*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	PA applies to patients 65 years or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Applies to New Starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Humira (s)

## Products Affected

- HUMIRA
- HUMIRA PEDIATRIC CROHNS START
- HUMIRA PEN
- HUMIRA PEN-CD/UC/HS STARTER
- HUMIRA PEN-PEDIATRIC UC START
- HUMIRA PEN-PS/UV/ADOL HS START
- HUMIRA PEN-PSOR/UEVEIT STARTER

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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), aminosalicilate [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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial, reauth): 12 mo.

PA Criteria	Criteria Details
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Ibrance (s)

## Products Affected

- IBRANCE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ICLUSIG (s)

## Products Affected

- ICLUSIG ORAL TABLET 10 MG, 15 MG, 30 MG, 45 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses: Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	All uses: 12 months
<b>Other Criteria</b>	All uses: Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Idhifa (s)

## Products Affected

- IDHIFA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Ilaris (s)

## Products Affected

- ILARIS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Periodic Fever Syndromes (Cryopyrin-Associated Periodic Syndromes (CAPS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), Familial Mediterranean Fever (FMF)). (Initial) Diagnosis of one of the autoinflammatory Periodic Fever Syndromes: CAPS (including Familial Cold Auto-inflammatory Syndrome (FCAS) and/or Muckle-Wells Syndrome (MWS)), TRAPS, HIDS/MKD, or FMF, AND The medication will not be used in combination with another biologic agent. Systemic juvenile idiopathic arthritis (sJIA) (Initial): Diagnosis of active sJIA AND The medication will not be used in combination with another biologic. Still's Disease (Initial): Diagnosis of Still's Disease, including Adult-Onset Still's Disease (AOSD) AND The medication will not be used in combination with another biologic.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Periodic Fever Syndromes (CAPS, TRAPS, HIDS/MKD, FMF) (initial): Prescribed by or in consultation with an immunologist, allergist, dermatologist, rheumatologist, neurologist or other medical specialist. SJIA, Still's Disease (initial): Prescribed by or in consultation with a rheumatologist.
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months
<b>Other Criteria</b>	SJIA, Still's Disease (initial): Trial and failure, contraindication, or intolerance to non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), methotrexate, or corticosteroids (e.g., methylprednisolone, prednisone). Periodic Fever Syndrome (CAPS, TRAPS, HIDS/MKD, FMF), SJIA, Still's Disease (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Ilumya (s)

## Products Affected

- ILUMYA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Plaque Psoriasis (initial): Prescribed by or in consultation with a dermatologist
<b>Coverage Duration</b>	Initial, reauth: 12 months
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Imbruvica (s)

## Products Affected

- IMBRUVICA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	All Uses: 12 months
<b>Other Criteria</b>	All Uses: Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Inbrija (s)

## Products Affected

- INBRIJA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Parkinson's disease (PD) (initial): Diagnosis of PD. Patient is experiencing intermittent OFF episodes. Used in combination with carbidopa/levodopa. Trial and failure, contraindication or intolerance to two of the following: MAO-B inhibitor (e.g., rasagiline, selegiline), dopamine agonist (e.g., pramipexole, ropinirole), or COMT Inhibitor (e.g., entacapone).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PD (initial): Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	PD (initial, reauth): 12 months
<b>Other Criteria</b>	PD (reauth): Documentation of positive clinical response to therapy. Used in combination with carbidopa/levodopa.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# INCRELEX (s)

## Products Affected

- INCRELEX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Initial: Prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	Initial, reauth: 12 months
<b>Other Criteria</b>	(Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Inflectra (s)

## Products Affected

- INFLECTRA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Crohn's Disease (CD) and Fistulizing Crohn's Disease (FCD) (initial): Dx of moderately to severely active CD or FCD. Ulcerative colitis (UC) (initial): Dx of moderately to severely active UC. Rheumatoid arthritis (RA) (initial): Diagnosis (Dx) of moderately to severely active RA. Ankylosing spondylitis (AS) (initial): Dx of active AS. Psoriatic arthritis (PsA) (initial): Dx of active PsA. Plaque psoriasis (initial): Dx of chronic severe (ie, extensive and/or disabling) plaque psoriasis. Sarcoidosis (initial): Dx of sarcoidosis. CD, FCD (initial): Trial and failure, contraindication or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine (Purinethol), azathioprine (Imuran), corticosteroids (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex, Trexall). UC (initial): TF/C/I to one of the following conventional therapies: corticosteroids, aminosalicylate [eg, mesalamine (Asacol/Pentasa/Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine/Sulfazine)], azathioprine (Imuran), 6-mercaptopurine (Purinethol). RA (initial): Receiving concurrent therapy with methotrexate (Rheumatrex/Trexall), or TF/C/I to methotrexate. AS (initial): TF/C/I to two or more NSAIDs (e.g., diclofenac, ibuprofen, meloxicam, naproxen). Sarcoidosis (initial): TF/C/I to one of the following: corticosteroid (eg, prednisone) OR immunosuppressant [eg, methotrexate (Rheumatrex/Trexall), cyclophosphamide, or azathioprine (Imuran)]. All indications (initial): One of the following: 1) Trial and failure or intolerance to Remicade or 2) For continuation of prior Inflectra therapy.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	<p>RA, AS: Prescribed or recommended by a rheumatologist. PsA: Prescribed or recommended by rheumatologist or dermatologist. Crohn's Disease, Fistulizing Crohn's Disease, UC: Prescribed or recommended by a gastroenterologist. Plaque Psoriasis: Prescribed or recommended by a dermatologist. Sarcoidosis (initial): Prescribed by or in consultation with a pulmonologist, dermatologist, or ophthalmologist.</p>
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months
<b>Other Criteria</b>	<p>Reauth (CD, UC, AS, PsA, RA, Sarcoidosis): Documentation of positive clinical response to therapy. Reauth (plaque psoriasis): Documentation of positive clinical response to therapy as evidenced by one of the following:</p>

Formulary ID 22333 Version 17 Effective Date: 09/01/2022

Last Updated: August 2022

PA Criteria	Criteria Details
	reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Ingrezza (s)

## Products Affected

- INGREZZA ORAL CAPSULE 40 MG, 60 MG, 80 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Tardive Dyskinesia (initial): Diagnosis of moderate to severe tardive dyskinesia. One of the following: a) patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication OR b) patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Initial: Prescribed by or in consultation with a neurologist or psychiatrist.
<b>Coverage Duration</b>	Initial: 3 months. Reauth: 12 months
<b>Other Criteria</b>	Tardive Dyskinesia (reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Inlyta (s)

---

**Products Affected**

- INLYTA

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

# Inqovi (s)

---

## Products Affected

- INQOVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Myelodysplastic syndrome (MDS): Diagnosis of myelodysplastic syndrome. Patient has ONE of the following French- American-British subtypes: a) refractory anemia, b) refractory anemia with ringed sideroblasts, c) refractory anemia with excess blasts, or d) chronic myelomonocytic leukemia (CMML).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Inrebic (s)

---

**Products Affected**

- INREBIC

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

# Intron A (s)

## Products Affected

- INTRON A
- INTRON A INJECTION SOLUTION  
10000000 UNIT/ML, 6000000 UNIT/ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	RCC: Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	HepB, HepC: 48 wks. Condylomata acuminata (genital or perianal): 6 wks. Other: 12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Iressa (s)

## Products Affected

- IRESSA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ISOTRETINOIN (s)

## Products Affected

- *accutane*
- *amnesteem*
- *claravis*
- *isotretinoin oral capsule 10 mg, 20 mg, 30 mg, 40 mg*
- *myorisan*
- *zenatane*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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)].
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Acne (initial): 5 months. Acne (reauth): Retreatment - 5 months, Dose Titration - 1 month
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Istodax (s)

## Products Affected

- ROMIDEPSIN INTRAVENOUS SOLUTION

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	CTCL, PTCL: Prescribed by or in consultation with an oncologist/hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Isturisa (s)

## Products Affected

- ISTURISA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Cushing's disease (initial): Prescribed by or in consultation with an endocrinologist.
<b>Coverage Duration</b>	Cushing's disease (initial, reauth): 12 months
<b>Other Criteria</b>	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).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Ivermectin (s)

## Products Affected

- *ivermectin oral*

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

# IVIG (s)

## Products Affected

- ASCENIV
- BIVIGAM
- *carimune nf intravenous solution reconstituted 12 gm, 6 gm*
- FLEBOGAMMA DIF
- *gammagard injection solution 1 gm/10ml, 10 gm/100ml, 20 gm/200ml, 5 gm/50ml*
- GAMMAGARD INJECTION SOLUTION 2.5 GM/25ML, 30 GM/300ML
- GAMMAGARD S/D LESS IGA
- GAMMAKED
- GAMMAPLEX
- GAMUNEX-C
- OCTAGAM INTRAVENOUS SOLUTION 1 GM/20ML, 10 GM/100ML, 10 GM/200ML, 2 GM/20ML, 2.5 GM/50ML, 20 GM/200ML, 25 GM/500ML, 5 GM/100ML, 5 GM/50ML
- PANZYGA
- PRIVIGEN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	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). Privigen only: Hyperprolinemia. Octagam only: Allergy to corn. Gammaplex only: Hereditary intolerance to fructose. Infants for whom sucrose or fructose tolerance has not been established.
<b>Required Medical Information</b>	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 400 mg/dL OR Patient has active bleeding or a platelet count less than 10 x 10 <sup>9</sup> /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/mm <sup>3</sup> . Continued in Other Criteria Section.



PA Criteria	Criteria Details
<b>Age Restrictions</b>	HIV (initial): patient is less than or equal to 12 years of age.
<b>Prescriber Restrictions</b>	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).
<b>Coverage Duration</b>	4 months: Solid organ transplant. 12 months: all other diagnoses.
<b>Other Criteria</b>	<p>[D] Neuromuscular Autoimmune Disorders 1) Chronic inflammatory demyelinating polyneuropathy. 2) Guillain-Barré syndrome. 3) Inflammatory myopathies (dermatomyositis or polymyositis) AND 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, cyclosporine, 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).</p> <p>[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 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 patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid 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 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.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# JAKAFI (s)

## Products Affected

- JAKAFI ORAL TABLET 10 MG, 15 MG, 20 MG, 25 MG, 5 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	12 months.
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# JUXTAPID (s)

## Products Affected

- JUXTAPID ORAL CAPSULE 10 MG, 20 MG, 30 MG, 40 MG, 5 MG, 60 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 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. Patient is receiving 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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	HoFH (initial, reauth): Prescribed by a cardiologist, endocrinologist, or lipid specialist.
<b>Coverage Duration</b>	HoFH (initial): 6 months. (reauth): 12 months
<b>Other Criteria</b>	HoFH (reauthorization): Patient continues to receive other lipid-lowering therapy. Submission of medical records (eg, chart notes, laboratory values) documenting LDL-C reduction while on therapy. Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Kalydeco (s)

## Products Affected

- KALYDECO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	CF (Initial): 4 months of age or older
<b>Prescriber Restrictions</b>	CF (initial): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist
<b>Coverage Duration</b>	CF (initial, reauth): 12 months
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Kanjinti (s)

## Products Affected

- KANJINTI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses: Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Kanuma (s)

---

## Products Affected

- KANUMA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a specialist experienced in the treatment of inborn errors of metabolism, gastroenterologist, or lipidologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Kesimpta (s)

## Products Affected

- KESIMPTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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]).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	MS (Initial, Reauth): Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	MS (Initial, Reauth): 12 months
<b>Other Criteria</b>	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]).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Kisqali (s)

## Products Affected

- KISQALI ORAL TABLET THERAPY  
PACK 200 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# KISQALI-FEMARA PACK (s)

## Products Affected

- KISQALI FEMARA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# KORLYM (s)

## Products Affected

- KORLYM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Initial: Prescribed by or in consultation with an endocrinologist.
<b>Coverage Duration</b>	Initial, reauth: 6 months
<b>Other Criteria</b>	Reauth: Documentation of one of the following: patient has improved glucose tolerance while on therapy or patient has stable glucose tolerance while on therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Koselugo (s)

## Products Affected

- KOSELUGO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with one of the following: oncologist or neurologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Kuvan (s)

## Products Affected

- *sapropterin dihydrochloride*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	PKU (Init): 2 months (Reauth): 12 months
<b>Other Criteria</b>	PKU (reauth): Documentation of a positive clinical response to therapy. Patient will continue to have blood Phe levels measured periodically during therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Kynmobi (s)

## Products Affected

- KYNMOBI
- KYNMOBI TITRATION KIT

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

# Lemtrada (s)

## Products Affected

- LEMTRADA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	MS: Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	MS: 12 months.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Lenvima (s)

## Products Affected

- LENVIMA ORAL CAPSULE THERAPY                      MG, 2 X 10 MG, 2 X 10 MG & 4 MG, 2 X 4  
PACK 10 & 4 MG, 10 MG, 10 MG & 2 X 4                      MG, 3 X 4 MG, 4 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# LETAIRIS (s)

## Products Affected

- *ambrisentan*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
<b>Coverage Duration</b>	PAH (Initial): 6 months. PAH (Reauth): 12 months
<b>Other Criteria</b>	PAH (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# LIDOCAINE TOPICAL (s)

## Products Affected

- *glydo*
- *lidocaine external ointment 5 %*
- *lidocaine hcl urethral/mucosal external prefilled syringe*
- *lidocaine-prilocaine external cream*
- *premium lidocaine*

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

# Lidoderm (s)

---

## Products Affected

- *lidocaine external patch 5 %*

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

# Livmarli (s)

## Products Affected

- LIVMARLI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	ALGS (initial): Patient is 1 year of age or older.
<b>Prescriber Restrictions</b>	ALGS (initial): Prescribed by or in consultation with a hepatologist.
<b>Coverage Duration</b>	ALGS (initial, reauth): 12 months.
<b>Other Criteria</b>	ALGS (reauth): Documentation of positive clinical response to therapy (e.g., reduced bile acids, reduced pruritus severity score).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# LONSURF (s)

## Products Affected

- LONSURF

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 KRAS wild-type tumors and trial and failure, contraindication, or intolerance to at least one anti-EGFR therapy (e.g., Vectibix, Erbitux) OR Patient has KRAS 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: fluoropyrimidine-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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Lorbrena (s)

## Products Affected

- LORBRENA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# LOTRONEX (s)

## Products Affected

- *alosetron hcl*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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].
<b>Age Restrictions</b>	Initial: 18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	IBS (initial): 12 weeks. IBS (reauth): 6 mo.
<b>Other Criteria</b>	IBS (reauthorization): Symptoms of IBS continue to persist, AND documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Lumakras (s)

## Products Affected

- LUMAKRAS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# LUMIZYME (s)

---

## Products Affected

- LUMIZYME

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



# LUPRON (s)

## Products Affected

- *leuprolide acetate injection*

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

# LUPRON DEPOT (s)

## Products Affected

- LUPRON DEPOT (1-MONTH)
- LUPRON DEPOT (3-MONTH)
- LUPRON DEPOT (4-MONTH)  
INTRAMUSCULAR KIT 30MG
- LUPRON DEPOT (6-MONTH)  
INTRAMUSCULAR KIT 45MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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) (initial): 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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Prostate CA: 12 mo. Endomet (init, reauth):6mo. UL (anemia):3 mo (fibroids):4 mo
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# LUPRON DEPOT PED (s)

## Products Affected

- LUPRON DEPOT-PED (1-MONTH)
- LUPRON DEPOT-PED (3-MONTH)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	CPP (initial, reauth): Prescribed by or in consultation with a pediatric endocrinologist.
<b>Coverage Duration</b>	CPP (init, reauth): 12 months
<b>Other Criteria</b>	CPP (reauthorization): LH levels have been suppressed to pre-pubertal levels.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Lynparza tablet (s)

## Products Affected

- LYNPARZA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Ovarian cancer, advanced disease with known or suspected BRCA mutation with 3 or more prior lines of chemotherapy: Diagnosis of advanced ovarian cancer. Presence of deleterious or suspected deleterious germline BRCA-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). Trial and failure, contraindication, or intolerance to three or more prior lines of chemotherapy (e.g., paclitaxel with cisplatin). 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 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.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	12 months

Formulary ID 22333 Version 17 Effective Date: 09/01/2022

Last Updated: August 2022

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 epithelial ovarian cancer, advanced fallopian tube cancer, or 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 homologous recombination repair (HRR) gene 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). Disease has progressed following prior treatment with one of the following: a) enzalutamide (Xtandi) or b) abiraterone (e.g., Zytiga, Yonsa). All indications: Approve for continuation of prior therapy.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# MAKENA (s)

## Products Affected

- MAKENA SUBCUTANEOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Preterm birth prophylaxis: Prescribed by or in consultation with a specialist in obstetrics and gynecology
<b>Coverage Duration</b>	Preterm birth prophylaxis: 21 weeks
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# MARINOL (s)

## Products Affected

- *dronabinol*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	CINV: 6 months. AIDS anorexia: 3 months.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Mavyret (s)

## Products Affected

- MAVYRET ORAL PACKET
- MAVYRET ORAL TABLET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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].
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	8 to 16 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# MAYZENT (s)

## Products Affected

- MAYZENT ORAL TABLET 0.25 MG, 1 MG, 2 MG
- MAYZENT STARTER PACK ORAL TABLET THERAPY PACK 0.25 MG, 12 X 0.25 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	MS (initial, reauth): Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	MS (initial, reauth): 12 months
<b>Other Criteria</b>	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Mekinist (s)

## Products Affected

- MEKINIST

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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).</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Mektovi (s)

## Products Affected

- MEKTOVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Migranal (s)

## Products Affected

- *dihydroergotamine mesylate nasal*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Initial, Reauth: Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.
<b>Coverage Duration</b>	Initial: 3 months. Reauth: 12 months.
<b>Other Criteria</b>	Reauth: Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Monjuvi (s)

## Products Affected

- MONJUVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	DLBCL: Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## MS INTERFERONS (non-preferred) (s)

### Products Affected

- REBIF
- REBIF REBIDOSE
- REBIF REBIDOSE TITRATION PACK
- REBIF TITRATION PACK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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: Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Extavia (interferon beta-1b), Plegridy (peginterferon beta-1a), or 2) for continuation of prior therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	MS (initial, reauth): Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	MS (initial, reauth): 12 months
<b>Other Criteria</b>	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## MS INTERFERONS (preferred) (s)

### Products Affected

- AVONEX PEN
- AVONEX PREFILLED
- AVONEX VIAL INTRAMUSCULAR KIT  
INTRAMUSCULAR KIT 30 MCG
- BETASERON
- EXTAVIA
- PLEGRIDY
- PLEGRIDY STARTER PACK  
SUBCUTANEOUS SOLUTION PEN-  
INJECTOR
- PLEGRIDY STARTER PACK  
SUBCUTANEOUS SOLUTION  
PREFILLED SYRINGE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	MS (initial, reauth): Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	MS (initial, reauth): 12 months
<b>Other Criteria</b>	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Mvasi (s)

## Products Affected

- MVASI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Non-Small Cell Lung Cancer: Excluded if squamous cell histology.
<b>Required Medical Information</b>	<p>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.</p> <p>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.</p> <p>Renal Cell Cancer: Diagnosis of metastatic renal cell cancer. Used in combination with interferon-alpha.</p> <p>Cervical Cancer: Diagnosis of carcinoma of the cervix. Disease is persistent, recurrent, or metastatic. Used in combination with one of the following: a) paclitaxel and cisplatin or b) paclitaxel and topotecan.</p> <p>Glioblastoma: Diagnosis of recurrent glioblastoma.</p> <p>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 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, and c) used in combination with one of the following: i) carboplatin and paclitaxel or ii) carboplatin and gemcitabine.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Hepatocellular Carcinoma (HCC): Diagnosis of hepatocellular carcinoma. Disease is unresectable or metastatic. Used in combination with

Formulary ID 22333 Version 17 Effective Date: 09/01/2022

Last Updated: August 2022



PA Criteria	Criteria Details
	Tecentriq (atezolizumab). Patient has not received prior systemic therapy. Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Myalept (s)

## Products Affected

- MYALEPT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Initial: Prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	Initial, reauth: 12 months
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Mycapssa (s)

## Products Affected

- MYCAPSSA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Acromegaly (initial): Diagnosis of acromegaly. One of the following: 1) Inadequate response to surgical resection and/or pituitary irradiation, or 2) Patient is not a candidate for surgical resection or pituitary irradiation. Patient has responded to and tolerated treatment with octreotide or lanreotide.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Acromegaly (initial, reauth): 12 months
<b>Other Criteria</b>	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)
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Myfembree (s)

## Products Affected

- MYFEMBREE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial: Diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids). Patient is premenopausal. One of the following: 1) History of inadequate control of bleeding following a trial of at least 3 months, or history of intolerance or contraindication to one of the following: combination (estrogen/progestin) contraceptive, progestins, or tranexamic acid or 2) Patient has had a previous interventional therapy to reduce bleeding. Treatment duration of therapy has not exceeded a total of 24 months.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Reauth: Patient has improvement in bleeding associated with uterine leiomyomas (fibroids) (e.g., significant/sustained reduction in menstrual blood loss per cycle, improved quality of life, etc.). Treatment duration of therapy has not exceeded a total of 24 months.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Naglazyme (s)

---

**Products Affected**

- NAGLAZYME

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

# NATPARA (s)

## Products Affected

- NATPARA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Hypocalcemia (initial): Prescribed by or in consultation with an endocrinologist.
<b>Coverage Duration</b>	Initial: 6 months. Reauth: 12 months
<b>Other Criteria</b>	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 in oral calcium intake, OR C) Patient has experienced a 50% or greater reduction in oral vitamin D intake.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Nerlynx (s)

## Products Affected

- NERLYNX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Neulasta (s)

## Products Affected

- NEULASTA
- NEULASTA ONPRO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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).</p> <p>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.</p> <p>Diagnosis of FN. Patient is at high risk for infection-associated complications.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses: Prescribed by or in consultation with a hematologist/oncologist
<b>Coverage Duration</b>	ARS: 1 mo. FN (prophylaxis, treatment): 3 mo or duration of tx.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Nexavar (s)

## Products Affected

- NEXAVAR
- *sorafenib tosylate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Nexletol (s)

## Products Affected

- NEXLETOL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial: One of the following diagnoses: A) Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following: (1) Both of the following: a) Untreated/pre-treatment LDL-C greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age), AND b) One of the following: i) Family history (hx) of myocardial infarction in 1st-degree relative less than 60 years of age, ii) Family hx of myocardial infarction in 2nd-degree relative less than 50 years of age, iii) Family hx of LDL-C greater than 190 mg/dL in 1st- or 2nd-degree relative, iv) Family hx of FH in 1st- or 2nd-degree relative, or v) Family hx of tendinous xanthomas and/or arcus cornealis in 1st- or 2nd-degree relative, or (2) Both of the following: a) Untreated/pre-treatment LDL-C greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age), AND b) One of the following: i) Functional mutation in the LDL receptor, ApoB, or PCSK9 gene, ii) Tendinous xanthomata, or iii) Arcus cornealis before age 45 OR B) Atherosclerotic cardiovascular disease (ASCVD) as confirmed by acute coronary syndromes, hx of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization (eg, percutaneous coronary intervention [PCI] or coronary artery bypass graft [CABG] surgery), stroke, transient ischemic attack, peripheral arterial disease presumed to be of atherosclerotic origin, or clinically significant coronary heart disease diagnosed by invasive or noninvasive testing (e.g., coronary angiography, stress test using treadmill, stress echocardiography or nuclear imaging). One of the following LDL-C values while on max tolerated statin tx within the last 120 days: (1) LDL-C greater than or equal to 70 mg/dL with ASCVD or (2) LDL-C greater than or equal to 100 mg/dL without ASCVD.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 6 months. Reauth: 12 months
<b>Other Criteria</b>	Initial, cont: One of the following: (1) Pt has been receiving at least 12 weeks of one high-intensity statin (HIS) therapy (tx) [ie, atorvastatin 40-80 mg, rosuvastatin 20-40 mg] and will continue to receive a HIS at max tolerated dose, OR (2) Both of the following: a) Pt is unable to tolerate

Formulary ID 22333 Version 17 Effective Date: 09/01/2022

Last Updated: August 2022

PA Criteria	Criteria Details
	<p>HIS as evidenced by one of the following intolerable and persistent (ie, more than 2 wks) symptoms: myalgia (muscle symptoms w/o CK elevations) or myositis (muscle symptoms w/ CK elevations less than 10 times ULN) AND b) Pt has been receiving at least 12 weeks of one moderate-intensity statin (MIS) [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 20-40 mg, pravastatin 40-80 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily, or Livalo (pitavastatin) 2-4 mg] or one low-intensity statin (LIS) [i.e., simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, Livalo (pitavastatin) 1 mg] tx and will continue to receive a MIS or LIS at max tolerated dose, OR (3) Pt is unable to tolerate low-, moderate-, or high-intensity statins as evidenced by one of the following intolerable and persistent (ie, more than 2 weeks) symptoms: myalgia (muscle symptoms without CK elevations) or myositis (muscle symptoms with CK elevations less than 10 times ULN), OR (4) Pt has a labeled contraindication to all statins, OR (5) Pt has experienced rhabdomyolysis or muscle symptoms w/ statin tx with CK elevations greater than 10 times ULN. AND Pt has been receiving at least 12 weeks of generic ezetimibe tx as adjunct to max tolerated statin tx or pt has a history of contraindication or intolerance to ezetimibe. Reauth: Documentation of positive clinical response to therapy (eg reduction in LDL-C levels). Pt continues to receive other lipid-lowering tx (eg statins, ezetimibe) at the max tolerated dose or pt has a documented inability to take other lipid-lowering therapy (eg statins, ezetimibe).</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Nexlizet (s)

## Products Affected

- NEXLIZET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial: One of the following diagnoses: A) Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following: (1) Both of the following: a) Untreated/pre-treatment LDL-C greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age), AND b) One of the following: i) Family history (hx) of myocardial infarction in 1st-degree relative less than 60 years of age, ii) Family hx of myocardial infarction in 2nd-degree relative less than 50 years of age, iii) Family hx of LDL-C greater than 190 mg/dL in 1st- or 2nd-degree relative, iv) Family hx of FH in 1st- or 2nd-degree relative, or v) Family hx of tendinous xanthomas and/or arcus cornealis in 1st- or 2nd-degree relative, or (2) Both of the following: a) Untreated/pre-treatment LDL-C greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age), AND b) One of the following: i) Functional mutation in the LDL receptor, ApoB, or PCSK9 gene, ii) Tendinous xanthomata, or iii) Arcus cornealis before age 45 OR B) Atherosclerotic cardiovascular disease (ASCVD) as confirmed by acute coronary syndromes, hx of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization (eg, percutaneous coronary intervention [PCI] or coronary artery bypass graft [CABG] surgery), stroke, transient ischemic attack, peripheral arterial disease presumed to be of atherosclerotic origin, or clinically significant coronary heart disease diagnosed by invasive or noninvasive testing (e.g., coronary angiography, stress test using treadmill, stress echocardiography or nuclear imaging). One of the following LDL-C values while on max tolerated statin tx within the last 120 days: (1) LDL-C greater than or equal to 70 mg/dL with ASCVD or (2) LDL-C greater than or equal to 100 mg/dL without ASCVD.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 6 months. Reauth: 12 months
<b>Other Criteria</b>	Initial, cont: One of the following: (1) Pt has been receiving at least 12 weeks of one high-intensity statin (HIS) therapy (tx) [ie, atorvastatin 40-80 mg, rosuvastatin 20-40 mg] and will continue to receive a HIS at max tolerated dose, OR (2) Both of the following: a) Pt is unable to tolerate

Formulary ID 22333 Version 17 Effective Date: 09/01/2022

Last Updated: August 2022

PA Criteria	Criteria Details
	<p>HIS as evidenced by one of the following intolerable and persistent (ie, more than 2 wks) symptoms: myalgia (muscle symptoms w/o CK elevations) or myositis (muscle symptoms w/ CK elevations less than 10 times ULN) AND b) Pt has been receiving at least 12 weeks of one moderate-intensity statin (MIS) [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 20-40 mg, pravastatin 40-80 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily, or Livalo (pitavastatin) 2-4 mg] or one low-intensity statin (LIS) [i.e., simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, Livalo (pitavastatin) 1 mg] tx and will continue to receive a MIS or LIS at max tolerated dose, OR (3) Pt is unable to tolerate low-, moderate-, or high-intensity statins as evidenced by one of the following intolerable and persistent (ie, more than 2 weeks) symptoms: myalgia (muscle symptoms without CK elevations) or myositis (muscle symptoms with CK elevations less than 10 times ULN), OR (4) Pt has a labeled contraindication to all statins, OR (5) Pt has experienced rhabdomyolysis or muscle symptoms w/ statin tx with CK elevations greater than 10 times ULN. AND Pt has been receiving at least 12 weeks of generic ezetimibe tx as adjunct to max tolerated statin tx or pt has a history of contraindication or intolerance to ezetimibe. Reauth: Documentation of positive clinical response to therapy (eg reduction in LDL-C levels). Pt continues to receive other lipid-lowering tx (eg statins, ezetimibe) at the max tolerated dose or pt has a documented inability to take other lipid-lowering therapy (eg statins, ezetimibe).</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# NINLARO (s)

## Products Affected

- NINLARO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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)].
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Northera (s)

## Products Affected

- *droxidopa*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	NOH (init): Prescribed by or in consultation with a cardiologist, neurologist, or nephrologist
<b>Coverage Duration</b>	NOH (init): 1 month (reauth): 12 months
<b>Other Criteria</b>	NOH (reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Nubeqa (s)

## Products Affected

- NUBEQA

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



# NUCALA (s)

## Products Affected

- NUCALA SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- NUCALA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 100 MG/ML, 40 MG/0.4ML
- NUCALA SUBCUTANEOUS SOLUTION RECONSTITUTED

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Asthma (init): Diagnosis of severe asthma. Asthma is an eosinophilic phenotype as defined by one of the following: baseline (pre-treatment) peripheral blood eosinophil level is greater than or equal to 150 cells/microliter or peripheral blood eosinophil levels were greater than or equal to 300 cells/microliter within the past 12 months. Patient has had at least one or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months or Patient has had any prior intubation for an asthma exacerbation or Patient has had a 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)]. Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) (init): Diagnosis of CRSwNP. Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone). Used in combination with another agent for CRSwNP. Eosinophilic Granulomatosis with Polyangiitis (EGPA) (init): Diagnosis of EGPA. Patient's disease has relapsed or is refractory to standard of care therapy (i.e., corticosteroid treatment with or without immunosuppressive therapy). Patient is currently receiving corticosteroid therapy (e.g., prednisolone, prednisone).</p>
<b>Age Restrictions</b>	Asthma (init): Age greater than or equal to 6 years
<b>Prescriber Restrictions</b>	Asthma (init, reauth): Prescribed by or in consultation with a pulmonologist or allergist/immunologist. CRSwNP (init, reauth): Prescribed by or in consultation with an allergist/immunologist, otolaryngologist, or pulmonologist. EGPA (init): Prescribed by or in

PA Criteria	Criteria Details
	consultation with a pulmonologist, rheumatologist or allergist/immunologist. HES (init): Prescribed by or in consultation with an allergist/immunologist or hematologist.
<b>Coverage Duration</b>	Asthma (init): 6 mo, Asthma (reauth): 12 months. CRSwNP, EGPA, HES (init, reauth): 12 months
<b>Other Criteria</b>	<p>Hypereosinophilic Syndrome (HES) (init): Diagnosis of HES. Patient has been diagnosed for at least 6 months. Verification that other non-hematologic secondary causes have been ruled out (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy). Patient is FIP1L1-PDGFR<math>\alpha</math>-negative. Patient has uncontrolled HES defined as both of the following: a) History of 2 or more flares within the past 12 months AND b) Pre-treatment blood eosinophil count greater than or equal to 1000 cells/microliter. Trial and failure, contraindication, or intolerance to corticosteroid therapy (e.g., prednisone) or cytotoxic/immunosuppressive therapy (e.g., hydroxyurea, cyclosporine, imatinib). Asthma (reauth): Documentation of positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second (FEV<sub>1</sub>), 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. CRSwNP (reauth): Documentation of positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS, 0-8 scale], improvement in nasal obstruction symptoms via visual analog scale [VAS, 0-10 scale]). Used in combination with another agent for CRSwNP. EGPA (reauth): Documentation of positive clinical response to therapy (e.g., increase in remission time). HES (reauth): Documentation of positive clinical response to therapy (e.g., reduction in flares, decreased blood eosinophil count, reduction in corticosteroid dose).</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Nuedexta (s)

## Products Affected

- NUEDEXTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PBA (initial): Prescribed by or in consultation with one of the following specialists: neurologist, psychiatrist.
<b>Coverage Duration</b>	PBA (initial/reauth): 12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Nuplazid (s)

## Products Affected

- NUPLAZID

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# NUVIGIL (s)

## Products Affected

- *armodafinil oral tablet 150 mg, 200 mg, 250 mg, 50 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 confirming that a sleep study is not feasible).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	OSA, SWD: Initial, Reauth: 6 mo. Narcolepsy: Initial, Reauth: 12 mo
<b>Other Criteria</b>	OSA, Narcolepsy (Reauth): Documentation of positive clinical response to armodafinil therapy. SWD (Reauth): Documentation of positive clinical response to armodafinil therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# OCREVUS (s)

## Products Affected

- OCREVUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Relapsing forms of multiple sclerosis (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 lesion). One of the following: 1) Failure after a trial of at least 4 weeks, contraindication, or intolerance to one of the following disease-modifying therapies for MS: A) Aubagio (teriflunomide), B) Kesimpta (ofatumumab), C) Lemtrada (alemtuzumab), D) Mavenclad (cladribine), E) Plegridy (peginterferon beta-1a), F) Tysabri (natalizumab), G) Any one of the interferon beta-1a injections (eg, Avonex), H) Any one of the interferon beta-1b injections (eg, Betaseron, Extavia), I) Any one of the oral fumarates (eg, brand Tecfidera, generic dimethyl fumarate), J) Any one of the glatiramer acetates (eg, Copaxone, Glatopa, generic glatiramer acetate), K) Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (eg, Gilenya [fingolimod], Mayzent [siponimod], Zeposia [ozanimod]), OR 2) For continuation of prior therapy. Primary progressive MS (initial): Diagnosis of primary progressive multiple sclerosis (PPMS). All indications (initial, reauth): 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], ofatumumab [Arzerra, Kesimpta]). Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses (initial, reauth): Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months
<b>Other Criteria</b>	All indications (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Odomzo (s)

## Products Affected

- ODOMZO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or dermatologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Ofev (s)

## Products Affected

- OFEV

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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. 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 fibrosis seen on imaging.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	IPF, SSc-ILD, Chronic Fibrosing ILDs with a Progressive Phenotype (initial): Prescribed by or in consultation with a pulmonologist
<b>Coverage Duration</b>	Initial, reauth: 12 months
<b>Other Criteria</b>	IPF, SSc-ILD, Chronic Fibrosing ILDs with a Progressive Phenotype (reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.

Formulary ID 22333 Version 17 Effective Date: 09/01/2022

Last Updated: August 2022



PA Criteria	Criteria Details
Off Label Uses	

# Onureg (s)

## Products Affected

- ONUREG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# OPSUMIT (s)

## Products Affected

- OPSUMIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
<b>Coverage Duration</b>	PAH: Initial: 6 months. Reauth: 12 months.
<b>Other Criteria</b>	PAH (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Opzelura (s)

## Products Affected

- OPZELURA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial: Diagnosis of mild to moderate atopic dermatitis. One of the following: a) Greater than or equal to 3% body surface area (BSA) involvement, or b) Involvement of sensitive body areas (e.g., face, hands, feet, scalp, groin). Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least two of the following: a) Medium or higher potency topical corticosteroid, b) Elidel (pimecrolimus) cream, c) Tacrolimus ointment, or d) Eucrisa (crisaborole) ointment. Patient is not receiving Opzelura in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine). Opzelura will only be used for short-term and/or non-continuous chronic treatment.
<b>Age Restrictions</b>	Initial: Patient is 12 years of age or older.
<b>Prescriber Restrictions</b>	Initial: Prescribed by or in consultation with a dermatologist or allergist/immunologist.
<b>Coverage Duration</b>	Initial: 12 weeks. Reauth: 6 months.
<b>Other Criteria</b>	Reauth: Documentation of a positive clinical response to therapy as evidenced by at least one of the following: a) Reduction in BSA involvement from baseline, b) Reduction in pruritus severity from baseline, or c) Improvement in quality of life from baseline. Patient is not receiving Opzelura in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine). Opzelura will only be used for short-term and/or non-continuous chronic treatment.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ORENCIA IV (s)

## Products Affected

- ORENCIA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	RA, JIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist.
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months
<b>Other Criteria</b>	All indications (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ORENCIA SC (s)

## Products Affected

- ORENCIA
- ORENCIA CLICKJECT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib/ER), OR b) for continuation of prior therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	RA, JIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist.
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months
<b>Other Criteria</b>	All indications (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Orenitram (s)

## Products Affected

- ORENITRAM ORAL TABLET  
EXTENDED RELEASE 0.25 MG, 1 MG,  
2.5 MG, 5 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
<b>Coverage Duration</b>	PAH: Initial: 6 months. Reauth: 12 months.
<b>Other Criteria</b>	PAH (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Orgovyx (s)

## Products Affected

- ORGOVYX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an urologist or oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Orilissa (s)

## Products Affected

- ORILISSA ORAL TABLET 150 MG, 200 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Endometriosis (EM) (initial - 150 mg): Diagnosis of moderate to severe pain associated with EM. One of the following: 1) History of inadequate pain control response following a trial of at least 3 months, or history of intolerance or contraindication to one of the following: danazol, combination (estrogen/progesterone) oral contraceptive, or progestins, or 2) Patient has had surgical ablation to prevent recurrence. EM (200 mg): Diagnosis of moderate to severe pain associated with EM. One of the following: 1) History of inadequate pain control response following a trial of at least 3 months, or history of intolerance or contraindication to one of the following: danazol, combination (estrogen/progesterone) oral contraceptive, or progestins, or 2) Patient has had surgical ablation to prevent recurrence.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	EM (init, reauth-150mg): 6 mo. EM (200mg): 6 mo.
<b>Other Criteria</b>	EM (reauthorization - 150 mg): Patient has improvement in pain associated with endometriosis (e.g., improvement in dysmenorrhea and nonmenstrual pelvic pain). Treatment duration has not exceeded a total of 24 months.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ORKAMBI (s)

## Products Affected

- ORKAMBI ORAL TABLET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	CF (Initial): Patient is 6 years of age or older
<b>Prescriber Restrictions</b>	CF (initial): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist
<b>Coverage Duration</b>	CF (initial, reauth): 12 months
<b>Other Criteria</b>	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).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Orkambi granules (s)

## Products Affected

- ORKAMBI ORAL PACKET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 2 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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	CF (Initial): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist
<b>Coverage Duration</b>	CF (initial, reauth): 12 months
<b>Other Criteria</b>	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 2 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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# OSPHENA (s)

## Products Affected

- OSPHENA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	All uses (Initial, reauth): 12 months
<b>Other Criteria</b>	Dyspareunia, Vaginal dryness (reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Oxandrin (s)

## Products Affected

- *oxandrolone oral tablet 10 mg, 2.5 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	bone pain: 1 month. Others (initial, reauth): 3 months
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Oxbryta (s)

## Products Affected

- OXBRYTA ORAL TABLET SOLUBLE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	Initial, Reauth: 12 months.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Oxlumo (s)

## Products Affected

- OXLUMO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Primary Hyperoxaluria Type 1 (PH1) (initial): Diagnosis of PH1. Diagnosis has been confirmed by both of the following: 1) One of the following: a) Elevated urinary oxalate excretion or b) Elevated plasma oxalate concentration, AND 2) Genetic testing demonstrating a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene. Patient has not received a liver transplant.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PH1 (initial, reauth): Prescribed by or in consultation with one of the following: nephrologist, urologist, geneticist, or specialist with expertise in the treatment of PH1.
<b>Coverage Duration</b>	PH1 (initial, reauth): 12 months.
<b>Other Criteria</b>	PH1 (reauth): Documentation of positive clinical response to therapy (e.g., decreased urinary oxalate excretion, decreased plasma oxalate concentration). Patient has not received a liver transplant.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Palforzia (s)

## Products Affected

- PALFORZIA ORAL PACKET 300 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Initial: Excluded if any of the following: 1) history of eosinophilic esophagitis (EoE) or eosinophilic gastrointestinal disease, OR 2) history of severe or life-threatening episode(s) of anaphylaxis or anaphylactic shock within the past 2 months, OR 3) severe or poorly controlled asthma
<b>Required Medical Information</b>	Initial: Diagnosis and clinical history of peanut allergy as documented by both of the following: a) a serum peanut-specific IgE level of greater than or equal to 0.35 kUA/L, AND b) a mean wheal diameter that is at least 3mm larger than the negative control on skin-prick testing for peanut. One of the following: 1) patient is 4 to 17 years of age and is in the initial dose escalation phase of therapy, OR 2) patient is 4 years of age and older and is in the up-dosing or maintenance phase of therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Initial, Reauth: Prescribed by or in consultation with an allergist/immunologist.
<b>Coverage Duration</b>	Initial, Reauth: 12 months.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Pegasys (s)

## Products Affected

- PEGASYS
- PEGASYS PROCLICK SUBCUTANEOUS SOLUTION AUTO-INJECTOR 180 MCG/0.5ML

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	HepB: 48 wks. HepC: Initial: 28 wks. Reauth: 20 wks.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# Pemazyre (s)

## Products Affected

- PEMAZYRE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hepatologist, gastroenterologist, or oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# PENNSAID (s)

## Products Affected

- *diclofenac sodium external solution 1.5 %*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial, reauth: 12 months
<b>Other Criteria</b>	Osteoarthritis of the knees (reauth): Documentation of positive clinical response to therapy (e.g., improvement in pain symptoms of osteoarthritis).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Phesgo (s)

## Products Affected

- PHESGO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Piqray (s)

## Products Affected

- PIQRAY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Polivy (s)

## Products Affected

- POLIVY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Pomalyst (s)

## Products Affected

- POMALYST

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All indications: Prescribed by or in consultation with an oncologist or hematologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Posaconazole (s)

## Products Affected

- NOXAFIL ORAL SUSPENSION
- *posaconazole*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Prophylaxis of SFI: 6 months. Tx of SFI: 3 months. OPC: 1 month.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Procysbi (s)

## Products Affected

- PROCYSBI ORAL CAPSULE DELAYED RELEASE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Nephropathic cystinosis: Diagnosis of nephropathic cystinosis, confirmed by elevated leukocyte cystine levels (LCL) or genetic analysis of the CTNS gene or demonstration of cysteine corneal crystals by slit lamp examination AND Trial and failure or intolerance to therapy with Cystagon (immediate-release cysteamine bitartrate).
<b>Age Restrictions</b>	1 year of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Promacta (s)

## Products Affected

- PROMACTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 thrombocytopenia. 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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	ITP(init, reauth): 12mo. HepC: 3mo(init), 12mo(reauth). 1stline SAA: 6mo. RefractSAA: 16wk-init, 12mo-reauth
<b>Other Criteria</b>	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

Formulary ID 22333 Version 17 Effective Date: 09/01/2022

Last Updated: August 2022

PA Criteria	Criteria Details
	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# PROVIGIL (s)

## Products Affected

- *modafinil*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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).</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Narcolepsy: Init, Reauth: 12 mo. All other indications: Init, Reauth: 6 mo.
<b>Other Criteria</b>	OSA, Narcolepsy, Idiopathic Hypersomnia (Reauth): Documentation of positive clinical response to modafinil therapy. SWD (Reauth):

Formulary ID 22333 Version 17 Effective Date: 09/01/2022

Last Updated: August 2022

PA Criteria	Criteria Details
	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Pulmozyme (s)

## Products Affected

- PULMOZYME

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cystic Fibrosis (CF) (Initial, Reauth): Diagnosis of CF.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	CF (initial, reauth): 12 months
Other Criteria	Part B vs D determination applies. 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).
Indications	All Medically-accepted Indications.
Off Label Uses	

# Pyrukynd (s)

## Products Affected

- PYRUKYND ORAL TABLET 20 MG, 5 MG, 50 MG
- PYRUKYND TAPER PACK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial: Diagnosis of hemolytic anemia confirmed by the presence of chronic hemolysis (e.g., increased indirect bilirubin, elevated lactated 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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Initial, Reauth: Prescribed by or in consultation with a hematologist.
<b>Coverage Duration</b>	Initial: 6 months. Reauth: 12 months.
<b>Other Criteria</b>	Reauth: One of the following: 1) Documentation of positive clinical response to therapy [e.g., hemoglobin greater than or equal to 1.5g/dL from baseline, reduction in transfusions of greater than or equal to 33% in the number of red blood cell units transfused during the fixed dose period compared with the patient's historical transfusion burden, improvement in markers of hemolysis from baseline (e.g., bilirubin, lactated dehydrogenase [LDH], haptoglobin, reticulocyte count)], OR 2) Discontinue Pyrukynd if no benefit has been observed by 24 weeks based on the hemoglobin level, hemolytic markers, and transfusion requirements.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Qinlock (s)

## Products Affected

- QINLOCK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# QUALAQUIN (s)

## Products Affected

- *quinine sulfate oral*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Excluded if used solely for the treatment or prevention of nocturnal leg cramps.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	7 days
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Radicava ORS (s)

## Products Affected

- RADICAVA ORS
- RADICAVA ORS STARTER KIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Amyotrophic lateral sclerosis (ALS) (initial): Submission of medical records (e.g., chart notes, previous medical history, diagnostic testing including: imaging, nerve conduction studies, laboratory values) to support a diagnosis of "definite" or "probable" ALS per the revised El Escorial diagnostic criteria. Patient has scores of greater than or equal to 2 in all items of the ALS Functional Rating Scale-Revised (ALSFRS-R) criteria at the start of treatment. Patient has a percent forced vital capacity (%FVC) of greater than or equal to 80% at the start of treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	ALS (initial): Prescribed by or in consultation with a neurologist.
<b>Coverage Duration</b>	Initial, reauth: 6 months
<b>Other Criteria</b>	ALS (reauthorization): Documentation of a benefit from therapy (e.g., slowing in the decline of functional abilities), and patient is not dependent on invasive ventilation or tracheostomy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# RAVICTI (s)

---

## Products Affected

- RAVICTI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Urea cycle disorders (UCDs) (Initial): Diagnosis of UCDs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	UCDs (Initial, reauth): 12 months
Other Criteria	UCDs (reauth): Documentation of positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# Recorlev (s)

## Products Affected

- RECORLEV

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial: Diagnosis of Cushing's syndrome. Patient is being treated for endogenous hypercortisolemia (e.g., pituitary adenoma, ectopic tumor, adrenal adenoma). One of the following: 1) Patient is not a candidate for surgery, OR 2) Surgery has not been curative. Trial and failure of at least 90 days, or intolerance to oral ketoconazole.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Initial: Prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	Initial: 6 months. Reauth: 12 months.
<b>Other Criteria</b>	Reauth: Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# REMICADE (s)

## Products Affected

- INFLIXIMAB
- REMICADE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Crohn's Disease (CD) and Fistulizing Crohn's Disease (FCD) (Initial): Diagnosis (Dx) of moderately to severely active CD or FCD. Failure, contraindication, or intolerance to one of the following conventional therapies: 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex/Trexall). Ulcerative colitis (UC) (Initial): Dx of moderately to severely active UC. Trial and failure, contraindication, or intolerance (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)]. Rheumatoid arthritis (RA) (Initial): Dx of moderately to severely active RA. One of the following: Receiving concurrent therapy with methotrexate (Rheumatrex/Trexall), OR TF/C/I to methotrexate (Rheumatrex/Trexall). Ankylosing spondylitis (AS) (Initial): Dx of active AS. TF/C/I to two NSAIDs (e.g., diclofenac, ibuprofen, meloxicam, naproxen). Psoriatic arthritis (PsA) (Initial): Dx of active PsA. Plaque psoriasis (Initial): Dx of chronic severe (ie, extensive and/or disabling) plaque psoriasis. Sarcoidosis (initial): TF/C/I to one immunosuppressant [eg, methotrexate (Rheumatrex/Trexall), cyclophosphamide, or azathioprine (Imuran)] AND TF/C/I to one corticosteroid (eg, prednisone).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	CD, FCD, UC (initial): Prescribed by or in consultation with a gastroenterologist. RA, AS (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with rheumatologist or dermatologist. Plaque Psoriasis (initial): Prescribed by or in consultation with a dermatologist. Sarcoidosis (initial): Prescribed by or in consultation with a pulmonologist, dermatologist, ophthalmologist.
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months
<b>Other Criteria</b>	Reauth (CD, UC, AS, PsA, RA): 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.

Formulary ID 22333 Version 17 Effective Date: 09/01/2022

Last Updated: August 2022

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Renflexis (s)

## Products Affected

- RENFLEXIS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Crohn's Disease (CD) and Fistulizing Crohn's Disease (FCD) (initial): Dx of moderately to severely active CD or FCD. Ulcerative colitis (UC) (initial): Dx of moderately to severely active UC. Rheumatoid arthritis (RA) (initial): Diagnosis (Dx) of moderately to severely active RA. Ankylosing spondylitis (AS) (initial): Dx of active AS. Psoriatic arthritis (PsA) (initial): Dx of active PsA. Plaque psoriasis (initial): Dx of chronic severe (ie, extensive and/or disabling) plaque psoriasis. Sarcoidosis (initial): Dx of sarcoidosis. CD, FCD (initial): Trial and failure, contraindication or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine (Purinethol), azathioprine (Imuran), corticosteroids (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex, Trexall). UC (initial): TF/C/I to one of the following conventional therapies: corticosteroids, aminosalicylate [eg, mesalamine (Asacol/Pentasa/Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine/Sulfazine)], azathioprine (Imuran), 6-mercaptopurine (Purinethol). RA (initial): Receiving concurrent therapy with methotrexate (Rheumatrex/Trexall), or TF/C/I to methotrexate. AS (initial): TF/C/I to two or more NSAIDs (e.g., diclofenac, ibuprofen, meloxicam, naproxen). Sarcoidosis (initial): TF/C/I to one of the following: corticosteroid (eg, prednisone) OR immunosuppressant [eg, methotrexate (Rheumatrex/Trexall), cyclophosphamide, or azathioprine (Imuran)]. All indications (initial): One of the following: 1) Trial and failure or intolerance to Remicade or 2) For continuation of prior Renflexis therapy.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	<p>Initial: RA, AS: Prescribed by or in consultation with a rheumatologist. PsA: Prescribed or in consultation with a rheumatologist or dermatologist. Crohn's Disease, Fistulizing Crohn's Disease, UC: Prescribed by or in consultation with a gastroenterologist. Plaque Psoriasis: Prescribed by or in consultation with a dermatologist. Sarcoidosis (initial): Prescribed by or in consultation with a pulmonologist, dermatologist, or ophthalmologist.</p>
<b>Coverage Duration</b>	All indications (initial, reauth): 12 months
<b>Other Criteria</b>	Reauthorization for CD, UC, AS, PsA, RA, Sarcoidosis: Documentation of positive clinical response to therapy. Reauthorization (plaque psoriasis):

Formulary ID 22333 Version 17 Effective Date: 09/01/2022

Last Updated: August 2022

PA Criteria	Criteria Details
	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# REPATHA (s)

## Products Affected

- REPATHA
- REPATHA SURECLICK
- REPATHA PUSHTRONEX SYSTEM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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, iv)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 submission of MR (eg chart notes, lab values) documenting 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): Sub of MR (eg, chart notes, lab values) documenting 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.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Initial/Reauth: Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist
<b>Coverage Duration</b>	Initial: 6 months. Reauth: 12 months

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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/o 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 contraindication or intolerance to ezetimibe. HoFH (init): One of the following: 1)Pt is receiving other lipid-lowering tx (eg statin, ezetimibe) or 2)Pt has a documented inability to take other lipid-lowering tx (eg statin, ezetimibe). HeFH/ASCVD/Primary HLD (reauth): Pt continues to receive other lipid-lowering tx (eg statins, ezetimibe) at max tolerated dose (unless pt has documented inability to take these medications). HoFH (reauth): One of the following: 1)Pt continues to receive other lipid-lowering tx (eg statin, ezetimibe) or 2)Pt has a documented inability to take other lipid-lowering tx (eg statin, ezetimibe). HeFH/ASCVD/Primary HLD/HoFH (reauth): Sub of MR (eg, lab values) documenting LDL reduction while on Repatha tx.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Retevmo (s)

## Products Affected

- RETEVMO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Lung Cancer, MTC: Prescribed by or in consultation with an oncologist. Thyroid Cancer: Prescribed by or in consultation with an endocrinologist or an oncologist.
<b>Coverage Duration</b>	Lung Cancer, MTC, Thyroid Cancer: 12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Revatio (s)

## Products Affected

- *sildenafil citrate oral tablet 20 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
<b>Coverage Duration</b>	PAH: Initial: 6 months. Reauth: 12 months.
<b>Other Criteria</b>	PAH (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Revlimid (s)

## Products Affected

- *lenalidomide*
- REVLIMID

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist/hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Rezurock (s)

## Products Affected

- REZUROCK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	cGVHD (initial): Prescribed by or in consultation with one of the following: hematologist, oncologist, or physician experienced in the management of transplant patients.
<b>Coverage Duration</b>	cGVHD (initial, reauth): 12 months
<b>Other Criteria</b>	cGVHD (reauth): Patient does not show evidence of progressive disease while on therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Rilutek (s)

---

## Products Affected

- *riluzole*

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

# Rinvoq (s)

## Products Affected

- RINVOQ ORAL TABLET EXTENDED RELEASE 24 HOUR 15 MG, 30 MG, 45 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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)
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	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



PA Criteria	Criteria Details
	dermatologist or allergist/immunologist. UC (initial): Prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	RA, PsA, AS, UC, AD (initial, reauth): 12 months.
<b>Other Criteria</b>	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).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Rozlytrek (s)

## Products Affected

- ROZLYTREK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Rubraca (s)

## Products Affected

- RUBRACA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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)].
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Ovarian cancer: Prescribed by or in consultation with an oncologist. Prostate cancer: Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# RUXIENCE (s)

## Products Affected

- RUXIENCE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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, 4) Diagnosis of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin's lymphoma OR, 5) 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) OR contraindication or intolerance to glucocorticoids (eg, prednisone).</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	NHL, CLL: Prescribed by or in consultation with a hematologist/oncologist. WG, MPA: Prescribed by or in consultation with a nephrologist, pulmonologist, or rheumatologist.
<b>Coverage Duration</b>	NHL, CLL: 12 months. WG, MPA: 3 months.
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

Formulary ID 22333 Version 17 Effective Date: 09/01/2022

Last Updated: August 2022

# Rydapt (s)

## Products Affected

- RYDAPT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses: Prescribed by or in consultation with a hematologist or oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# SABRIL (s)

## Products Affected

- *vigabatrin*
- *vigadrone*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Sandostatin (s)

## Products Affected

- *octreotide acetate injection*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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.</p> <p>Carcinoid tumor (initial): Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea or flushing episodes.</p> <p>Vasoactive intestinal peptide tumor (initial): Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months
<b>Other Criteria</b>	<p>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.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Sarclisa (s)

## Products Affected

- SARCLISA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist/hematologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Scemblix (s)

## Products Affected

- SCEMBLIX ORAL TABLET 20 MG, 40 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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), Tassigna (nilotinib), Iclusig (ponatinib)], OR 2) Disease is T315I mutation positive.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# SCIG (s)

## Products Affected

- CUTAQUIG
- CUVITRU
- HIZENTRA
- HYQVIA SUBCUTANEOUS KIT 10 GM/100ML, 20 GM/200ML, 30 GM/300ML, 5 GM/50ML
- XEMBIFY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	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).
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	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).
<b>Coverage Duration</b>	Initial, reauth: 12 months
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Secuado (s)

## Products Affected

- SECUADO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# SIGNIFOR (s)

## Products Affected

- SIGNIFOR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Cushing's disease (initial): Prescribed by or in consultation with an endocrinologist.
<b>Coverage Duration</b>	Cushing's disease (initial, reauth): 12 months
<b>Other Criteria</b>	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).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# SIGNIFOR LAR (s)

## Products Affected

- SIGNIFOR LAR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Acromegaly (initial): Diagnosis of acromegaly. One of the following: a) Inadequate response to surgery or b) Patient is not a candidate for surgery. 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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Cushing's disease (initial): Prescribed by or in consultation with an endocrinologist.
<b>Coverage Duration</b>	Acromegaly: Initial: 6 months, Reauth: 12 months. Cushing's disease (init, reauth): 12 months
<b>Other Criteria</b>	Acromegaly (reauth): Documentation of positive clinical response to therapy (e.g., patient's growth hormone (GH) level or insulin-like growth factor 1 (IGF-1) level for age and gender has normalized/improved). 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).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# SIMPONI ARIA (s)

## Products Affected

- SIMPONI ARIA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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 therapy. Polyarticular Juvenile Idiopathic Arthritis (PJIA): Diagnosis of active PJIA. One of the following: TF/C/I to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior therapy. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior therapy. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. One of the following: TF/C/I to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior therapy.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	RA, PJIA, AS (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a rheumatologist or dermatologist.
<b>Coverage Duration</b>	All Indications (Initial, reauth): 12 months
<b>Other Criteria</b>	All Indications (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Skyrizi (s)

## Products Affected

- SKYRIZI
- SKYRIZI (150 MG DOSE)
- SKYRIZI PEN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. Psoriatic arthritis (PsA) (Initial): Diagnosis of active PsA.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Plaque psoriasis (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist.
<b>Coverage Duration</b>	Plaque psoriasis, PsA (Initial, reauth): 12 months
<b>Other Criteria</b>	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 (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Skytrofa (s)

## Products Affected

- SKYTROFA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Pediatric Growth Hormone Deficiency (PGHD) (initial): One of the following: A) History of neonatal hypoglycemia associated with pituitary disease, B) Diagnosis of panhypopituitarism, OR C) Both of the following: 1) Diagnosis of PGHD as confirmed by one of the following: a) Height is documented by one of the following (utilizing age and gender growth charts related to height): i) height is greater than 2.0 standard deviations (SD) below midparental height OR ii) height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender), b) Growth velocity is greater than 2 SD below mean for age and gender, or c) Delayed skeletal maturation of greater than 2 SD below mean for age and gender (eg, delayed greater than 2 years compared with chronological age), AND 2) Documentation of one of the following: a) Patient is male with bone age less than 16 years, OR b) Patient is female with bone age less than 14 years. Patient weight is 11.5 kg or greater. Trial and failure or intolerance to both of the following: a) Genotropin AND b) Nutropin, Nutropin AQ, or Nutropin AQ NuSpin.
<b>Age Restrictions</b>	PGHD (initial): 1 year of age or older.
<b>Prescriber Restrictions</b>	PGHD (initial, reauth): Prescribed by or in consultation with an endocrinologist.
<b>Coverage Duration</b>	PGHD (initial, reauth): 12 months.
<b>Other Criteria</b>	PGHD (reauth): Both of the following: 1) Expected adult height not attained AND 2) Documentation of expected adult height goal.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Somatuline Depot (s)

## Products Affected

- SOMATULINE DEPOT  
SUBCUTANEOUS SOLUTION 120  
MG/0.5ML, 60 MG/0.2ML, 90 MG/0.3ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	All uses: 12 months
<b>Other Criteria</b>	All Indications: Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Somavert (s)

## Products Affected

- SOMAVERT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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)
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	Initial and reauth: 12 months
<b>Other Criteria</b>	Acromegaly (reauth): Patient has experienced a positive clinical response to therapy (biochemical control, decrease or normalization of IGF-1 levels).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Sporanox (s)

## Products Affected

- *itraconazole oral*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Systemic fungal infxn:6mo.Candidiasis:1 mo.Fingernail onycho:5wks.Toenail onycho, other:3mo.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Spravato (s)

## Products Affected

- SPRAVATO (56 MG DOSE)
- SPRAVATO (84 MG DOSE)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a psychiatrist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Sprycel (s)

## Products Affected

- SPRYCEL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All Uses: Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	All Uses: 12 months
<b>Other Criteria</b>	All Uses: Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Stelara (IV) (s)

## Products Affected

- STELARA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	One time
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# STELARA (s)

## Products Affected

- STELARA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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: TF/C/I to Humira (adalimumab) and 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 (tofacitinib), OR for continuation of prior therapy.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	<p>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.</p>
<b>Coverage Duration</b>	All uses (Initial, reauth): 12 months
<b>Other Criteria</b>	<p>Reauth (PsA, CD, UC): Documentation of positive clinical response to therapy. Reauth (plaque psoriasis): Documentation of positive clinical</p>

Formulary ID 22333 Version 17 Effective Date: 09/01/2022

Last Updated: August 2022

PA Criteria	Criteria Details
	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Stivarga (s)

## Products Affected

- STIVARGA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	mCRC, GIST: Prescribed by or in consultation with an oncologist. HCC: Prescribed by or in consultation with an oncologist, hepatologist, or gastroenterologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Strensiq (s)

## Products Affected

- STRENSIQ

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Hypophosphatasia: Prescribed by or in consultation with a specialist experienced in the treatment of inborn errors of metabolism or endocrinologist
<b>Coverage Duration</b>	Hypophosphatasia: 12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# SUPPRELIN LA (s)

## Products Affected

- SUPPRELIN LA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	CPP (initial, reauth): Prescribed by or in consultation with a pediatric endocrinologist.
<b>Coverage Duration</b>	CPP (init, reauth): 12 months
<b>Other Criteria</b>	CPP (reauthorization): LH levels have been suppressed to pre-pubertal levels.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Sutent (s)

## Products Affected

- *sunitinib malate*
- SUTENT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses: Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	All uses: 12 months
<b>Other Criteria</b>	All Indications: Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Sylatron (s)

## Products Affected

- SYLATRON SUBCUTANEOUS KIT 200 MCG, 300 MCG, 600 MCG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or dermatologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Symdeko (s)

## Products Affected

- SYMDEKO ORAL TABLET THERAPY  
PACK 100-150 & 150 MG, 50-75 & 75 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial: Diagnosis of cystic fibrosis. One of the following: 1) 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) OR 2) Patient has at least one mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence 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).
<b>Age Restrictions</b>	Initial: Patient is 6 years of age or older
<b>Prescriber Restrictions</b>	Initial: Prescribed by or in consultation with a pulmonologist or specialist affiliated with a CF care center
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Reauth: Documentation of a positive clinical response to therapy (e.g., improvement in lung function or decreased number of pulmonary exacerbations).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Symlin (s)

## Products Affected

- SYMLINPEN 120
- SYMLINPEN 60

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial: One of the following diagnoses: A) Type 1 diabetes OR B) Type 2 diabetes. Patient has failed to achieve desired glucose control despite optimal insulin therapy. Patient is taking concurrent mealtime insulin therapy (e.g., Humulin, Humalog, Novolin, Novolog).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Reauth: Patient has experienced an objective response to therapy demonstrated by an improvement in HbA1c from baseline. Patient is receiving concurrent mealtime insulin therapy (e.g., Humulin, Humalog, Novolin, Novolog).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# SYNAGIS (s)

## Products Affected

- SYNAGIS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	<p>Prescribed by or in consultation with a pediatric specialist (i.e., pulmonologist, neonatologist, neurologist, cardiologist, pediatric intensivist, or infectious disease specialist).</p>
<b>Coverage Duration</b>	<p>5 months (5 doses) during RSV season.</p>
<b>Other Criteria</b>	
<b>Indications</b>	<p>All Medically-accepted Indications.</p>

Formulary ID 22333 Version 17 Effective Date: 09/01/2022

Last Updated: August 2022



PA Criteria	Criteria Details
Off Label Uses	

# SYNDROS (s)

## Products Affected

- SYNDROS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Nausea and Vomiting Associated with Cancer Chemotherapy (CINV): Patient is receiving cancer chemotherapy. Trial and failure, contraindication, or intolerance (TF/C/I) to a 5HT-3 receptor antagonist (eg, Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]). TF/C/I 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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	CINV: 6 months. AIDS anorexia: 3 months.
<b>Other Criteria</b>	Subject to Part B vs. Part D review. CINV: Approve for continuation of therapy for treatment covered under Part B when patient is receiving chemotherapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Synribo (s)

## Products Affected

- SYNRIBO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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, Tassigna, and Bosulif, Iclusig).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	CML: Prescribed by or in consultation with a hematologist/oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# SYPRINE (s)

## Products Affected

- CLOVIQUE ORAL CAPSULE 250 MG
- *trientine hcl*

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

# Tabrecta (s)

## Products Affected

- TABRECTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# TAFAMIDIS (s)

## Products Affected

- VYNDAMAX
- VYNDAQEL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	ATTR-CM (initial, reauth): Prescribed by or in consultation with a cardiologist
<b>Coverage Duration</b>	ATTR-CM (initial, reauth): 12 months
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Tafinlar (s)

## Products Affected

- TAFINLAR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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 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) .</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

Formulary ID 22333 Version 17 Effective Date: 09/01/2022

Last Updated: August 2022

# Tagrisso (s)

## Products Affected

- TAGRISSO ORAL TABLET 40 MG, 80 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# TALTZ (s)

## Products Affected

- TALTZ

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. 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): Diagnosis of active PsA. 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), or Xeljanz/XR (tofacitinib/ER), OR for continuation of prior therapy. Ankylosing spondylitis (AS) (initial): Diagnosis of active AS. One of the following: a) Either TF/C/I 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 one non-steroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, meloxicam, naproxen). One of the following: a) Trial and failure, contraindication, or intolerance to Cosentyx (secukinumab), OR b) for continuation of prior therapy.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	<p>Plaque Psoriasis (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. AS, nr-axSpA (initial): Prescribed by or in consultation with a rheumatologist.</p>
<b>Coverage Duration</b>	Initial, reauth: 12 months
<b>Other Criteria</b>	<p>PsA, AS, nr-axSpA (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</p>

PA Criteria	Criteria Details
	body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Talzenna (s)

## Products Affected

- TALZENNA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# TARCEVA (s)

## Products Affected

- *erlotinib hcl*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses: Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	All uses: 12 months
<b>Other Criteria</b>	All Indications: Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Targretin (s)

## Products Affected

- *bexarotene*
- TARGRETIN EXTERNAL

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

# Tarpeyo (s)

## Products Affected

- TARPEYO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 m <sup>2</sup> . 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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a nephrologist.
<b>Coverage Duration</b>	9 months.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Tasigna (s)

---

**Products Affected**

- TASIGNA

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

# Tavalisse (s)

## Products Affected

- TAVALISSE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	ITP (initial): Prescribed by or in consultation with a hematologist/oncologist.
<b>Coverage Duration</b>	ITP (initial, reauth): 12 months
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Tavneos (s)

## Products Affected

- TAVNEOS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Initial, Reauth: Prescribed by or in consultation with a nephrologist, pulmonologist, or rheumatologist
<b>Coverage Duration</b>	Initial, Reauth: 12 months
<b>Other Criteria</b>	Reauth: Patient does not show evidence of progressive disease while on therapy. Patient is receiving concurrent immunosuppressant therapy (e.g., azathioprine, cyclophosphamide, methotrexate, rituximab).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Tazverik (s)

## Products Affected

- TAZVERIK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Epithelioid sarcoma: Prescribed by or in consultation with an oncologist. Follicular lymphoma: Prescribed by or in consultation with an oncologist or hematologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# TECFIDERA (s)

## Products Affected

- *dimethyl fumarate oral*
- *dimethyl fumarate starter pack*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	MS (initial, reauth): Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	MS (initial, reauth): 12 months
<b>Other Criteria</b>	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Tegsedi (s)

## Products Affected

- TEGSEDI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	hATTR amyloidosis (initial): Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	hATTR amyloidosis (initial, reauth): 12 months
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Tepmetko (s)

## Products Affected

- TEPMETKO

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

# TERIPARATIDE (s)

## Products Affected

- FORTEO
- TERIPARATIDE (RECOMBINANT)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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, risedronate, 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.</p> <p>Glucocorticoid-Induced Osteoporosis: See Other Criteria section.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	All uses (initial): 24 months. All uses (reauth): 12 months.
<b>Other Criteria</b>	<p>Glucocorticoid-Induced Osteoporosis (initial): Diagnosis of glucocorticoid-induced osteoporosis. History of prednisone or its equivalent at a dose greater than or equal to 5mg/day for greater than or equal to 3 months. One of the following: 1) BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site), or 2) 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</p>

Formulary ID 22333 Version 17 Effective Date: 09/01/2022

Last Updated: August 2022

PA Criteria	Criteria Details
	<p>other countries or regions, or 3) History of one of the 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)].</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Testosterone (s)

## Products Affected

- ANDRODERM
- STRIANT BUCCAL 30 MG
- *testosterone cypionate intramuscular*
- *testosterone transdermal gel 12.5 mg/act (1%), 20.25 mg/1.25gm (1.62%), 20.25 mg/act (1.62%), 25 mg/2.5gm (1%), 40.5 mg/2.5gm (1.62%), 50 mg/5gm (1%)*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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. Patient is a transgender male (female-to-male).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	HG(init): (New to T tx:6 mo. New to plan and cont T tx:12 mo), (reauth): 12 mo. GD: 12 mo.
<b>Other Criteria</b>	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



PA Criteria	Criteria Details
	bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# TESTOSTERONE ENANTHATE (s)

## Products Affected

- *testosterone enanthate intramuscular*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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. Patient is a transgender male (female-to-male).</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	<p>HG(init): (New to T tx:6 mo. Cont T tx:12 mo), (reauth): 12 mo. BC, GD: 12 mo. DP: 6 mo.</p>
<b>Other Criteria</b>	<p>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.</p>

Formulary ID 22333 Version 17 Effective Date: 09/01/2022

Last Updated: August 2022

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Thalomid (s)

## Products Affected

- THALOMID

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	MM: Prescribed by or in consultation with an oncologist/hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Tibsovo (s)

## Products Affected

- TIBSOVO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# TOPICAL RETINOID (s)

---

## Products Affected

- *tretinoin external cream 0.025 %, 0.05 %*

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# TRACLEER (s)

## Products Affected

- *bosentan*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
<b>Coverage Duration</b>	PAH (Initial): 6 months. PAH (Reauth): 12 months
<b>Other Criteria</b>	PAH (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Trazimera (s)

## Products Affected

- TRAZIMERA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses: Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# TRELSTAR (s)

---

## Products Affected

- TRELSTAR MIXJECT INTRAMUSCULAR SUSPENSION RECONSTITUTED 11.25 MG, 22.5 MG

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# Tremfya (s)

## Products Affected

- TREMFYA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. Trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab), Cosentyx (secukinumab), OR for continuation of prior therapy. Psoriatic Arthritis (PsA) (initial): Diagnosis of active PsA. Either TF/C/I to two of the following, or attestation that a trial may be inappropriate: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab), Rinvoq (upadacitinib), or Xeljanz/XR (tofacitinib/ER), OR for continuation of prior therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Plaque psoriasis (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist.
<b>Coverage Duration</b>	All Indications (Initial, reauth): 12 months
<b>Other Criteria</b>	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 (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Trikafta (s)

## Products Affected

- TRIKAFTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	CF (initial): 6 years of age or older.
<b>Prescriber Restrictions</b>	CF (initial): Prescribed by or in consultation with a pulmonologist or specialist affiliated with a CF care center.
<b>Coverage Duration</b>	CF (initial, reauth): 12 months
<b>Other Criteria</b>	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).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Triptodur (s)

## Products Affected

- TRIPTODUR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	CPP (initial, reauth): Prescribed by or in consultation with a pediatric endocrinologist.
<b>Coverage Duration</b>	CPP (Initial, reauth): 12 months
<b>Other Criteria</b>	CPP (reauthorization): LH levels have been suppressed to pre-pubertal levels.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Trodelvy (s)

## Products Affected

- TRODELVY

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# Truseltiq (s)

## Products Affected

- TRUSELTIQ (100MG DAILY DOSE)
- TRUSELTIQ (125MG DAILY DOSE)
- TRUSELTIQ (50MG DAILY DOSE)
- TRUSELTIQ (75MG DAILY DOSE)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hepatologist, gastroenterologist, or oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Tukysa (s)

## Products Affected

- TUKYSA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Turalio (s)

## Products Affected

- TURALIO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Tykerb (s)

## Products Affected

- *lapatinib ditosylate*
- TYKERB

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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)].
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Tymlos (s)

## Products Affected

- TYMLOS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	24 months (max 24 months of therapy per lifetime)
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# TYSABRI (s)

## Products Affected

- TYSABRI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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, Humira [adalimumab], infliximab). CD (initial and reauth): Not used in combination with an immunosuppressant (eg, 6-MP, azathioprine, cyclosporine, or methotrexate). Not used in combination with a TNF-inhibitor (eg, Enbrel [etanercept], Humira [adalimumab], or infliximab).</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	MS (init, reauth): Prescribed by or in consultation with a neurologist. CD (initial): Prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	MS (init, reauth): 12mo. CD (Init): 3 mo. CD (Reauth): 6 mo if not on steroids. Otherwise, 3 mo.

PA Criteria	Criteria Details
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Ubrelvy (s)

## Products Affected

- UBRELVY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Initial: 18 years of age or older.
<b>Prescriber Restrictions</b>	Initial, Reauth: Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.
<b>Coverage Duration</b>	Initial: 3 months. Reauth: 12 months.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Udenyca (s)

## Products Affected

- UDENYCA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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 with neutropenia.            Diagnosis of FN. Patient is at high risk for infection-associated complications. Acute radiation syndrome (ARS) (off-label): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS).</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses: Prescribed by or in consultation with a hematologist/oncologist
<b>Coverage Duration</b>	ARS: 1 mo. FN (prophylaxis, treatment): 3 mo or duration of tx.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Ukoniq (s)

## Products Affected

- UKONIQ ORAL TABLET 200 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Marginal zone lymphoma (MZL): Diagnosis of MZL. Disease is one of the following: relapsed or refractory. Patient 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.).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	MZL/FL: Prescribed by or in consultation with a hematologist/oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Valchlor (s)

## Products Affected

- VALCHLOR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.].
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or dermatologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Varizig (s)

## Products Affected

- VARIZIG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Presence of contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication).
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 months (approve one dose only)
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Vascepa (s)

## Products Affected

- *icosapent ethyl*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial/Reauth: 12 months
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Venclexta (s)

## Products Affected

- VENCLEXTA
- VENCLEXTA STARTING PACK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL): Diagnosis of CLL or SLL. Acute Myeloid Leukemia (AML): 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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# VENTAVIS (s)

## Products Affected

- VENTAVIS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
<b>Coverage Duration</b>	PAH (Initial): 6 months. (Reauth): 12 months
<b>Other Criteria</b>	Subject to Part B vs D review. PAH (Reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Verzenio (s)

## Products Affected

- VERZENIO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 human epidermal growth factor receptor 2 (HER2)-negative. 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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Vioice (s)

## Products Affected

- VIJOICE ORAL TABLET THERAPY  
PACK 125 MG, 200 & 50 MG, 50 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial: Diagnosis of PIK3CA-related overgrowth spectrum (PROS). Documentation of mutation in the PIK3CA gene. Documentation of severe clinical manifestations (e.g., congenital lipomatous overgrowth, vascular malformations, epidermal nevi, scoliosis/skeletal and spinal [CLOVES], facial infiltrating lipomatosis [FIL], klippel-trenaunay syndrome [KTS], megalencephaly-capillary malformation polymicrogyria [MCAP]).
<b>Age Restrictions</b>	Initial: Patient is 2 years of age or older.
<b>Prescriber Restrictions</b>	Initial, Reauth: Prescribed by or in consultation with a physician who specializes in the treatment of PROS.
<b>Coverage Duration</b>	Initial: 6 months. Reauth: 12 months.
<b>Other Criteria</b>	Reauth: Documentation of positive clinical response to therapy (e.g., radiological response defined as a 20% or greater reduction from baseline in the sum of target lesion volume).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Vimizim (s)

## Products Affected

- VIMIZIM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial, reauth: 12 months
<b>Other Criteria</b>	Reauth: Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Vitrakvi (s)

## Products Affected

- VITRAKVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Vizimpro (s)

## Products Affected

- VIZIMPRO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Vonjo (s)

---

**Products Affected**

- VONJO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 $50 \times 10^9/L$ .
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Voriconazole Injection (s)

## Products Affected

- *voriconazole intravenous*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 <i>Scedosporium apiospermum</i> (asexual form of <i>Pseudallescheria boydii</i> ) or <i>Fusarium</i> spp. including <i>Fusarium solani</i> . For fusariosis: Patient is intolerant of, or refractory to, other therapy (e.g., liposomal amphotericin B, amphotericin B lipid complex).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 weeks
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Vosevi (s)

## Products Affected

- VOSEVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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].
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	12 to 24 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Votrient (s)

## Products Affected

- VOTRIENT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses: Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Voxzogo (s)

## Products Affected

- VOXZOGO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial: Patient has open epiphyses. Diagnosis of achondroplasia as confirmed by one of the following: 1) Both of the following: a) Patient has clinical manifestations characteristic of achondroplasia (e.g., macrocephaly, frontal bossing, midface retrusion, disproportionate short stature with rhizomelic shortening of the arms and the legs, brachydactyly, trident configuration of the hands, thoracolumbar kyphosis, and accentuated lumbar lordosis) and b) Patient has radiographic findings characteristic of achondroplasia (e.g., large calvaria and narrowing of the foramen magnum region, undertubulated, shortened long bones with metaphyseal abnormalities, narrowing of the interpedicular distance of the caudal spine, square ilia and horizontal acetabula, small sacrosciatic notches, proximal scooping of the femoral metaphyses, and short and narrow chest), OR 2) Molecular genetic testing confirmed c.1138G to A or c.1138G to C variant (i.e., p.Gly380Arg mutation) in the fibroblast growth factor receptor-3 (FGFR3) gene. Patient did not have limb-lengthening surgery in the previous 18 months and does not plan on having limb-lengthening surgery while on Voxzogo therapy.
<b>Age Restrictions</b>	Initial: Patient is 5 years of age or older.
<b>Prescriber Restrictions</b>	Initial, Reauth: Prescribed by or in consultation with a clinical geneticist, endocrinologist, or a physician who has specialized expertise in the management of achondroplasia.
<b>Coverage Duration</b>	Initial, Reauth: 12 months.
<b>Other Criteria</b>	Reauth: Patient continues to have open epiphyses. Documentation of a positive clinical response to therapy as evidenced by one of the following: 1) Improvement in annualized growth velocity (AGV) compared to baseline, OR 2) Improvement in height Z-score compared to baseline.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Vumerity (s)

## Products Affected

- VUMERITY
- VUMERITY (STARTER) ORAL CAPSULE DELAYED RELEASE 231 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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: 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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	MS (initial, reauth): Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	MS (initial, reauth): 12 months
<b>Other Criteria</b>	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Welireg (s)

---

**Products Affected**

- WELIREG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Xalkori (s)

## Products Affected

- XALKORI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	NSCLC: Prescribed by or in consultation with an oncologist. ALCL: Prescribed by or in consultation with an oncologist or hematologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Xcopri (s)

---

## Products Affected

- XCOPRI

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

# XELJANZ (s)

## Products Affected

- XELJANZ
- XELJANZ XR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	RA/PJIA/PsA/AS (initial, reauth): 12 months. UC (init): 4 mo. UC (reauth): 12 mo.
<b>Other Criteria</b>	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).

Formulary ID 22333 Version 17 Effective Date: 09/01/2022

Last Updated: August 2022

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Xenazine (s)

## Products Affected

- *tetrabenazine*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	All uses: (initial) 3 months. (Reauth) 12 months.
<b>Other Criteria</b>	All indications (Reauth): Documentation of clinical response and benefit from therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Xermelo (s)

## Products Affected

- XERMELO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Initial: Prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist
<b>Coverage Duration</b>	Initial: 6 months. Reauth: 12 months
<b>Other Criteria</b>	Carcinoid syndrome diarrhea (Reauthorization): Documentation of a positive clinical response to therapy AND drug will continue to be used in combination with SSA therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Xgeva (s)

## Products Affected

- XGEVA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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)).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	GCTB, HCM: Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	MM/BMST, GCTB: 12 mo. HCM: 2 mo.
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Xifaxan (s)

## Products Affected

- XIFAXAN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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].
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	TD: 14 days. HE (prophylaxis, treatment): 12 months. IBS-D (initial, reauth): 2 weeks.
<b>Other Criteria</b>	IBS-D (reauth): Patient experiences IBS-D symptom recurrence.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Xolair (s)

## Products Affected

- XOLAIR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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, hydroxyzine, doxepin. Used concurrently with an H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamines. 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 in combination with another agent for nasal polyps.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	<p>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.</p>

PA Criteria	Criteria Details
<b>Coverage Duration</b>	Asthma, init: 6 mo, reauth: 12 mo. CIU, init: 3 mo, reauth: 6 mo. NP, init/reauth: 12 mo.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Xospata (s)

## Products Affected

- XOSPATA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Xpovio (s)

## Products Affected

- XPOVIO (100 MG ONCE WEEKLY)
- XPOVIO (40 MG ONCE WEEKLY)
- XPOVIO (40 MG TWICE WEEKLY)
- XPOVIO (60 MG ONCE WEEKLY)
- XPOVIO (60 MG TWICE WEEKLY)
- XPOVIO (80 MG ONCE WEEKLY)
- XPOVIO (80 MG TWICE WEEKLY)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist/hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Xtandi (s)

---

## Products Affected

- XTANDI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	CRPC, M-CSPC: Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# XYREM (s)

## Products Affected

- XYREM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses (initial): Prescribed by or in consultation with one of the following: neurologist, psychiatrist, or sleep medicine specialist.
<b>Coverage Duration</b>	All uses (initial): 6 months. All uses (reauth): 12 months
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Zavesca (s)

---

## Products Affected

- *miglustat*

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

# Zejula (s)

## Products Affected

- ZEJULA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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). Treatment of advanced ovarian cancer after three or more chemotherapies: Diagnosis of advanced ovarian cancer, advanced fallopian tube cancer, or advanced primary peritoneal cancer. Patient has been treated with three or more prior chemotherapy regimens. Patient's cancer is associated with homologous recombination deficiency (HRD) positive status defined by one of the following: (a) a deleterious or suspected deleterious BRCA mutation or (b) both of the following: (1) genomic instability and (2) cancer has progressed more than 6 months after response to the last platinum-based chemotherapy (e.g., cisplatin, carboplatin).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Zelboraf (s)

## Products Affected

- ZELBORAF

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Melanoma: Prescribed by or in consultation with an oncologist. Erdheim-Chester Disease: Prescribed by or in consultation with a hematologist/oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	All indications: Approve for continuation of therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Zeposia (s)

## Products Affected

- ZEPOSIA
- ZEPOSIA 7-DAY STARTER PACK
- ZEPOSIA STARTER KIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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. Ulcerative Colitis (UC) (init): Diagnosis of moderately to severely active UC. One of the following: a) Trial and failure, contraindication, or intolerance to two of the following, or attestation demonstrating a trial may be inappropriate: Humira (adalimumab), Rinvoq (upadacitinib), or Xeljanz IR (tofacitinib IR)/Xeljanz XR (tofacitinib XR), OR b) for continuation of prior therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	MS (initial, reauth): Prescribed by or in consultation with a neurologist. UC (init): Prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	MS (initial, reauth): 12 months. UC (init): 12 weeks, (reauth): 12 months.
<b>Other Criteria</b>	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression). UC (reauth): Documentation of positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Zepzelca (s)

## Products Affected

- ZEPZELCA

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

# Zirabev (s)

## Products Affected

- ZIRABEV

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Non-Small Cell Lung Cancer: Excluded if squamous cell histology.
<b>Required Medical Information</b>	<p>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.</p> <p>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.</p> <p>Renal Cell Cancer: Diagnosis of metastatic renal cell cancer. Used in combination with interferon-alpha.</p> <p>Cervical Cancer: Diagnosis of carcinoma of the cervix. Disease is persistent, recurrent, or metastatic. Used in combination with one of the following: a) paclitaxel and cisplatin or b) paclitaxel and topotecan.</p> <p>Glioblastoma: Diagnosis of recurrent glioblastoma.</p> <p>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 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, and c) used in combination with one of the following: i) carboplatin and paclitaxel or ii) carboplatin and gemcitabine.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Hepatocellular Carcinoma (HCC): Diagnosis of hepatocellular carcinoma. Disease is unresectable or metastatic. Used in combination with

Formulary ID 22333 Version 17 Effective Date: 09/01/2022

Last Updated: August 2022

PA Criteria	Criteria Details
	Tecentriq (atezolizumab). Patient has not received prior systemic therapy. Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Zokinvy (s)

## Products Affected

- ZOKINVY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Patient is 12 months of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Zoladex (s)

## Products Affected

- ZOLADEX SUBCUTANEOUS IMPLANT  
10.8 MG, 3.6 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 1 1.25 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.
<b>Age Restrictions</b>	Endometriosis: 18 years or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Zolinza (s)

---

**Products Affected**

- ZOLINZA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# Zorbtive (s)

## Products Affected

- ZORBTIVE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Short Bowel Syndrome (SBS): Diagnosis of SBS. Patient is currently receiving specialized nutritional support (eg, intravenous parenteral nutrition, fluid, and micronutrient supplements). Patient has not previously received 4 weeks of treatment with Zorbtive (somatropin).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	SBS: 4 weeks.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Zydelig (s)

## Products Affected

- ZYDELIG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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]). Follicular Lymphoma (FL): Diagnosis of FL. The patient has relapsed on at least two prior systemic therapies (eg, rituximab, alkylating agents [cyclophosphamide, chlorambucil], anthracyclines [doxorubicin, daunorubicine], purine analogs [fludarabine]). Small lymphocytic lymphoma (SLL): Diagnosis of SLL. The patient has relapsed on at least two prior systemic therapies (eg, rituximab, alkylating agents [cyclophosphamide, chlorambucil], anthracyclines [doxorubicin, daunorubicine], purine analogs [fludarabine]).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	All uses: Prescribed by or in consultation with an oncologist/hematologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# Zykadia (s)

## Products Affected

- ZYKADIA
- ZYKADIA ORAL CAPSULE 150 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ZYTIGA (preferred) (s)

## Products Affected

- *abiraterone acetate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	mCRPC, mCSPC: Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	mCRPC, mCSPC: 12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## Index of Drugs

### A

abiraterone acetate.....	364
accutane .....	124
ACTEMRA ACTPEN .....	1, 2
ACTEMRA SUBCUTANEOUS.....	1, 2
ACTIMMUNE .....	3
ADBRY .....	4
ADEMPAS .....	6
AFINITOR DISPERZ.....	8
AFINITOR ORAL TABLET 10 MG.....	7
AIMOVIG SUBCUTANEOUS SOLUTION AUTO-INJECTOR 140 MG/ML, 70 MG/ML.....	9, 10
ALDURAZYME.....	11
ALECENSA.....	12
alose tron hcl.....	150
ALUNBRIG ORAL TABLET 180 MG, 30 MG, 90 MG.....	15
ALUNBRIG ORAL TABLET THERAPY PACK.....	15
alyq.....	5
ambrisentan .....	144
amnestem.....	124
ANADROL-50 ORAL TABLET 50 MG .....	17
ANDRODERM.....	296, 297
ARALAST NP.....	13
ARCALYST .....	18
armodafinil oral tablet 150 mg, 200 mg, 250 mg, 50 mg.....	189
ASCENIV .....	128, 129
AUBAGIO .....	19
AURYXIA.....	20
AUSTEDO.....	21
AVONEX PEN.....	167
AVONEX PREFILLED.....	167
AVONEX VIAL INTRAMUSCULAR KIT INTRAMUSCULAR KIT 30 MCG.....	167
AYVAKIT.....	22

### B

BAFIERTAM .....	23
BALVERSA .....	24
BENLYSTA.....	25
BESREMI.....	26
BETASERON.....	167
bexarotene.....	285
BIVIGAM.....	128, 129
bosentan.....	303
BOSULIF .....	27

BRAFTOVI.....	28
BRIVIACT ORAL.....	29
BRUKINSA.....	30

### C

CABLIVI .....	31
CABOMETYX.....	32
CALQUENCE.....	33
CAMZYOS.....	34
CAPRELSA ORAL TABLET 100 MG, 300 MG.....	35
carimune nf intravenous solution reconstituted 12 gm, 6 gm.....	128, 129
carisoprodol oral tablet 350 mg.....	36
CAYSTON.....	37
CERDELGA .....	38
CHOLBAM .....	39
CIBINQO.....	41
ciclodan.....	42
ciclopirox external solution.....	42
CIMZIA PREFILLED KIT.....	43, 44
CIMZIA STARTER KIT .....	43, 44
CINRYZE .....	45
claravis.....	124
CLOVIQUE ORAL CAPSULE 250 MG ..	276
COMETRIQ.....	46
COPIKTRA.....	47
CORLANOR ORAL SOLUTION.....	48
CORLANOR ORAL TABLET.....	48
COSENTYX (300 MG DOSE) .....	49, 50
COSENTYX 150 MG/ML.....	49, 50
COSENTYX SENSOREADY (300 MG) ..	49,
50	
COSENTYX SENSOREADY PEN.....	49, 50
COTELLIC.....	51
CUTAQUIG.....	250
CUVITRU.....	250
CYSTARAN.....	52

### D

dalfampridine er.....	16
DALIRESP .....	54
DANYELZA .....	55
DARZALEX FASPRO.....	57, 58
DAURISMO.....	59
deferasirox granules.....	60
deferasirox oral tablet.....	60
deferasirox oral tablet soluble .....	60
deferiprone.....	89
DIACOMIT.....	61

diclofenac sodium external solution 1.5 % .....	211	FENSOLVI (6 MONTH).....	87
dihydroergotamine mesylate injection .....	53	fentanyl citrate buccal lozenge on a handle .....	88
dihydroergotamine mesylate nasal.....	164	FINTEPLA.....	90
dimethyl fumarate oral .....	291	FIRMAGON.....	92
dimethyl fumarate starter pack.....	291	FIRMAGON (240 MG DOSE).....	92
dronabinol.....	159	FLEBOGAMMA DIF.....	128, 129
droxidopa.....	183	FORTEO.....	294, 295
DUPIXENT SUBCUTANEOUS SOLUTION PEN-INJECTOR 200 MG/1.14ML, 300 MG/2ML.....	62, 63	FOTIVDA .....	93
DUPIXENT SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 100 MG/0.67ML, 200 MG/1.14ML, 300 MG/2ML.....	62, 63	<b>G</b>	
<b>E</b>		GALAFOLD.....	94
ELAPRASE .....	64	GAMASTAN.....	95
ELIGARD SUBCUTANEOUS KIT 22.5 MG, 30 MG, 45 MG, 7.5 MG.....	65	gammagard injection solution 1 gm/10ml, 10 gm/100ml, 20 gm/200ml, 5 gm/50ml. 128, 129	
ELYXYB.....	66	GAMMAGARD INJECTION SOLUTION 2.5 GM/25ML, 30 GM/300ML.....	128, 129
EMGALITY SUBCUTANEOUS SOLUTION AUTO-INJECTOR 120 MG/ML.....	67, 68	GAMMAGARD S/D LESS IGA.....	128, 129
EMGALITY SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 100 MG/ML, 120 MG/ML.....	67, 68	GAMMAKED .....	128, 129
ENBREL .....	69	GAMMAPLEX.....	128, 129
ENBREL MINI.....	69	GAMUNEX-C.....	128, 129
ENBREL SUBCUTANEOUS SOLUTION RECONSTITUTED 25 MG.....	69	GATTEX.....	96
ENBREL SURECLICK.....	69	GAVRETO.....	97
ENSPRYNG.....	70	GENOTROPIN .....	102, 103
ENTYVIO.....	71	GENOTROPIN MINIQUICK.....	102, 103
EPIDIOLEX.....	73	GILENYA .....	98
ERIVEDGE .....	76	GILOTRIF.....	99
ERLEADA .....	77	glatiramer acetate subcutaneous solution prefilled syringe 20 mg/ml, 40 mg/ml .	100
erlotinib hcl.....	284	glydo.....	145
ESBRIET .....	78	<b>H</b>	
EUCRISA.....	79	HIZENTRA.....	250
everolimus oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg.....	7	HUMIRA.....	106, 107
everolimus oral tablet soluble.....	8	HUMIRA PEDIATRIC CROHNS START .....	106, 107
EVRYSDI .....	80, 81	HUMIRA PEN.....	106, 107
EXKIVITY.....	82	HUMIRA PEN-CD/UC/HS STARTER... 106, 107	
EXSERVAN .....	83	HUMIRA PEN-PEDIATRIC UC START 106, 107	
EXTAVIA.....	167	HUMIRA PEN-PS/UV/ADOL HS START .....	106, 107
<b>F</b>		HUMIRA PEN-PSOR/UEIT STARTER106, 107	
FABRAZYME.....	84	HYQVIA SUBCUTANEOUS KIT 10 GM/100ML, 20 GM/200ML, 30 GM/300ML, 5 GM/50ML.....	250
FARYDAK ORAL CAPSULE 10 MG, 15 MG, 20 MG.....	85	<b>I</b>	
FASENRA.....	86	IBRANCE .....	108
FASENRA PEN.....	86	icatibant acetate .....	91

ICLUSIG ORAL TABLET 10 MG, 15 MG, 30 MG, 45 MG.....	109	MG, 2 X 10 MG, 2 X 10 MG & 4 MG, 2 X 4 MG, 3 X 4 MG, 4 MG .....	143
icosapent ethyl.....	322	leuprolide acetate injection.....	153
IDHIFA.....	110	lidocaine external ointment 5 %.....	145
ILARIS.....	111	lidocaine external patch 5 %.....	146
ILUMYA.....	112	lidocaine hcl urethral/mucosal external prefilled syringe.....	145
imatinib mesylate.....	101	lidocaine-prilocaine external cream .....	145
IMBRUVICA.....	113	LIVMARLI.....	147
INBRIJA.....	114	LONSURF.....	148
INCRELEX.....	115	LORBRENA .....	149
INFLECTRA.....	116, 117	LUMAKRAS .....	151
INFLIXIMAB.....	229, 230	LUMIZYME.....	152
INGREZZA ORAL CAPSULE 40 MG, 60 MG, 80 MG.....	118	LUPRON DEPOT (1-MONTH) .....	154
INLYTA.....	119	LUPRON DEPOT (3-MONTH) .....	154
INQOVI.....	120	LUPRON DEPOT (4-MONTH) INTRAMUSCULAR KIT 30MG .....	154
INREBIC .....	121	LUPRON DEPOT (6-MONTH) INTRAMUSCULAR KIT 45MG .....	154
INTRON A.....	122	LUPRON DEPOT-PED (1-MONTH) .....	155
INTRON A INJECTION SOLUTION 1000000 UNIT/ML, 6000000 UNIT/ML .....	122	LUPRON DEPOT-PED (3-MONTH).....	155
IRESSA.....	123	LYNPARZA.....	156, 157
isotretinoin oral capsule 10 mg, 20 mg, 30 mg, 40 mg.....	124	<b>M</b>	
ISTURISA .....	126	MAKENA SUBCUTANEOUS.....	158
itraconazole oral.....	259	MAVYRET ORAL PACKET.....	160
ivermectin oral.....	127	MAVYRET ORAL TABLET .....	160
<b>J</b>		MAYZENT ORAL TABLET 0.25 MG, 1 MG, 2 MG.....	161
JAKAFI ORAL TABLET 10 MG, 15 MG, 20 MG, 25 MG, 5 MG .....	130	MAYZENT STARTER PACK ORAL TABLET THERAPY PACK 0.25 MG, 12 X 0.25 MG .....	161
JUXTAPID ORAL CAPSULE 10 MG, 20 MG, 30 MG, 40 MG, 5 MG, 60 MG....	131	megestrol acetate oral suspension 40 mg/ml, 625 mg/5ml .....	104
<b>K</b>		megestrol acetate oral tablet.....	105
KALYDECO .....	132	MEKINIST .....	162
KANJINTI.....	133	MEKTOVI.....	163
KANUMA .....	134	miglustat.....	351
KESIMPTA.....	135	modafinil.....	220, 221
KISQALI FEMARA .....	137	MONJUVI.....	165
KISQALI ORAL TABLET THERAPY PACK 200 MG .....	136	MVASI.....	168, 169
KORLYM.....	138	MYALEPT .....	170
KOSELUGO.....	139	MYCAPSSA .....	171
KYNMOBI .....	141	MYFEMBREE.....	172
KYNMOBI TITRATION KIT.....	141	myorisan .....	124
<b>L</b>		<b>N</b>	
lapatinib ditosylate.....	313	NAGLAZYME.....	173
LEMTRADA .....	142	NATPARA .....	174
lenalidomide.....	237	NERLYNX.....	175
LENVIMA ORAL CAPSULE THERAPY PACK 10 & 4 MG, 10 MG, 10 MG & 2 X 4		NEULASTA.....	176
		NEULASTA ONPRO.....	176

NEXAVAR.....	177	PHESGO.....	212
NEXLETOL.....	178, 179	PIQRAY .....	213
NEXLIZET.....	180, 181	pirfenidone .....	78
NINLARO.....	182	PLEGRIDY.....	167
NOXAFIL ORAL SUSPENSION.....	216	PLEGRIDY STARTER PACK	
NUBEQA.....	184	SUBCUTANEOUS SOLUTION PEN-	
NUCALA SUBCUTANEOUS SOLUTION		INJECTOR .....	167
AUTO-INJECTOR .....	185, 186	PLEGRIDY STARTER PACK	
NUCALA SUBCUTANEOUS SOLUTION		SUBCUTANEOUS SOLUTION	
PREFILLED SYRINGE 100 MG/ML, 40		PREFILLED SYRINGE .....	167
MG/0.4ML .....	185, 186	POLIVY.....	214
NUCALA SUBCUTANEOUS SOLUTION		POMALYST.....	215
RECONSTITUTED .....	185, 186	posaconazole.....	216
NUDEXTA .....	187	premium lidocaine .....	145
NUPLAZID.....	188	PRIVIGEN.....	128, 129
<b>O</b>		PROCRIPT.....	74, 75
OCREVUS.....	190	PROCYSBI ORAL CAPSULE DELAYED	
OCTAGAM INTRAVENOUS SOLUTION 1		RELEASE.....	217
GM/20ML, 10 GM/100ML, 10 GM/200ML,		PROLASTIN-C INTRAVENOUS SOLUTION	
2 GM/20ML, 2.5 GM/50ML, 20		RECONSTITUTED .....	14
GM/200ML, 25 GM/500ML, 5 GM/100ML,		PROMACTA.....	218, 219
5 GM/50ML.....	128, 129	PULMOZYME.....	222
octreotide acetate injection .....	247	pyrimethamine oral .....	56
ODOMZO.....	191	PYRUKYND ORAL TABLET 20 MG, 5 MG,	
OFEV.....	192, 193	50 MG .....	223
ONUREG.....	194	PYRUKYND TAPER PACK.....	223
OPSUMIT .....	195	<b>Q</b>	
OPZELURA.....	196	QINLOCK.....	224
ORENCIA .....	197, 198	quinine sulfate oral.....	225
ORENCIA CLICKJECT.....	198	<b>R</b>	
ORENITRAM ORAL TABLET EXTENDED		RADICAVA ORS .....	226
RELEASE 0.25 MG, 1 MG, 2.5 MG, 5		RADICAVA ORS STARTER KIT .....	226
MG.....	199	RAVICTI.....	227
ORGOVYX.....	200	REBIF .....	166
ORLISSA ORAL TABLET 150 MG, 200 MG		REBIF REBIDOSE.....	166
.....	201	REBIF REBIDOSE TITRATION PACK..	166
ORKAMBI ORAL PACKET .....	203	REBIF TITRATION PACK.....	166
ORKAMBI ORAL TABLET .....	202	RECORLEV .....	228
OSPHENA .....	204	REMICADE .....	229, 230
oxandrolone oral tablet 10 mg, 2.5 mg..	205	RENFLEXIS.....	231, 232
OXBRYTA ORAL TABLET SOLUBLE...	206	REPATHA.....	233, 234
OXLUMO.....	207	REPATHA PUSHTRONEX SYSTEM...	233,
<b>P</b>		234	
PALFORZIA ORAL PACKET 300 MG...	208	REPATHA SURECLICK.....	233, 234
PANZYGA.....	128, 129	RETEVMO .....	235
PEGASYS.....	209	REVLIMID.....	237
PEGASYS PROCLICK SUBCUTANEOUS		REZUROCK.....	238
SOLUTION AUTO-INJECTOR 180		riluzole .....	239
MCG/0.5ML.....	209		
PEMAZYRE .....	210		



RINVOQ ORAL TABLET EXTENDED RELEASE 24 HOUR 15 MG, 30 MG, 45 MG.....	240, 241
ROMIDEPSIN INTRAVENOUS SOLUTION .....	125
ROZLYTREK .....	242
RUBRACA .....	243
RUXIENCE .....	244
RYDAPT .....	245
<b>S</b>	
sajazir .....	91
sapropterin dihydrochloride.....	140
SARCLISA .....	248
SCSEMBLIX ORAL TABLET 20 MG, 40 MG .....	249
SECUADO .....	251
SIGNIFOR.....	252
SIGNIFOR LAR.....	253
sildenafil citrate oral tablet 20 mg.....	236
SIMPONI ARIA.....	254
SKYRIZI.....	255
SKYRIZI (150 MG DOSE).....	255
SKYRIZI PEN.....	255
SKYTROFA.....	256
sofosbuvir-velpatasvir .....	72
SOMATULINE DEPOT SUBCUTANEOUS SOLUTION 120 MG/0.5ML, 60 MG/0.2ML, 90 MG/0.3ML.....	257
SOMAVERT.....	258
sorafenib tosylate .....	177
SPRAVATO (56 MG DOSE) .....	260
SPRAVATO (84 MG DOSE) .....	260
SPRYCEL .....	261
STELARA .....	262, 263, 264
STIVARGA.....	265
STRENSIQ.....	266
STRIANT BUCCAL 30 MG .....	296, 297
sunitinib malate .....	268
SUPPRELIN LA .....	267
SUTENT .....	268
SYLATRON SUBCUTANEOUS KIT 200 MCG, 300 MCG, 600 MCG .....	269
SYMDEKO ORAL TABLET THERAPY PACK 100-150 & 150 MG, 50-75 & 75 MG.....	270
SYMLINPEN 120.....	271
SYMLINPEN 60 .....	271
SYNAGIS.....	272, 273
SYNDROS .....	274
SYNRIBO.....	275

<b>T</b>	
TABRECTA.....	277
tadalafil (pah).....	5
tadalafil oral tablet 2.5 mg, 5 mg .....	40
TAFINLAR.....	279
TAGRISSO ORAL TABLET 40 MG, 80 MG .....	280
TALTZ.....	281, 282
TALZENNA.....	283
TARGRETIN EXTERNAL .....	285
TARPEYO.....	286
TASIGNA .....	287
TAVALISSE.....	288
TAVNEOS.....	289
TAZVERIK.....	290
TEGSEDI .....	292
TEPMETKO .....	293
TERIPARATIDE (RECOMBINANT).....	294, 295
testosterone cypionate intramuscular ...	296, 297
testosterone enanthate intramuscular...	298, 299
testosterone transdermal gel 12.5 mg/act (1%), 20.25 mg/1.25gm (1.62%), 20.25 mg/act (1.62%), 25 mg/2.5gm (1%), 40.5 mg/2.5gm (1.62%), 50 mg/5gm (1%)	296, 297
tetrabenazine.....	341
THALOMID.....	300
TIBSOVO.....	301
TRAZIMERA.....	304
TRELSTAR MIXJECT INTRAMUSCULAR SUSPENSION RECONSTITUTED 11.25 MG, 22.5 MG.....	305
TREMFYA.....	306
tretinoin external cream 0.025 %, 0.05 % .....	302
trientine hcl.....	276
TRIKAFTA.....	307
TRIPTODUR .....	308
TRODELVY.....	309
TRUSELTIQ (100MG DAILY DOSE).....	310
TRUSELTIQ (125MG DAILY DOSE).....	310
TRUSELTIQ (50MG DAILY DOSE).....	310
TRUSELTIQ (75MG DAILY DOSE).....	310
TUKYSA.....	311
TURALIO .....	312
TYKERB.....	313
TYMLOS.....	314
TYSABRI.....	315, 316

<b>U</b>			
UBRELVY .....	317	XELJANZ XR.....	339, 340
UDENYCA .....	318	XEMBIFY .....	250
UKONIQ ORAL TABLET 200 MG.....	319	XERMELO.....	342
<b>V</b>		XGEVA.....	343
VALCHLOR.....	320	XIFAXAN.....	344
VARIZIG .....	321	XOLAIR.....	345, 346
VENCLEXTA.....	323	XOSPATA .....	347
VENCLEXTA STARTING PACK.....	323	XPOVIO (100 MG ONCE WEEKLY).....	348
VENTAVIS .....	324	XPOVIO (40 MG ONCE WEEKLY) .....	348
VERZENIO.....	325	XPOVIO (40 MG TWICE WEEKLY) .....	348
vigabatrin .....	246	XPOVIO (60 MG ONCE WEEKLY) .....	348
vigadrone .....	246	XPOVIO (60 MG TWICE WEEKLY) .....	348
VIJOICE ORAL TABLET THERAPY PACK		XPOVIO (80 MG ONCE WEEKLY) .....	348
125 MG, 200 & 50 MG, 50 MG.....	326	XPOVIO (80 MG TWICE WEEKLY) .....	348
VIMIZIM.....	327	XTANDI.....	349
VITRAKVI .....	328	XYREM .....	350
VIZIMPRO.....	329	<b>Z</b>	
VONJO .....	330	ZEJULA.....	352
voriconazole intravenous.....	331	ZELBORAF .....	353
VOSEVI .....	332	ZEMAIRA.....	13
VOTRIENT.....	333	zenatane .....	124
VOXZOGO.....	334	ZEPOSIA .....	354
VUMERITY .....	335	ZEPOSIA 7-DAY STARTER PACK.....	354
VUMERITY (STARTER) ORAL CAPSULE		ZEPOSIA STARTER KIT .....	354
DELAYED RELEASE 231 MG .....	335	ZEPZELCA.....	355
VYNDAMAX.....	278	ZIRABEV.....	356, 357
VYNDAQEL .....	278	ZOKINVY .....	358
<b>W</b>		ZOLADEX SUBCUTANEOUS IMPLANT	
WELIREG .....	336	10.8 MG, 3.6 MG .....	359
<b>X</b>		ZOLINZA.....	360
XALKORI .....	337	ZORBTIVE .....	361
XCOPRI.....	338	ZYDELIG.....	362
XELJANZ.....	339, 340	ZYKADIA.....	363
		ZYKADIA ORAL CAPSULE 150 MG .....	363