ABIRATERONE

Products Affected

- *abiraterone acetate*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Castration-resistant metastatic prostate cancer and used in combination with prednisone, or B.) High risk, castration-sensitive metastatic prostate cancer and used in combination with prednisone
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ACITRETIN

Products Affected

- *acitretin*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Severely impaired liver or kidney function, B.) Chronic abnormally elevated blood lipid values, C.) Concomitant use of methotrexate or tetracyclines, D.) Pregnancy
Required Medical Information	Diagnosis of severe, recalcitrant psoriasis (including plaque, guttate, erythrodermic palmar- plantar and pustular) AND patient must have tried and failed, contraindication or intolerance to one formulary first line agent (e.g., Topical Corticosteroids (betamethasone, fluocinonide, desoximetasone),Topical Calcipotriene/Calcitriol, Topical Calcipotriene, OR Topical Tazarotene)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ACTIMMUNE

Products Affected

- ACTIMMUNE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Chronic granulomatous disease for use in reducing the frequency and severity of serious infections, or B.) Severe, malignant osteopetrosis (SMO)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ADEMPAS

Products Affected

- ADEMPAS

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant administration with nitrates or nitric oxide donors (such as amyl nitrate) in any form, B.) Concomitant administration with phosphodiesterase inhibitors, including specific PDE-5 inhibitors (such as sildenafil, tadalafil, or vardenafil) or non-specific PDE inhibitors (such as dipyridamole or theophylline), C.) Pregnancy, or D.) Patients with pulmonary hypertension associated with idiopathic interstitial pneumonia
Required Medical Information	Diagnosis of one of the following A.) Pulmonary arterial hypertension (WHO group I) and diagnosis was confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.), or B.) Chronic thromboembolic pulmonary hypertension (CTEPH, WHO group 4) and patient has persistent or recurrent disease after surgical treatment (e.g., pulmonary endarterectomy) or has CTEPH that is inoperable (Female patients must be enrolled in the ADEMPAS REMS program)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	Initial: 6 months, Renewal: 12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

AFINITOR

Products Affected

- *everolimus oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Hypersensitivity to everolimus or excipients, or B.) Hypersensitivity to rapamycin derivatives (e.g. sirolimus)
Required Medical Information	Diagnosis of one of the following A.) Renal angiomyolipoma and tuberous sclerosis complex (TSC) not requiring immediate surgery, B.) Advanced hormone receptor-positive, HER2 negative breast cancer in postmenopausal women and taken in combination with exemestane, after failure with letrozole or anastrozole, C.) Progressive, well-differentiated, nonfunctional neuroendocrine tumors of gastrointestinal or lung origin and disease is unresectable, locally advanced, or metastatic, D.) Pancreatic progressive neuroendocrine tumors and disease is unresectable, locally advanced, or metastatic, E.) Advanced renal cell carcinoma (RCC) after failure with sunitinib or sorafenib, F.) Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex in patients who are not candidates for curative surgical resection
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ALECENSA

Products Affected

- ALECENSA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of metastatic anaplastic lymphoma kinase (ALK) positive non-small cell lung cancer as detected by an FDA-approved test
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ALOSETRON

Products Affected

- *alosetron hcl*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Constipation, B.) History of Chronic or severe constipation or sequelae from constipation, C.) History of ischemic colitis, intestinal obstruction, stricture, toxic megacolon, GI perforation, adhesions, diverticulitis, Crohns disease, ulcerative colitis, D.) History of severe hepatic impairment, E.) History of impaired intestinal circulation, thrombophlebitis, or hypercoagulable state, or F.) Coadministration with fluvoxamine
Required Medical Information	Diagnosis of irritable bowel syndrome, severe diarrhea-predominant
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ALPHA-1 PROTEINASE INHIBITOR

Products Affected

- PROLASTIN-C INTRAVENOUS SOLUTION RECONSTITUTED

PA Criteria	Criteria Details
Exclusion Criteria	Immunoglobulin A (IgA) deficiency with antibodies against IgA
Required Medical Information	Diagnosis of alpha-1 proteinase inhibitor (alpha-1 antitrypsin) deficiency in adult patients with emphysema
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	12 months
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ALUNBRIG

Products Affected

- ALUNBRIG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of anaplastic lymphoma kinase-positive (ALK) metastatic non-small cell lung cancer (NSCLC)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

AMBRISENTAN

Products Affected

- *ambrisentan*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Pregnancy, or B.) Idiopathic pulmonary fibrosis (IPF), including those with pulmonary hypertension
Required Medical Information	Diagnosis of pulmonary arterial hypertension classified as WHO Group I, confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	Initial: 6 months, Renewal: 12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ARCALYST

Products Affected

- ARCALYST

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Cryopyrin-associated periodic syndromes (CAPS), including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells Syndrome (MWS), B.) Deficiency of interleukin-1 receptor antagonist (DIRA) and patient requires maintenance therapy for remission, or C.) Recurrent pericarditis (RP) and reduction in risk of recurrence
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ARIKAYCE

Products Affected

- ARIKAYCE

PA Criteria	Criteria Details
Exclusion Criteria	Known sensitivity to any aminoglycoside
Required Medical Information	Diagnosis of pulmonary Mycobacterium avium complex (MAC) infection and used as part of a combination antibacterial regimen in treatment refractory patients (greater than 6 months of a multidrug background regimen)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist or pulmonologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

AURYXIA

Products Affected

- AURYXIA

PA Criteria	Criteria Details
Exclusion Criteria	Iron overload syndrome (e.g. hemochromatosis)
Required Medical Information	Diagnosis of hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or nephrologist
Coverage Duration	12 months
Other Criteria	Ferric Citrate is NOT approvable for iron deficiency anemia per Part D law
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

AUSTEDO

Products Affected

- AUSTEDO

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Suicidal ideation and/or untreated or inadequately treated depression, B.) Hepatic impairment, C.) Taking MAOIs, reserpine, or tetrabenazine
Required Medical Information	Diagnosis of one of the following A.) Chorea associated with Huntington's disease (Huntington's chorea), or B.) Tardive dyskinesia
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or psychiatrist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

AYVAKIT

Products Affected

- AYVAKIT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Unresectable or metastatic gastrointestinal stromal tumor, with a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations, or B.) Advanced systemic mastocytosis (AdvSM), including patients with aggressive systemic mastocytosis, systemic mastocytosis with an associated hematological neoplasm, or mast cell leukemia
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

BALVERSA

Products Affected

- BALVERSA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of locally advanced or metastatic urothelial carcinoma with susceptible FGFR3 or FGFR2 genetic alterations and patient has progressed during or following at least one line of prior platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

BENLYSTA

Products Affected

- BENLYSTA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Active, autoantibody-positive, system lupus erythematosus (SLE), or B.) Active lupus nephritis and patient is receiving standard therapy
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist or rheumatologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

BESREMI

Products Affected
- BESREMI

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Existence of, or history of severe psychiatric disorders (severe depression, suicidal ideation, or suicide attempt), B.) Hypersensitivity to interferons including interferon alfa-2b or excipients, C.) Hepatic impairment (Child-Pugh B or C), D.) History or presence of active serious or untreated autoimmune disease, or E.) Immunosuppressed transplant recipients
Required Medical Information	Diagnosis of polycythemia vera
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

BEXAROTENE GEL

Products Affected

- *bexarotene external*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of primary cutaneous T-cell lymphoma (CTCL Stage 1A/1B) and patient had an inadequate response, is intolerant to, or has a contraindication to at least one prior systemic therapy (e.g., corticosteroids) indicated for cutaneous manifestations of CTCL
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

BEXAROTENE ORAL

Products Affected

- *bexarotene oral*

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of cutaneous T-cell lymphoma (CTCL) and patient is not a candidate for or had an inadequate response, is intolerant to, or has a contraindication to at least one prior systemic therapy (e.g., corticosteroids) for cutaneous manifestations of CTCL
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

BOSENTAN

Products Affected

- *bosentan*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant cyclosporine A or glyburide therapy, or B.) Pregnancy
Required Medical Information	Diagnosis of pulmonary arterial hypertension (WHO Group I) and patient has New York Heart Association (NYHA) Functional Class II-IV, confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e. g., patient is frail, elderly, etc.)
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	Initial: 6 months, Renewal: 12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

BOSULIF

Products Affected

- BOSULIF

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) with resistance or inadequate response to prior therapy, or B.) Newly diagnosed chronic phase Philadelphia chromosome-positive (Ph+) CML
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

BRAFTOVI

Products Affected

- BRAFTOVI ORAL CAPSULE 75 MG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) unresectable or metastatic melanoma with documented BRAF V600E or V600K mutation as detected by a FDA-approved test and used in combination with binimetinib, or B.) metastatic colorectal cancer with documented BRAF V600E mutation as detected by a FDA-approved test, patient has received prior therapy, and braftovi used in combination with cetuximab.
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

BRUKINSA

Products Affected

- BRUKINSA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following: A.) mantle cell lymphoma (MCL) and patient has received at least one prior therapy or B.) Treatment of adult patients with Waldenstrom macroglobulinemia or C.) Treatment of adult patients with relapsed or refractory marginal zone lymphoma who have received at least one anti-CD20-based regimen
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

BYLVAY

Products Affected

- BYLVAY
- BYLVAY (PELLETS) ORAL CAPSULE SPRINKLE 200 MCG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of progressive familial intrahepatic cholestasis-associated pruritus
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

CABOMETYX

Products Affected

- CABOMETYX

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Advanced renal cell carcinoma, B.) Advanced hepatocellular carcinoma (HCC) and patient has been previously treated with sorafenib, C.) Advanced renal cell carcinoma and used as first line treatment in combination with nivolumab, or D.) Treatment of adults and pediatric patients 12 years and older with locally advanced or metastatic differentiated thyroid cancer that has progressed following VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

CALQUENCE

Products Affected

- CALQUENCE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Mantle cell lymphoma (MCL) and patient has received at least 1 prior therapy, B.) Chronic lymphocytic leukemia (CLL), or C.) Small lymphocytic lymphoma (SLL)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

CAMZYOS

Products Affected

- CAMZYOS

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) in adult patients
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

CAPRELSA

Products Affected
- CAPRELSA

PA Criteria	Criteria Details
Exclusion Criteria	Congenital long QT syndrome
Required Medical Information	Diagnosis of metastatic or unresectable locally advanced medullary thyroid cancer (MTC) AND disease is symptomatic or progressive
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

CARGLUMIC ACID

Products Affected

- *carglumic acid oral tablet soluble*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) N-acetyl glutamate synthase (NAGS) deficiency with acute or chronic hyperammonemia, or B.) Propionic or methylmalonic acidemia with acute hyperammonemia
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

CAYSTON

Products Affected

- CAYSTON

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of cystic fibrosis (confirmed by appropriate diagnostic or genetic testing) and patient has suspected or confirmed Pseudomonas aeruginosa lung infection
Age Restrictions	7 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

CLOBAZAM

Products Affected

- *clobazam oral suspension*
- *clobazam oral tablet*
- SYMPAZAN

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of seizures associated with Lennox-Gastaut syndrome
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

CNS STIMULANTS

Products Affected

- *armodafinil*
- *modafinil*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Obstructive sleep apnea (OSA) confirmed by sleep lab evaluation, B.) Narcolepsy confirmed by sleep lab evaluation, or C.) Shift work disorder (SWD)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

COMETRIQ

Products Affected

- COMETRIQ (100 MG DAILY DOSE) ORAL KIT 80 & 20 MG
- COMETRIQ (140 MG DAILY DOSE) ORAL KIT 3 X 20 MG & 80 MG
- COMETRIQ (60 MG DAILY DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of progressive, metastatic medullary thyroid cancer
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

COPIKTRA

Products Affected

- COPIKTRA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Relapsed or refractory chronic lymphocytic leukemia, or B.) Small lymphocytic lymphoma
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

CORLANOR

Products Affected

- CORLANOR ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Decompensated acute heart failure, B.) hypotension (i.e. blood pressure less than 90/50 mmHg), C.) sick sinus syndrome or sinoatrial block or 3rd degree AV block (unless a functioning demand pacemaker is present), D.) bradycardia (i.e., resting heart rate less than 60 bpm prior to treatment), E.) Severe hepatic impairment (Child-Pugh C), F.) Pacemaker dependent (heart rate maintained exclusively by the pacemaker), G.) Concomitant use of strong CYP3A4 inhibitors
Required Medical Information	Diagnosis of one of the following A.) stable, symptomatic chronic heart failure with left ventricular ejection fraction 35% or less, who are in sinus rhythm with resting heart rate 70 beats per minute or more and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use, or B.) stable, symptomatic heart failure due to dilated cardiomyopathy in patients who are in sinus rhythm with an elevated heart rate
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

COSENTYX

Products Affected

- COSENTYX (300 MG DOSE)
- COSENTYX SENSOREADY (300 MG)
- COSENTYX SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 75 MG/0.5ML

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Ankylosing spondylitis and patient has trial and failure, contraindication, or intolerance to two preferred products, (i.e. Humira, Enbrel), B.) Moderate to severe plaque psoriasis in adults and patient has trail and failure, contraindication, or intolerance to two preferred products, (i.e. Humira, Enbrel, Skyrizi, Stelara), C.) Moderate to severe plaque psoriasis in patients 6 years to less than 18 years of age and patient has failed or is intolerant to Enbrel and Stelara, D.) Active psoriatic arthritis in adult patient and has trial and failure, contraindication, or intolerance to two preferred products, (i.e. Humira, Enbrel, Stelara), E.) Active psoriatic arthritis in patients 2 years to less than 18 years of age, F.) Non-radiographic axial spondyloarthritis or G.) Active enthesitis-related arthritis
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Screening for latent tuberculosis infection is required prior to initiation of treatment
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

COTELLIC

Products Affected

- COTELLIC

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of unresectable or metastatic malignant melanoma with BRAF V600E OR V600K mutation, and documentation of combination therapy with vemurafenib (Zelboraf)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

CYSTEAMINE OPHTH

Products Affected

- CYSTADROPS
- CYSTARAN

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of cystinosis and patient has corneal cystine crystal accumulation
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

DALFAMPRIDINE

Products Affected

- *dalfampridine er*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) History of seizure. B.) Moderate or severe renal impairment (creatinine clearance less than or equal to 50 mL/minute)
Required Medical Information	Diagnosis of multiple sclerosis and patient must demonstrate sustained walking impairment, but with the ability to walk 25 feet (with or without assistance) prior to starting dalfampridine
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

DAURISMO

Products Affected
- DAURISMO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of newly diagnosed acute myeloid leukemia (AML) and used in combination with cytarabine in patients 75 years of age or older OR in patients that have comorbidities that preclude use of intensive induction chemotherapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

DEFERASIROX

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Creatinine clearance less than 40 mL/min, B.) Poor performance status, C.) Platelet count less than 50 x 10(9)/L, D.) Advanced malignancy, E.) High-risk myelodysplastic syndrome (MDS)
Required Medical Information	Diagnosis of one of the following A.) Chronic iron overload in patients with non-transfusion-dependent thalassemia syndromes who have liver iron concentrations of at least 5 mg Fe/g dry weight AND serum ferritin level greater than 300 mcg/L, or B.) Chronic iron overload due to blood transfusions (transfusion hemosiderosis) as evidenced by transfusion of at least 100 mL/kg packed red blood cells AND serum ferritin level greater than 1000 mcg/L
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

DEFERIPRONE

Products Affected

- *deferiprone*
- FERRIPROX ORAL SOLUTION
- FERRIPROX ORAL TABLET 1000 MG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Must meet all of the following 1.) Diagnosis of transfusional iron overload due to thalassemia syndromes, sickle cell disease, or other anemias, 2.) Patient has failed prior chelation therapy, and 3.) Patient has an absolute neutrophil count greater than 1.5 x 10(9)/L
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

DIACOMIT

Products Affected

- DIACOMIT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of severe myoclonic epilepsy in infancy (Dravet syndrome) in patients taking clobazam
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

DICLOFENAC TOPICAL

Products Affected

- *diclofenac sodium external gel 3 %*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of Actinic keratosis
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

DIMETHYL FUMARATE

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

DRONABINOL

Products Affected

- *dronabinol*

PA Criteria	Criteria Details
Exclusion Criteria	Sesame oil hypersensitivity
Required Medical Information	Diagnosis of one of the following A.) Anorexia associated to AIDS, or B.) Chemotherapy-induced nausea and vomiting
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	6 months
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

DROXIDOPA

Products Affected

- *droxidopa*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of symptomatic neurogenic orthostatic hypotension (nOH) caused by primary autonomic failure (e.g., Parkinson disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

DUPIXENT

Products Affected

- DUPIXENT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Moderate to severe atopic dermatitis and patient has trial/failure, contraindication, or intolerance to two of the following 1.) Topical corticosteroid, and/or 2.) Topical calcineurin inhibitor, B.) Eosinophilic phenotype or oral corticosteroid- dependent moderate to severe asthma and used as an adjunct treatment, C.) Chronic rhinosinusitis with nasal polyposis and used as an adjunct treatment, or D.) Eosinophilic esophagitis
Age Restrictions	6 months of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

EMGALITY

Products Affected

- EMGALITY

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Chronic or episodic migraine disorder and patient has documented trial, inadequate response, or contraindication to at least 2 generic formulary drugs used for migraine prevention (i.e., propranolol, topiramate, divalproex, timolol), or B.) Episodic cluster headache
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

EMSAM

Products Affected

- EMSAM

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant use with any of the following: SSRIs, SNRIs, clomipramine, imipramine, meperidine, tramadol, methadone, pentazocine, propoxyphene, dextromethorphan, carbamazepine, or B.) Pheochromocytoma
Required Medical Information	Diagnosis of major depressive disorder and patient had trial of at least 2 generic oral antidepressants from differing classes (at least one should be from the following list: selective serotonin reuptake inhibitors, serotonin and norepinephrine reuptake inhibitors, mirtazapine, or bupropion unless contraindicated), unless unable to take any oral medication AND Patient had an adequate washout period (for patients previously on agents requiring a washout period)
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ENBREL

Products Affected

- ENBREL MINI
- ENBREL SUBCUTANEOUS SOLUTION 25 MG/0.5ML
- ENBREL SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- ENBREL SURECLICK SUBCUTANEOUS SOLUTION AUTO-INJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis, B.) Moderate to severe polyarticular juvenile idiopathic arthritis, C.) Psoriatic arthritis, D.) Ankylosing spondylitis, or E.) Moderate to severe chronic plaque psoriasis in patients who are candidates for systemic therapy or phototherapy
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Screening for latent tuberculosis infection is required prior to initiation of treatment
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ENDARI

Products Affected

- ENDARI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of sickle cell disease AND one of the following 1.) Patient has acute complications and is being treated with Hydroxyurea, or 2.) Patient has acute complications and is unable to tolerate Hydroxyurea
Age Restrictions	5 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

EPIDIOLEX

Products Affected

- EPIDIOLEX

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Lennox-Gastaut syndrome, B.) Severe myoclonic epilepsy in infancy (Dravet syndrome), or C.) Seizures associated with tuberous sclerosis complex
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

EPOETIN THERAPY

Products Affected

- RETACRIT INJECTION SOLUTION 10000 UNIT/ML, 10000 UNIT/ML(1ML), 2000 UNIT/ML, 20000 UNIT/ML, 3000 UNIT/ML, 4000 UNIT/ML, 40000 UNIT/ML

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Non-myeloid neoplastic disease and utilized for the treatment of chemotherapy induced anemia, B.) HIV infection and utilized for the treatment of zidovudine induced anemia, C.) Chronic kidney disease resulting in anemia, or D.) High risk surgical candidate status at risk for perioperative blood loss and undergoing elective, noncardiac, or nonvascular surgery
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ERIVEDGE

Products Affected

- ERIVEDGE

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of one of the following A.) Metastatic basal cell carcinoma, or B.) Locally advanced basal cell carcinoma that has recurred following surgery or the patient is not a candidate for surgery or radiation
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ERLEADA

Products Affected

- ERLEADA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Nonmetastatic, castration-resistant prostate cancer, or B.) Metastatic, castration-sensitive prostate cancer
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ERLOTINIB

Products Affected
- *erlotinib hcl*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Locally advanced, unresectable, or metastatic pancreatic cancer and erlotinib will be used in combination with gemcitabine, B.) Locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility AND one of the following 1.) Erlotinib will be used as first-line treatment, 2.) Failure with at least one prior chemotherapy regimen, or 3.) No evidence of disease progression after four cycles of first-line platinum-based chemotherapy and erlotinib will be used as maintenance treatment
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ESBRIET

Products Affected

- ESBRIET ORAL CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of idiopathic pulmonary fibrosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

EVEROLIMUS SUSPENSION

Products Affected

- *everolimus oral tablet soluble*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Hypersensitivity to everolimus or excipients, or B.) Hypersensitivity to rapamycin derivatives (e.g. sirolimus)
Required Medical Information	Diagnosis of one of the following A.) Tuberous sclerosis complex (TSC)-associated partial-onset seizures, or B.) Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex in patients who are not candidates for curative surgical resection
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

EVRYSDI

Products Affected

- EVRYSDI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of spinal muscular atrophy (SMA)
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

EXKIVITY

Products Affected

- EXKIVITY

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of metastatic non-small cell lung cancer (NSCLC) with EGFR exon 20 insertion mutations (as confirmed by an FDA-approved test) AND whose disease has progressed on or after platinum-based chemotherapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

FEBUXOSTAT

Products Affected

- *febuxostat*

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of azathioprine or mercaptopurine
Required Medical Information	Diagnosis of Gout and all of the following 1.) documented inadequate treatment response, adverse event, or contraindication to maximally titrated dose of Allopurinol, and 2.) patients with established cardiovascular disease, prescriber attests that benefit of treatment outweighs the risk of treatment
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

FENTANYL ORAL

Products Affected

- *fentanyl citrate buccal lozenge on a handle*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Management of acute or postoperative pain (including headache/migraine, dental pain, and use in the emergency room), B.) Use in opioid non-tolerant patients, C.) Known or suspected gastrointestinal obstruction, including paralytic ileus, D.) Acute or severe bronchial asthma and used in an unmonitored setting (absence of resuscitative equipment)
Required Medical Information	Must meet all of the following 1.) Diagnosis of cancer-related breakthrough pain, 2.) Patient is currently receiving/tolerant to around-the-clock opioid therapy for persistent cancer pain, and 3.) Patient and prescriber are enrolled in the TIRF REMS Access Program
Age Restrictions	16 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

FENTANYL PATCH

Products Affected

- *fentanyl*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Management of acute or postoperative pain (including headache/migraine, dental pain, and use in the emergency room), B.) Mild or intermittent pain management, C.) Use in opioid non-tolerant patients, D.) Known or suspected gastrointestinal obstruction, including paralytic ileus, E.) Acute or severe bronchial asthma and used in an unmonitored setting (absence of resuscitative equipment)
Required Medical Information	Must meet all of the following 1.) Patient is opioid tolerant (taking for one week or longer at least 60mg of morphine or equivalent daily) and 2.) Patient has tried at least one extended release oral opioids or is unable to take extended release oral opioids secondary to allergy, adverse events, swallowing difficulty, or uncontrollable nausea/vomiting
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

FINTEPLA

Products Affected

- FINTEPLA

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant use of an MAOI, or B.) Use within 14 days of discontinuing an MAOI
Required Medical Information	Diagnosis of Severe myoclonic epilepsy in infancy (Dravet syndrome) or seizures associated with Lennox-Gastaut syndrome
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

FIRMAGON

Products Affected

- FIRMAGON (240 MG DOSE)
- FIRMAGON SUBCUTANEOUS SOLUTION RECONSTITUTED 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of advanced or metastatic prostate cancer
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

FOTIVDA

Products Affected

- FOTIVDA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of relapsed or refractory advanced renal cell cancer (RCC) following 2 or more prior systemic therapies
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

GATTEX

Products Affected

- GATTEX

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of short bowel syndrome and patient is dependent on parenteral support
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

GAVRETO

Products Affected

- GAVRETO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Metastatic RET fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test, B.) Advanced or metastatic RET-mutant medullary thyroid cancer and patient requires systemic therapy, or C.) Advanced or metastatic RET fusion-positive thyroid and patient requires systemic therapy and is radioactive iodine-refractory, when radioactive iodine is appropriate
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

GILENYA

Products Affected

- GILENYA ORAL CAPSULE 0.5 MG

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Recent (within the last 6 months) occurrence of: myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure, B.) History or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker, C.) Baseline QTC interval greater than or equal to 500 milliseconds, D.) Receiving concurrent treatment with Class Ia or Class III anti-arrhythmic drugs (quinidine, procainamide, amiodarone, sotalol)
Required Medical Information	Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis
Age Restrictions	10 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

GILOTRIF

Products Affected

- GILOTRIF

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Metastatic non-small cell lung cancer (NSCLC) in patients whose tumors have nonresistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test, or B.) Metastatic squamous NSCLC with progression after platinum-based chemotherapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

GLATIRAMER

Products Affected

- COPAXONE SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- *glatiramer acetate*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

GROWTH HORMONE

Products Affected

- OMNITROPE SUBCUTANEOUS SOLUTION CARTRIDGE
- OMNITROPE SUBCUTANEOUS SOLUTION RECONSTITUTED

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Use for growth promotion in pediatric patients with closed epiphyses, B.) Acute critical illness caused by complications following open-heart or abdominal surgery, multiple accidental trauma, or acute respiratory failure, C.) Active malignancy, D.) Active proliferative or severe nonproliferative diabetic retinopathy, E.) Prader-Willi Syndrome in patients who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment
Required Medical Information	Diagnosis of pediatric indication: A.) GHD and bone age at least 1 year or 2 standard deviations (SD) delayed compared with chronological age and 2 stim tests with peak GH secretion below 10 ng/mL or IGF-1/IGFBP3 level more than 2 SDS below mean if CNS pathology, h/o irradiation, or proven genetic cause, B.) SGA and birth weight or length 2 or more SDS below mean for gestational age and fails to manifest catch up growth by age 2 (height 2 or more SDS below mean for age and gender), C.) CRI and nutritional status has been optimized, metabolic abnormalities have been corrected, and patient has not had renal transplant D.) SHOX deficiency or Noonan syndrome E.) PWS confirmed by genetic testing, F.) Turner Syndrome confirmed by chromosome analysis. For GHD, CRI, SHOX deficiency, Noonan syndrome, and PWS one of the following height more than 3 SDS below mean for age and gender, or height more than 2 SDS below mean with GV more than 1 SDS below mean, or GV over 1 year 2 SDS below mean. OR Diagnosis of an adult indication: A.) childhood- or adult-onset GHD confirmed by 2 standard GH stim tests (provide assay): 1 test must be insulin tolerance test (ITT) with blood glucose nadir less than 40 mg/dL (2.2 mmol/L). If contraindicated, use a standardized stim test (i.e. arginine plus GH releasing hormone [preferred], glucagon, arginine), B.) GHD with at least 1 other pituitary hormone deficiency and failed at least 1 GH stim test (ITT preferred), C.) GHD with panhypopituitarism (3 or more pituitary hormone deficiencies), D.) GHD with irreversible hypothalamic-pituitary structural lesions due to tumors, surgery or

PA Criteria	Criteria Details
	radiation of pituitary or hypothalamus region AND a subnormal IGF-1 (after at least 1 month off GH therapy) AND Objective evidence of GHD complications, such as: low bone density, increased visceral fat mass, or cardiovascular complications AND Completed linear growth (GV less than 2 cm/year) AND GH has been discontinued for at least 1 month (if previously receiving GH)
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an Endocrinologist or Nephrologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

HEPATITIS B

Products Affected

- *adefovir dipivoxil*
- BARACLUDE ORAL SOLUTION
- *entecavir*
- VEMLIDY

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of chronic hepatitis B and all of the following 1.) Patient has or had evidence of viral replication prior to initiation, 2.) Patient has evidence of persistent elevations in serum aminotransferase (ALT or AST) or histologically active disease, and 3.) Patient is receiving anti-retroviral therapy if the patient has HIV co-infection
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

HEPATITIS C

Products Affected

- MAVYRET
- *sofosbuvir-velpatasvir*
- VOSEVI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of HCV genotype, subtype and quantitative HCV RNA (viral load) testing any time prior to therapy. Must document cirrhosis status, prior treatment history (if any), and planned duration of treatment. All genotypes will require trial/failure, contraindication to, or intolerance to Mavyret or Sofosbuvir-Velpatasvir prior to the approval of Vosevi.
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist
Coverage Duration	Duration of approval per AASLD Guidelines
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

HRM ANTIPSYCHOTIC

Products Affected

- *aripiprazole*
- *asenapine maleate*
- CAPLYTA
- *chlorpromazine hcl oral*
- *clozapine*
- FANAPT
- FANAPT TITRATION PACK
- *fluphenazine hcl injection*
- *fluphenazine hcl oral*
- *haloperidol lactate*
- *haloperidol oral*
- LATUDA
- *loxapine succinate oral*
- LYBALVI
- *molindone hcl*
- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET 10 MG
- *olanzapine*
- *paliperidone er*
- *perphenazine oral*
- *quetiapine fumarate er*
- *quetiapine fumarate oral tablet 100 mg, 200 mg, 25 mg, 300 mg, 400 mg, 50 mg*
- REXULTI
- *risperidone*
- SECUADO
- *thioridazine hcl oral*
- *thiothixene oral*
- *trifluoperazine hcl oral*
- VERSACLOZ
- VRAYLAR
- *ziprasidone hcl*
- *ziprasidone mesylate*

PA Criteria	Criteria Details
Exclusion Criteria	Diagnosis of dementia-related psychosis, in the absence of other compendia supported indications not otherwise excluded from Part D
Required Medical Information	For patients greater than or equal to 65 years old, who have had at least 1 claim for any dementia medication (donepezil, galantamine, rivastigmine, memantine or Namzaric) within the past 120 days, a coverage determination will be approved for FDA-approved indications not otherwise excluded from Part D.
Age Restrictions	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
Prescriber Restrictions	None
Coverage Duration	12 months

PA Criteria	Criteria Details
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

HUMIRA

Products Affected

- HUMIRA PEDIATRIC CROHNS START SUBCUTANEOUS PREFILLED SYRINGE KIT 80 MG/0.8ML, 80 MG/0.8ML & 40MG/0.4ML
- HUMIRA PEN SUBCUTANEOUS PEN-INJECTOR KIT
- HUMIRA PEN-CD/UC/HS STARTER
- HUMIRA PEN-PEDIATRIC UC START
- HUMIRA PEN-PS/UV/ADOL HS START SUBCUTANEOUS PEN-INJECTOR KIT 40 MG/0.8ML
- HUMIRA PEN-PSOR/UVEIT STARTER
- HUMIRA SUBCUTANEOUS PREFILLED SYRINGE KIT 10 MG/0.1ML, 20 MG/0.2ML, 40 MG/0.4ML, 40 MG/0.8ML

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis, B.) Moderate to severe polyarticular juvenile idiopathic arthritis, C.) Psoriatic arthritis, D.) Ankylosing spondylitis, E.) Moderate to severe chronic plaque psoriasis in patients who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate, F.) Moderate to severe Crohn's disease in patients who have had an inadequate response to conventional therapy, G.) Moderate to severe ulcerative colitis in patients who have had an inadequate response to immunosuppressants (e.g. corticosteroids, azathioprine), H.) Non-infectious uveitis (including intermediate, posterior, and panuveitis), or I.) Moderate to severe hidradenitis suppurativa
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Screening for latent tuberculosis infection is required prior to initiation of treatment

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

HYFTOR

Products Affected

- HYFTOR

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of facial angiofibroma associated with tuberous sclerosis
Age Restrictions	6 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

IBRANCE

Products Affected

- IBRANCE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Advanced or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer used in combination with fulvestrant and disease has progressed following endocrine therapy, or B.) Advanced or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer used in combination with an aromatase inhibitor in postmenopausal women or men
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ICATIBANT

Products Affected

- FIRAZYR

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following and used as treatment for acute attacks A.) Hereditary angioedema (HAE) with C1 inhibitor deficiency (Type 1) confirmed by laboratory testing, or B.) HAE with C1 inhibitor dysfunction (Type 2) confirmed by laboratory testing, or C.) HAE with normal C1 inhibitor (Type 3) confirmed by laboratory testing and one of the following 1.) Positive test for an F12, angiopoietin-1, or plasminogen gene mutation, or 2.) Family history of angioedema and the angioedema was refractory to a trial of an antihistamine for at least one month
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an allergist, hematologist, or immunologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ICATIBANT - GENERIC

Products Affected

- *icatibant acetate*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following and used as treatment for acute attacks A.) Hereditary angioedema (HAE) with C1 inhibitor deficiency (Type 1) confirmed by laboratory testing, or B.) HAE with C1 inhibitor dysfunction (Type 2) confirmed by laboratory testing, or C.) HAE with normal C1 inhibitor (Type 3) confirmed by laboratory testing and one of the following 1.) Positive test for an F12, angiopoietin-1, or plasminogen gene mutation, or 2.) Family history of angioedema and the angioedema was refractory to a trial of an antihistamine for at least one month. Requests for generic Icatibant require trial and failure or contraindication to brand Firazyr.
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an allergist, hematologist, or immunologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ICLUSIG

Products Affected

- ICLUSIG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML) in adult patients who are T315I-positive or for whom no other tyrosine kinase inhibitor therapy is indicated, B.) Chronic phase, chronic myeloid leukemia (CML) in adult patients with resistance or intolerance to at least two prior kinase inhibitors, or C.) Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) in adult patients who are T315I-positive or for whom no other tyrosine kinase inhibitor therapy is indicated
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

IDHIFA

Products Affected
- IDHIFA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase 2 (IDH2) mutation as detected by an FDA approved test
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

IMATINIB

Products Affected

- *imatinib mesylate*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML), B.) Ph+ acute lymphoblastic leukemia (ALL), C.) Gastrointestinal stromal tumor (GIST) where patient has documented c-KIT (CD117) positive unresectable or metastatic malignant GIST or patient had resection of c-KIT positive GIST and imatinib will be used as an adjuvant therapy, D.) Dermatofibrosarcoma protuberans that is unresectable, recurrent, or metastatic, E.) Hypereosinophilic syndrome or chronic eosinophilic leukemia, F.) Myelodysplastic syndrome 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
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

IMBRUVICA

Products Affected
- IMBRUVICA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Mantle cell lymphoma (MCL) and patient has received at least one prior therapy, B.) Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL), C.) Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion, D.) Waldenstrom's macroglobulinemia (WM), E.) Marginal zone lymphoma (MZL) and patient requires systemic therapy and has received at least one prior anti-CD20-based therapy, or F.) Chronic graft vs host disease (cGVHD) after failure of a least one first-line corticosteroid therapy
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

INBRIJA

Products Affected

- INBRIJA

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concurrent use with nonselective monoamine oxidase inhibitors (MAOIs) (e.g. phenelzine and tranylcypromine), B.) Recent use (within 2 weeks) with a nonselective MAOI
Required Medical Information	Must meet all of the following 1.) Diagnosis of Parkinson's disease and 2.) Patient is on concurrent therapy with carbidopa/levodopa
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

INCRELEX

Products Affected
- INCRELEX

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Active or suspected malignancy, B.) Use for growth promotion in patients with closed epiphyses, or C.) Intravenous administration
Required Medical Information	Diagnosis of one of the following A.) Severe primary insulin-like growth factor-1 (IGF-1) deficiency and utilized for pediatric treatment of growth failure, or B.) Growth hormone (GH) gene deletion and patient has developed neutralizing antibodies to GH and utilized for pediatric treatment of growth failure
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

INLYTA

Products Affected

- INLYTA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Advanced renal cell carcinoma and patient failed one or more systemic therapies for renal cell carcinoma (e.g., sunitinib-, bevacizumab-, temsirolimus-, or cytokine-containing regimens), or B.) Advanced renal cell carcinoma and used as first-line therapy in combination with avelumab or pembrolizumab
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

INQOVI

Products Affected

- INQOVI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

INREBIC

Products Affected

- INREBIC

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF).
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

INTRON A

Products Affected

- INTRON A INJECTION SOLUTION RECONSTITUTED 10000000 UNIT, 50000000 UNIT

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Autoimmune hepatitis, B.) Decompensated liver disease, C.) Pregnancy, D.) When used in combination with ribavirin: hemoglobinopathies (e.g., thalassemia major, sickle cell anemia), men with female partners who are pregnant, renal function impairment (CrCl less than 50 mL/min)
Required Medical Information	Diagnosis of one of the following A.) Hairy cell leukemia, B.) Condylomata acuminata involving external surfaces to the genital or perianal areas, C.) AIDS-related Kaposi's sarcoma, D.) Clinically aggressive follicular lymphoma and the medication will be used concurrently with anthracycline-containing chemotherapy or is not a candidate for anthracycline-containing chemotherapy, E.) Malignant melanoma and the request for coverage is within 56 days of surgery and the patient is at high risk of disease recurrence, F.) Chronic hepatitis B with compensated liver disease and patient has or had evidence of hepatitis B viral replication prior to initiation and patient has been serum hepatitis B surface antigen-positive for at least 6 months, or G.) Chronic hepatitis C with compensated liver disease and is receiving combination therapy with ribavirin, unless ribavirin is contraindicated, and the medication will not be used as part of triple therapy with a protease inhibitor and patient has a clinical reason for not using peginterferon
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Condylomata: 3 months, HBV E antigen positive and Kaposi sarcoma: 16 weeks, Other: 12 months
Other Criteria	B vs D determination required per CMS guidance

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

IRESSA

Products Affected

- IRESSA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of metastatic non-small cell lung cancer (NSCLC) and must meet all of the following 1.) Tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility and 2.) Used as first-line treatment
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ISTURISA

Products Affected

- ISTURISA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of Cushing's disease in patients for whom pituitary surgery is not an option or has not been curative
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ITRACONAZOLE

Products Affected

- *itraconazole oral*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Ventricular dysfunction (e.g., congestive heart failure (CHF) or history of CHF), B.) Concurrent therapy with a CYP3A4 substrate (e.g., methadone, lovastatin, simvastatin, etc.), C.) Concurrent use of CYP2D6 inhibitors (e.g., bupropion, fluoxetine, paroxetine, quinidine, terbinafine), D.) Renal or hepatic impairment and concomitant use of colchicine, fesoterodine, solifenacin, or telithromycin, E.) Pregnancy
Required Medical Information	Diagnosis of one of the following A.) Systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis), or B.) Onychomycosis confirmed by one of the following: positive potassium hydroxide (KOH) preparation, fungal culture, or nail biopsy
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	6 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ITRACONAZOLE SOLN

Products Affected
- *itraconazole oral*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Ventricular dysfunction (e.g., congestive heart failure (CHF) or history of CHF), B.) Concurrent therapy with a CYP3A4 substrate (e.g., methadone, lovastatin, simvastatin, etc.), C.) Concurrent use of CYP2D6 inhibitors (e.g., bupropion, fluoxetine, paroxetine, quinidine, terbinafine), D.) Renal or hepatic impairment and concomitant use of colchicine, fesoterodine, solifenacin, or telithromycin, E.) Pregnancy
Required Medical Information	Diagnosis of candidiasis (esophageal or oropharyngeal) that is refractory to treatment with fluconazole
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	6 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

IVERMECTIN

Products Affected

- *ivermectin oral*

PA Criteria	Criteria Details
Exclusion Criteria	Prevention or treatment of COVID-19
Required Medical Information	Diagnosis of one of the following: A.) Strongyloidiasis of the intestinal tract or B.) Onchocerciasis
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	1 month
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

IVIG

Products Affected

- GAMMAGARD INJECTION SOLUTION 2.5 GM/25ML
- GAMMAGARD S/D LESS IGA
- GAMMAKED INJECTION SOLUTION 1 GM/10ML
- GAMMAPLEX INTRAVENOUS SOLUTION 10 GM/100ML, 10 GM/200ML, 20 GM/200ML, 5 GM/50ML
- GAMUNEX-C INJECTION SOLUTION 1 GM/10ML
- OCTAGAM INTRAVENOUS SOLUTION 1 GM/20ML, 2 GM/20ML
- PRIVIGEN INTRAVENOUS SOLUTION 20 GM/200ML

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) IgA deficiency with antibody formation and a history of hypersensitivity, or B.) History of anaphylaxis or severe systemic reaction to human immune globulin, C.) Hereditary intolerance to fructose, D.) Hyperprolinemia (type I or II), E.) Severe thrombocytopenia or any coagulation disorder which would contraindicate IM injections
Required Medical Information	Supporting statement of diagnosis from the physician
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

JAKAFI

Products Affected

- JAKAFI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis, B.) Polycythemia vera AND patient has had an inadequate response to or is intolerant of hydroxyurea, C.) Acute graft versus host disease AND disease is refractory to steroid therapy, or D.) Chronic graft versus host disease after failure of 1 or 2 lines of systemic therapy
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	6 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

JUXTAPID

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Moderate to severe liver impairment or active liver disease including unexplained persistent abnormal liver function tests, B.) Pregnancy, or C.) Concomitant use with strong or moderate CYP3A4 inhibitors
Required Medical Information	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 (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
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	Initial: 6 months, Renewal: 12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

KALYDECO

Products Affected

- KALYDECO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of cystic fibrosis (CF) and the patient has 1 mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

KESIMPTA

Products Affected

- KESIMPTA

PA Criteria	Criteria Details
Exclusion Criteria	Active Hepatitis B infection
Required Medical Information	Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

KISQALI

Products Affected

- KISQALI (200 MG DOSE)
- KISQALI (400 MG DOSE)
- KISQALI (600 MG DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Hormone receptor (HR)-positive, HER-2 negative advanced or metastatic breast cancer in pre/perimenopausal or postmenopausal women and used in combination with an aromatase inhibitor, or B.) Hormone receptor (HR)-positive, HER-2 negative advanced or metastatic breast cancer in postmenopausal women and used in combination with fulvestrant
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

KISQALI FEMARA

Products Affected

- KISQALI FEMARA (400 MG DOSE)
- KISQALI FEMARA (600 MG DOSE)
- KISQALI FEMARA(200 MG DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of hormone receptor (HR)-positive, HER-2 negative advanced or metastatic breast cancer in pre/perimenopausal or postmenopausal women
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

KORLYM

Products Affected

- KORLYM

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) pregnancy, B.) coadministration with simvastatin, lovastatin, or CYP3A substrates with narrow therapeutic ranges, C.) concomitant treatment with systemic corticosteroids for serious medical conditions or illnesses, D.) history of unexplained vaginal bleeding, E.) endometrial hyperplasia with atypia or endometrial carcinoma
Required Medical Information	Diagnosis of endogenous Cushing syndrome in patients with type 2 diabetes mellitus or glucose intolerance and must meet all of the following 1.) Used to control hyperglycemia secondary to hypercortisolism, and 2.) Patient has failed or is not a candidate for surgery
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

KOSELUGO

Products Affected
- KOSELUGO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of neurofibromatosis type 1 (NF1) in a patient who has symptomatic, inoperable plexiform neurofibromas (PN)
Age Restrictions	2 years of age to 17 years of age
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

KYNMOBI

Products Affected

- KYNMOBI

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with 5-HT(3) receptor antagonists (e.g.. ondansetron, granisetron, dolasetron, palonosetron, alosetron etc.)
Required Medical Information	Diagnosis of Parkinson's disease (PD) and patient is experiencing acute intermittent hypomobility (defined as off episodes characterized by muscle stiffness, slow movements, or difficulty starting movements)
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

LAPATINIB

Products Affected

- *lapatinib ditosylate*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of advanced or metastatic breast cancer with tumors that overexpress human epidermal growth factor receptor 2 (HER2) AND meets one of the following A.) Used in combination with capecitabine in a patient who has received prior therapy including an anthracycline, a taxane, and trastuzumab, OR B.) Used in combination with letrozole in a postmenopausal female for whom hormonal therapy is indicated
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

LENALIDOMIDE

Products Affected

- *lenalidomide*

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of one of the following A.) Multiple myeloma and medication will be used in combination with dexamethasone, B.) Autologous hematopoietic stem-cell transplantation (HSCT) in multiple myeloma patients, C.) Transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndrome (MDS) associated with a deletion 5q cytogenetic abnormality or without additional cytogenetic abnormalities, D.) Mantle cell lymphoma whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib, E.) Follicular lymphoma and used in combination with rituximab, or F.) Marginal zone lymphoma and used in combination with rituximab
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

LENVIMA

Products Affected

- LENVIMA (10 MG DAILY DOSE)
- LENVIMA (12 MG DAILY DOSE)
- LENVIMA (14 MG DAILY DOSE)
- LENVIMA (18 MG DAILY DOSE)
- LENVIMA (20 MG DAILY DOSE)
- LENVIMA (24 MG DAILY DOSE)
- LENVIMA (4 MG DAILY DOSE)
- LENVIMA (8 MG DAILY DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer, B.) Advanced renal cell carcinoma, in combination with everolimus, following one prior anti-angiogenic therapy, C.) Unresectable hepatocellular carcinoma, first-line therapy, D.) Advanced endometrial carcinoma that is not microsatellite instability-high or mismatch repair deficient, in combination with pembrolizumab, when disease has progressed following prior systemic therapy AND patient is not a candidate for curative surgery or radiation, or E.) Advanced renal cell carcinoma, in combination with pembrolizumab
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

LEUKINE

Products Affected

- LEUKINE INJECTION SOLUTION RECONSTITUTED

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Patient has undergone allogeneic or autologous bone marrow transplant (BMT) and engraftment is delayed or failed, B.) Patient is undergoing autologous peripheral-blood progenitor cell transplant to mobilize progenitor cells for collection by leukapheresis, C.) Medication will be used for myeloid reconstitution after an autologous or allogeneic BMT, D.) Patient has acute myeloid leukemia and administration will be after completion of induction chemotherapy, E.) Hematopoietic subsyndrome of acute radiation syndrome (H-ARS) or F.) Autologous peripheral blood stem cell transplant, Following myeloablative chemotherapy.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

LEUPROLIDE

Products Affected

- ELIGARD
- *leuprolide acetate injection*
- LUPRON DEPOT (1-MONTH)
- LUPRON DEPOT (3-MONTH)
- LUPRON DEPOT (4-MONTH)
- LUPRON DEPOT (6-MONTH)

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of one of the following A.) Advanced or metastatic prostate cancer and patient has failed or is intolerant to Eligard (7.5 mg 1-month, 22.5 mg 3-month, 30 mg 4-month, & 45 mg 6-month depots only), B.) Endometriosis (3.75 mg 1-month & 11.25 mg 3-month depots only), C.) Anemia due to uterine leiomyomata (Fibroids) (3.75 mg 1-month &11.25 mg 3-month depots only) and patient is preoperative, or D.) Central precocious puberty (idiopathic or neurogenic) in children
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

LIDOCAINE PATCH

Products Affected

- *lidocaine external patch 5 %*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Pain associated with diabetic neuropathy, B.) Pain associated with cancer-related neuropathy, C.) Post-herpetic neuralgia, D.) Chronic back pain, or E.) Osteoarthritis of the knee or hip
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

LINEZOLID

Products Affected

- *linezolid intravenous solution 600 mg/300ml*
- *linezolid oral*

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of MAOI therapy
Required Medical Information	Diagnosis of one of the following A.) Community acquired pneumonia, B.) Hospital-acquired pneumonia, C.) Vancomycin-resistant Enterococcus faecium infection, D.) Complicated skin and skin structure infections, or E.) Uncomplicated skin and skin structure infections
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	1 month
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

LIVMARLI

Products Affected

- LIVMARLI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of cholestatic pruritus in patients with Alagille syndrome (ALGS)
Age Restrictions	1 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

LIVTENCITY

Products Affected
- LIVTENCITY

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of post-transplant cytomegalovirus (CMV) infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet
Age Restrictions	12 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

LONSURF

Products Affected

- LONSURF

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Metastatic colorectal cancer, previously treated with fluoropyrimidine, oxaliplatin, and irinotecan-based regimens, an anti-VEGF therapy, and if RAS wild-type, an anti-EGFR therapy, or B.) Metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least 2 prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan and if appropriate, HER2/neu-targeted therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

LORBRENA

Products Affected
- LORBRENA

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with strong CYP3A4 inducers
Required Medical Information	Diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

LUMAKRAS

Products Affected

- LUMAKRAS

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC) as determined by an FDA-approved test and patient has received at least one prior systemic therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

LUPKYNIS

Products Affected

- LUPKYNIS

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin)
Required Medical Information	Initial: Diagnosis of systemic lupus erythematosus (SLE) with active lupus nephritis (LN) Classes III, IV, V (alone or in combination), and all of the following: 1.) Baseline renal function of 45 mL/min/1.73 m2 or greater, 2.) Will be used in combination with a background immunosuppressive therapy regimen (e.g. mycophenolate, oral steroids, etc). Renewal: Improvement in urine protein to creatinine ratio (UPCR) (i.e. less than or equal to 0.5 mg/mg) AND estimated glomerular filtration rate (eGFR) of 60 mL/min/1.73 m2 or greater, or no confirmed decrease from baseline in eGFR of greater than 20%
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist or nephrologist
Coverage Duration	Initial: 12 months, Renewal: 12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

LYNPARZA

Products Affected

- LYNPARZA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) HER2-negative, deleterious or suspected deleterious germline BRCA mutated metastatic breast cancer and patient has been previously treated with chemotherapy in neoadjuvant, adjuvant, or metastatic setting, B.) Advanced ovarian cancer with known or suspected BRCA mutation as detected by an FDA-approved test AND patient has trial and failure, contraindication, or intolerance to 3 or more prior lines of chemotherapy, C.) Recurrent epithelial ovarian cancer, recurrent fallopian tube cancer, or recurrent primary peritoneal cancer and used for maintenance treatment in patients who are in complete or partial response to platinum-based chemotherapy (e.g. cisplatin, carboplatin), D.) Deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients with complete or partial response to first-line platinum-based chemotherapy, E.) Deleterious or suspected deleterious germline BRCA-mutated metastatic pancreatic adenocarcinoma and disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen, F.) Advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency positive status defined by either a deleterious or suspected deleterious BRCA-mutation and/or genomic instability AND are using in combination with bevacizumab for maintenance treatment, or G.) Deleterious or suspected deleterious germline or somatic homologous recombination repair gene mutated metastatic castration-resistant prostate cancer in patients who have progressed following prior treatment with enzalutamide or abiraterone
Age Restrictions	18 years of age and older
Prescriber Restrictions	None

PA Criteria	Criteria Details
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

MATULANE

Products Affected

- MATULANE

PA Criteria	Criteria Details
Exclusion Criteria	Inadequate marrow reserve
Required Medical Information	Diagnosis of Hodgkin's Disease, Stages III and IV and used in combination with other anticancer drugs
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

MAYZENT

Products Affected

- MAYZENT
- MAYZENT STARTER PACK

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) CYP2C9*3/*3 genotype, B.) In the last 6 months experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, Class III-IV heart failure, or C.) Presence of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker
Required Medical Information	Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS) and have history of/or contraindication to Avonex, Betaseron, Copaxone, Gilenya, Kesimpta, or Vumerity, or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

MEKINIST

Products Affected

- MEKINIST

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and used in combination with dabrafenib and no locoregional treatment options, B.) Malignant melanoma with lymph node involvement and following complete resection with BRAF V600E or V600K mutations and used in combination with dabrafenib, C.) Unresectable or metastatic malignant melanoma with BRAF V600E or V600K mutations and used in combination with dabrafenib or as monotherapy, D.) Metastatic non-small cell lung cancer, with BRAF V600E mutation, in combination with dabrafenib, or E.) Unresectable or metastatic solid tumors with BRAF V600E mutation, in combination with dabrafenib, and have progressed following prior treatment and have no satisfactory alternative treatment options
Age Restrictions	6 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

MEKTOVI

Products Affected

- MEKTOVI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of unresectable or metastatic malignant melanoma with documented BRAF V600E or V600K mutation as detected by an FDA approved test AND used in combination with encorafenib
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

METHOXSALEN

Products Affected

- *methoxsalen rapid*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Aphakia, B.) Melanoma or a history of melanoma, C.) Invasive squamous cell carcinomas, or D.) History of a light sensitive disease/skin photosensitivity disorder such systemic lupus erythematosus (SLE), porphyria cutanea tarda, erythropoietic protoporphyria, variegate porphyria, xeroderma pigmentosum or albinism
Required Medical Information	Diagnosis of one of the following A.) Psoriasis, or B.) Vitiligo
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist, immunologist, or dermatologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

MIGLUSTAT

Products Affected

- *miglustat*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of mild to moderate type 1 Gaucher disease and patient is not a candidate for enzyme replacement therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

MS INTERFERONS

Products Affected

- AVONEX PEN INTRAMUSCULAR AUTO-INJECTOR KIT
- AVONEX PREFILLED INTRAMUSCULAR PREFILLED SYRINGE KIT
- BETASERON SUBCUTANEOUS KIT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

NATPARA

Products Affected

- NATPARA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of hypoparathyroidism and used to control hypocalcemia
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

NERLYNX

Products Affected

- NERLYNX

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Early stage HER2-positive breast cancer and used following adjuvant trastuzumab therapy, or B.) Advanced or metastatic HER2-positive breast cancer, used in combination with capecitabine, AND patient has received 2 or more prior anti-HER2-based regimens in the metastatic setting
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

NINLARO

Products Affected

- NINLARO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of multiple myeloma, used in combination with lenalidomide and dexamethasone, AND patient has history of at least 1 prior therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

NITISINONE

Products Affected

- *nitisinone*
- ORFADIN ORAL CAPSULE 20 MG
- ORFADIN ORAL SUSPENSION

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of hereditary tyrosinemia type 1
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

NUBEQA

Products Affected

- NUBEQA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Non-metastatic, castration-resistant prostate cancer, or B.) Metastatic hormone-sensitive prostate cancer in combination with docetaxel
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

NUCALA

Products Affected

- NUCALA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Severe asthma with eosinophilic phenotype, B.) Eosinophilic granulomatosis with polyangiitis (EGPA), C.) Hypereosinophilic syndrome lasting at least 6 months without an identifiable non-hematologic secondary cause, or D.) Chronic rhinosinusitis with nasal polyps and used as an adjunct treatment
Age Restrictions	6 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

NUEDEXTA

Products Affected
- NUEDEXTA

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) History of prolonged QT interval, congenital long QT syndrome or Torsades de pointes, B.) Heart failure, C.) Complete AV block without an implanted pacemaker or high risk of complete AV block, D.) Concomitant use with quinidine, quinine, mefloquine, or drugs that prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine, pimozide), E.) Concomitant use with MAOIs or within 14 days of MAOI therapy, F.) History of quinine-, mefloquine-, or quinidine-induced thrombocytopenia, bone marrow depression, or lupus-like syndrome
Required Medical Information	Diagnosis of pseudobulbar affect
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

OCTREOTIDE

Products Affected

- *octreotide acetate injection solution 100 mcg/ml, 1000 mcg/ml, 200 mcg/ml, 50 mcg/ml, 500 mcg/ml*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Acromegaly and patient has inadequate response to or is ineligible for surgery, radiation, or bromocriptine mesylate, or B.) Metastatic carcinoid syndrome, or C.) Vasoactive intestinal peptide-secreting tumors (VIPomas) with associated diarrhea
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ODOMZO

Products Affected

- ODOMZO

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of locally advanced basal cell carcinoma of the skin and one of the following A.) Cancer has recurred following surgery or radiation therapy, B.) Patient is not a candidate for surgery or radiation therapy.
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

OFEV

Products Affected

- OFEV

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Idiopathic pulmonary fibrosis (IPF), B.) Systemic sclerosis-associated interstitial lung disease (ILD), or C.) Chronic fibrosing interstitial lung disease with a progressive phenotype
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ONUREG

Products Affected

- ONUREG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of acute myeloid leukemia (AML) used in maintenance treatment for adult patients who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

OPSUMIT

Products Affected

- OPSUMIT

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of pulmonary arterial hypertension (WHO Group I), confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e. g., patient is frail, elderly, etc.)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	Initial: 6 months, Renewal: 12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ORGOVYX

Products Affected

- ORGOVYX

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of advanced prostate cancer
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ORKAMBI

Products Affected

- ORKAMBI ORAL PACKET 100-125 MG, 150-188 MG
- ORKAMBI ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of cystic fibrosis (CF) with documented homozygous F508del mutation confirmed by FDA-approved CF mutation test
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

OSPHENA

Products Affected
- OSPHENA

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Undiagnosed abnormal genital bleeding, B.) Known or suspected estrogen-dependent neoplasia, C.) Active deep vein thrombosis (DVT), pulmonary embolism (PE), or a history of these conditions, D.) Active arterial thromboembolic disease (e.g. stroke, myocardial infarction) or a history of these conditions, or E.) Pregnancy
Required Medical Information	Diagnosis of one of the following A.) Moderate to severe dyspareunia due to vulvar and vaginal atrophy associated with menopause, or B.) Moderate to severe vaginal dryness due to vulvar and vaginal atrophy associated with menopause
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

OXANDROLONE

Products Affected

- *oxandrolone oral*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Known or suspected carcinoma of the prostate or breast in males, B.) Carcinoma of the breast in females with hypercalcemia, C.) Pregnancy, D.) Nephrosis or nephrotic phase of nephritis, E.) Hypercalcemia
Required Medical Information	Diagnosis of one of the following A.) Bone pain associated with osteoporosis, B.) Protein catabolism associated with chronic corticosteroid administration, or C.) Used as adjunctive therapy to promote weight gain after weight loss associated with one of the following 1.) Extensive surgery, 2.) Chronic infections, 3.) Severe trauma, or 4.) Failure to gain or maintain at least 90% of ideal body weight without definite pathophysiologic reasons
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	3 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

PANRETIN

Products Affected

- PANRETIN

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of AIDS-related Kaposi's sarcoma with cutaneous lesions and systemic anti-Kaposi's Sarcoma therapy is not required (e.g., more than 10 new KS lesions in the prior month, symptomatic lymphedema, symptomatic pulmonary KS, or symptomatic visceral involvement)
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

PEGYLATED INTERFERON

Products Affected

- PEGASYS SUBCUTANEOUS SOLUTION 180 MCG/ML
- PEGASYS SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Autoimmune hepatitis, B.) Hepatic decompensation (Child-Pugh score greater than 6 (Class B and C) in cirrhotic patients before treatment, OR hepatic decompensation (Child-Pugh score greater than or equal to 6) in cirrhotic patients co-infected with hepatitis C and HIV before treatment, C.) Hypersensitivity reactions, including urticaria, bronchoconstriction, anaphylaxis, or Stevens-Johnson syndrome to alfa interferons or any component of the product, or D.) Pregnancy with concomitant ribavirin use
Required Medical Information	Diagnosis of one of the following A.) Chronic hepatitis B infection, or B.) Chronic hepatitis C and required criteria will be applied consistent with current AASLD-IDSA guidance with compensated liver disease
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

PEMAZYRE

Products Affected
- PEMAZYRE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.)Previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with confirmed fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test, or B.) Relapsed or refractory myeloid/lymphoid neoplasms with fibroblast growth factor receptor 1 rearrangement
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist, gastroenterologist, or hepatologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

PENICILLAMINE

Products Affected

- *penicillamine oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Breastfeeding, B.) During Pregnancy (except for treatment of Wilson's disease), C.) Hypersensitivity to penicillamine products, D.) Penicillamine-related aplastic anemia/agranulocytosis, E.) Rheumatoid arthritis patients with history or evidence of renal insufficiency
Required Medical Information	Diagnosis of one of the following A.) Cystinuria, B.) Rheumatoid arthritis, or C.) Wilson's disease
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

PIQRAY

Products Affected

- PIQRAY (200 MG DAILY DOSE)
- PIQRAY (250 MG DAILY DOSE)
- PIQRAY (300 MG DAILY DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of hormone receptor (HR) positive, HER2-negative, PIK3CA-mutated, advanced or metastatic breast cancer and must meet all of the following 1.) Used in combination with fulvestrant, 2.) Disease has progressed on or after an endocrine-based regimen, and 3.) Patient is a male or postmenopausal female
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

PIRFENIDONE

Products Affected

- *pirfenidone oral tablet 267 mg, 801 mg*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of idiopathic pulmonary fibrosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

POMALYST

Products Affected

- POMALYST

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of one of the following A.) AIDS-related Kaposi sarcoma and patient has failure on highly active antiretroviral therapy (HAART), B.) Kaposi sarcoma in HIV-negative adults, or C.) Multiple myeloma and in combination with dexamethasone in adults who have received at least 2 prior therapies (including lenalidomide and a proteasome inhibitor) and have demonstrate disease progression on or within 60 days of completion of the last therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

POSACONAZOLE

Products Affected

- NOXAFIL ORAL SUSPENSION
- *posaconazole*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant treatment with sirolimus, B.) Concomitant use of CYP3A4 substrates that prolong QT interval (pimozide, quinidine), C.) Concomitant use of HMG-CoA Reductase inhibitors primarily metabolized through CYP3A4, or D.) Concomitant use of ergot alkaloids
Required Medical Information	Diagnosis of one of the following A.) Oropharyngeal candidiasis, B.) Patient is severely immunocompromised and requires prophylaxis of invasive aspergillosis or candidiasis due to high risk of infection, or C.) Invasive aspergillosis
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 weeks
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

PREVYMIS

Products Affected
- PREVYMIS ORAL

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant use with pimozide or ergot alkaloids (ergotamine, dihydroergotamine), B.) Concomitant use with pitavastatin or simvastatin when coadministered with cyclosporine
Required Medical Information	Must meet both of the following 1.) Patient is CMV-seropositive (R+), 2.) Patient is receiving an allogeneic hematopoietic stem cell transplant (HSCT)
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	6 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

PROMACTA

Products Affected

- PROMACTA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Chronic idiopathic thrombocytopenic purpura (ITP), B.) Chronic hepatitis C infection associated thrombocytopenia, or C.) Severe aplastic anemia with insufficient response to immunosuppressive therapy or in combination with standard immunosuppressive therapy
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

PYRUKYND

Products Affected

- PYRUKYND
- PYRUKYND TAPER PACK

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of hemolytic anemia with pyruvate kinase (PK) deficiency
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

QINLOCK

Products Affected

- QINLOCK

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of advanced gastrointestinal stromal tumor (GIST) and patient has received prior treatment with 3 or more kinase inhibitors, including imatinib
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

QUININE SULFATE

Products Affected

- *quinine sulfate oral*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Prolongation of QT interval, B.) Glucose-6-phosphate dehydrogenase deficiency, C.) Myasthenia gravis, D.) Known hypersensitivity to mefloquine or quinidine, E.) Optic neuritis, F.) Diagnosis of Blackwater fever
Required Medical Information	Diagnosis of one of the following A.) uncomplicated Plasmodium falciparum malaria, B.) uncomplicated Plasmodium vivax malaria, or C.) babesiosis
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	1 month
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

RAVICTI

Products Affected

- RAVICTI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of urea cycle disorders
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

REGRANEX

Products Affected

- REGRANEX

PA Criteria	Criteria Details
Exclusion Criteria	Known neoplasm at the site of application
Required Medical Information	Diagnosis of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply
Age Restrictions	16 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

REPATHA

Products Affected

- REPATHA
- REPATHA PUSHTRONEX SYSTEM
- REPATHA SURECLICK

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH), B.) homozygous familial hypercholesterolemia, C.) established cardiovascular disease and myocardial infarction prophylaxis, stroke prophylaxis, or coronary revascularization prophylaxis is required, or D.) clinical atherosclerotic cardiovascular disease (CVD) as defined as one of the following 1.) acute coronary syndrome, 2.) history of myocardial infarction, 3.) stable/unstable angina, 4.) coronary or other arterial revascularization, 5.) stroke, 6.) transient ischemic stroke (TIA), or 7.) peripheral arterial disease presumed to be atherosclerotic region
Age Restrictions	10 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

RETEVMO

Products Affected

- RETEVMO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Advanced or metastatic RET-mutant medullary thyroid cancer (MTC) in patients who require systemic therapy, B.) Metastatic RET fusion-positive non-small cell lung cancer (NSCLC), or C.) Advanced or metastatic RET fusion-positive thyroid cancer in patients who require systemic therapy and are refractory to radioactive iodine, if appropriate
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

REVLIMID

Products Affected

- REVLIMID ORAL CAPSULE 2.5 MG, 20 MG

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of one of the following A.) Multiple myeloma and medication will be used in combination with dexamethasone, B.) Autologous hematopoietic stem-cell transplantation (HSCT) in multiple myeloma patients, C.) Transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndrome (MDS) associated with a deletion 5q cytogenetic abnormality or without additional cytogenetic abnormalities, D.) Mantle cell lymphoma whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib, E.) Follicular lymphoma and used in combination with rituximab, or F.) Marginal zone lymphoma and used in combination with rituximab
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

REZUROCK

Products Affected

- REZUROCK

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of chronic graft-vs-host disease in adult and pediatric patients at least 12 years of age after failure of at least 2 prior lines of systemic therapy.
Age Restrictions	12 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

RILUZOLE

Products Affected

- *riluzole*
- TIGLUTIK

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of amyotrophic lateral sclerosis (ALS)
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

RINVOQ

Products Affected

- RINVOQ

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis, B.) Active psoriatic arthritis, C.) Moderate to severe atopic dermatitis and patient has trial/failure, contraindication, or intolerance to two of the following 1.) Topical corticosteroid and/or 2.) Topical calcineurin inhibitor, D.) Moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more tumor necrosis factor blockers, or E.) Active ankylosing spondylitis who have had an inadequate response or intolerance to one or more tumor necrosis factor blockers
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Screening for latent tuberculosis infection is required prior to initiation of treatment
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ROZLYTREK

Products Affected

- ROZLYTREK

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) ROS1-positive metastatic non-small cell lung cancer (NSCLC), or B.) Solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have either progressed following treatment or have no satisfactory alternative therapy
Age Restrictions	12 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

RUBRACA

Products Affected

- RUBRACA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Epithelial ovarian, fallopian tube, or primary peritoneal cancer with deleterious BRCA mutation (germline and/or somatic) as detected by an FDA-approved test and patient has been treated with 2 or more prior lines of chemotherapy, B.) Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, used as maintenance treatment, and patient is in complete or partial response to platinum-based chemotherapy, or C.) Deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer and patient has been treated with androgen receptor-directed therapy and a taxane-based chemotherapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

RYDAPT

Products Affected

- RYDAPT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) treatment naive FLT3 mutation-positive acute myelogenous leukemia (AML) and must be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation therapy, or B.) systemic mastocytosis or mast cell leukemia
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SAPROPTERIN

Products Affected

- *sapropterin dihydrochloride oral packet*
- *sapropterin dihydrochloride oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of hyperphenylalaninemia (HPA) caused by tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Initial: 2 months, Renewal: 12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SCEMBLIX

Products Affected

- SCEMBLIX

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs), or B.) Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) with the T315I mutation
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SIGNIFOR

Products Affected

- SIGNIFOR

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of Cushing disease and patient has had inadequate response to or is not a candidate for surgery. For renewal: Documentation of a clinically meaningful reduction in 24-hour urinary free cortisol (UFC) levels or improvement in signs or symptoms of the disease
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	Initial: 6 months, Renewal: 12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SILDENAFIL

Products Affected

- *sildenafil citrate oral tablet 20 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Nitrate therapy, including intermittent use, B.) Concomitant use with riocguat or other guanylate cyclase stimulators, C.) Concomitant use with HIV protease inhibitors or elvitegravir/cobicistat/tenofovir/emtricitabine
Required Medical Information	Diagnosis of pulmonary arterial hypertension (WHO Group I), confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.)
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SIRTURO

Products Affected

- SIRTURO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Must meet all of the following 1.) Diagnosis of pulmonary multidrug resistant tuberculosis (MDR-TB) and 2.) Used in combination with at least 3 other antibiotics for the treatment of pulmonary multi-drug resistant tuberculosis
Age Restrictions	5 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist
Coverage Duration	24 weeks
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SKYRIZI

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Moderate to severe plaque psoriasis and patient is a candidate for systemic therapy or phototherapy, B.) Active psoriatic arthritis in adults, or C.) Moderately to severely active Crohn's disease in adults
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Screening for latent tuberculosis infection is required prior to initiation of treatment
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SOLTAMOX

Products Affected

- SOLTAMOX

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant coumarin-type anticoagulant therapy, B.) history of thromboembolic disease such as DVT or PE
Required Medical Information	Diagnosis of breast cancer and documentation of inability to swallow tablet formulation
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SOMAVERT

Products Affected

- SOMAVERT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of acromegaly and patient has had an inadequate response to or is ineligible for surgery or radiation therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SORAFENIB

Products Affected

- *sorafenib tosylate*

PA Criteria	Criteria Details
Exclusion Criteria	Squamous cell lung cancer being treated with carboplatin and paclitaxel
Required Medical Information	Diagnosis of one of the following A.) Advanced renal cell carcinoma, B.) Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma that is refractory to radioactive iodine treatment, or C.) Unresectable hepatocellular carcinoma
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SPRYCEL

Products Affected

- SPRYCEL

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, B.) Chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy, C.) Ph+ acute lymphoblastic leukemia (ALL) with resistance or intolerance to prior therapy, or D.) Newly diagnosed Ph+ ALL in combination with chemotherapy
Age Restrictions	1 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

STELARA

Products Affected

- STELARA SUBCUTANEOUS SOLUTION 45 MG/0.5ML
- STELARA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Moderate to severely active Crohn disease, B.) Moderate to severe plaque psoriasis, C.) Active psoriatic arthritis, or D.) Moderate to severe active ulcerative colitis
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Screening for latent tuberculosis infection is required prior to initiation of treatment
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

STIVARGA

Products Affected

- STIVARGA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Metastatic colorectal cancer in patients previously treated with fluoropyrimidine, oxaliplatin, and irinotecan containing chemotherapy, anti-VEGF therapy, and if RAS wild type, anti-EGFR therapy, B.) Liver carcinoma in patients previously treated with sorafenib, or C.) Locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) after treatment with imatinib and sunitinib
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SUNITINIB

Products Affected

- *sunitinib malate*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Gastrointestinal stromal tumor after disease progression on or intolerance to imatinib, B.) Pancreatic neuroendocrine tumors in a patient with unresectable locally advanced or metastatic disease, C.) Advanced renal cell carcinoma, or D.) Renal cell carcinoma and used as adjuvant therapy following nephrectomy in patients who are at high risk for recurrence
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SUNOSI

Products Affected

- SUNOSI

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant use of an MAOI, or B.) Use within 14 days of discontinuing an MAOI
Required Medical Information	Diagnosis of one of the following A.) narcolepsy with excessive daytime drowsiness and has trial of/or contraindication to modafinil or armodafinil, or B.) obstructive sleep apnea (OSA) with excessive daytime drowsiness and has trial of/or contraindication to modafinil or armodafinil
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SYMDEKO

Products Affected

- SYMDEKO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of cystic fibrosis (CF) and must meet one of the following 1.) Patient is homozygous for the F508del mutation, or 2.) Patient has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor verified by an FDA-cleared CF mutation test
Age Restrictions	6 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation
Coverage Duration	Initial: 6 months, Renewal: 12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SYMLIN

Products Affected

- SYMLINPEN 120 SUBCUTANEOUS SOLUTION PEN-INJECTOR
- SYMLINPEN 60 SUBCUTANEOUS SOLUTION PEN-INJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Confirmed diagnosis of gastroparesis, B.) Hypoglycemia unawareness
Required Medical Information	Diagnosis of type 1 or type 2 diabetes mellitus and patient uses mealtime insulin therapy and has failed to achieve desired glucose control
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SYNAREL

Products Affected

- SYNAREL

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) pregnancy, B.) breastfeeding, C.) undiagnosed abnormal vaginal bleeding
Required Medical Information	Diagnosis of one of the following A.) Central precocious puberty, or B.) Endometriosis
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SYNRIBO

Products Affected

- SYNRIBO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of chronic or accelerated phase chronic myeloid leukemia (CML) and patient has tried and failed or has a contraindication or intolerance to at least 2 tyrosine kinase inhibitors
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TABRECTA

Products Affected

- TABRECTA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of metastatic non-small cell lung cancer (NSCLC) in patients whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TAFINLAR

Products Affected

- TAFINLAR

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Locally advanced or metastatic anaplastic thyroid carcinoma with BRAF V600E mutation, in combination with trametinib and no satisfactory locoregional treatment options, B.) Metastatic non-small cell lung cancer with BRAF V600E mutation, in combination with trametinib or in patients previously treated as monotherapy, C.) Unresectable or metastatic malignant melanoma with BRAF V600E or V600K mutation, or D.) Unresectable or metastatic solid tumors with BRAF V600E mutation, in combination with trametinib, and have progressed following prior treatment and have no satisfactory alternative treatment options
Age Restrictions	6 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TAGRISSO

Products Affected

- TAGRISSO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Metastatic non-small cell lung cancer (NSCLC) with EGFR exon 19 deletion or exon 21 L858R mutation and used as first line therapy, B.) Metastatic non-small cell lung cancer with T790M EGFR mutation (as confirmed by an FDA-approved test) AND whose disease has progressed on or after EGFR tyrosine kinase inhibitor therapy, or C.) Non-small cell lung cancer (NSCLC) with tumor epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations (as confirmed by an FDA-approved test) AND patient requires adjuvant therapy after tumor resection
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TAKHZYRO

Products Affected

- TAKHZYRO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following, used as routine prophylaxis, and patient has trial of, or contraindication to Firazyr A.) Hereditary angioedema (HAE) with C1 inhibitor deficiency (Type 1) confirmed by laboratory testing, or B.) HAE with C1 inhibitor dysfunction (Type 2) confirmed by laboratory testing, or C.) HAE with normal C1 inhibitor (Type 3) confirmed by laboratory testing and one of the following 1.) Positive test for an F12, angiopoietin-1, or plasminogen gene mutation, or 2.) Family history of angioedema and the angioedema was refractory to a trial of an antihistamine for at least one month
Age Restrictions	12 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a hematologist, immunologist, or allergist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TALZENNA

Products Affected

- TALZENNA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated (gBRCAm), human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TASIGNA

Products Affected

- TASIGNA

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Long QT syndrome, B.) Uncorrected hypokalemia, C.) Uncorrected hypomagnesemia
Required Medical Information	Diagnosis of one of the following A.) Newly diagnosed chronic phase Philadelphia chromosome-positive chronic myelogenous leukemia (CML), B.) Chronic phase or accelerated phase Philadelphia chromosome-positive CML in a patient with resistance or intolerance to prior therapy that included imatinib, or C.) Chronic phase Philadelphia chromosome-positive CML in a patient with resistance or intolerance to prior tyrosine-kinase inhibitor therapy
Age Restrictions	1 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TAVNEOS

Products Affected

- TAVNEOS

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TAZAROTENE

Products Affected

- *tazarotene external cream*
- *tazarotene external gel*
- TAZORAC EXTERNAL CREAM 0.05 %
- TAZORAC EXTERNAL GEL

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of one of the following A.) Acne vulgaris and patient has trial with at least one generic topical acne product, or B.) Stable moderate to severe plaque psoriasis with 20% or less body surface area involvement and patient has trial with at least one other topical psoriasis product (e.g., medium to high potency corticosteroid and/or vitamin D analogs)
Age Restrictions	12 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TAZVERIK

Products Affected
- TAZVERIK

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Metastatic or locally advanced epithelioid sarcoma in patients not eligible for complete resection, B.) Relapsed or refractory follicular lymphoma in patients whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies, or C.) Relapsed or refractory follicular lymphoma in patients who have no satisfactory alternative treatment options
Age Restrictions	16 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TEFLARO

Products Affected

- TEFLARO

PA Criteria	Criteria Details
Exclusion Criteria	Known serious hypersensitivity to cephalosporin class
Required Medical Information	Diagnosis of one of the following A.) acute bacterial skin and skin structure infection and patient has documented culture and sensitivity to Teflaro, or B.) community acquired pneumonia and patient has documented culture and sensitivity to Teflaro
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	2 weeks
Other Criteria	B vs D determination required per CMS guidance (i.e. Part B for patients with chronic kidney disease on dialysis)
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TEGSEDI

Products Affected

- TEGSEDI

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Platelet count less than 100,000 per microliter, B.) Urinary protein to creatinine ratio (UPCR) of 1000 mg/g or higher
Required Medical Information	Diagnosis of Polyneuropathy of hereditary transthyretin-mediated amyloidosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TEPMETKO

Products Affected

- TEPMETKO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of metastatic non-small cell lung cancer (NSCLC) with mesenchymal-epithelial transition (MET) exon 14 skipping alterations
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TERIPARATIDE

Products Affected

- *teriparatide (recombinant)*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Osteoporosis in postmenopausal female patient with high risk for fracture and patient has contraindication or has tried/had inadequate response to a bisphosphonate or Tymlos, B.) Primary or hypogonadal osteoporosis in male patient with high risk for fracture and patient has contraindication or has tried/had inadequate response to a bisphosphonate, or C.) Osteoporosis due to associated sustained systemic glucocorticoid therapy in patient with high risk for fracture and patient has contraindication or has tried/had inadequate response to a bisphosphonate
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	Initial: 12 months, Renewal: 12 months (Maximum 24 month treatment per patient lifetime)
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TESTOSTERONES

Products Affected

- *testosterone cypionate intramuscular solution 100 mg/ml, 200 mg/ml, 200 mg/ml (1 ml)*
- *testosterone enanthate intramuscular solution*
- *testosterone transdermal gel 10 mg/act (2%), 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%)*
- *testosterone transdermal solution*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Carcinoma of the breast (males only), B.) Known or suspected carcinoma of the prostate, C.) Pregnancy
Required Medical Information	Diagnosis of one of the following A.) Hypogonadotropic hypogonadism, B.) Inoperable metastatic breast cancer in women who are postmenopausal (testosterone enanthate), C.) Primary hypogonadism, or D.) Delayed puberty (testosterone enanthate). Diagnosis of hypogonadism must be confirmed by a low-for-age serum testosterone (total or free) level defined by the normal laboratory reference value
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TETRABENAZINE

Products Affected

- *tetrabenazine*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Actively suicidal, B.) Untreated or inadequately treated depression, C.) Impaired hepatic function, D.) Concomitant use of monoamine oxidase inhibitors, E.) Concomitant use of reserpine or within 20 days of discontinuing reserpine
Required Medical Information	Diagnosis of chorea associated with Huntington's disease
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

THALOMID

Products Affected

- THALOMID

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of one of the following A.) Multiple myeloma that is newly diagnosed, or B.) Erythema nodosum leprosum (ENL)
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or infectious disease specialist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TIBSOVO

Products Affected

- TIBSOVO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 mutation (as detected by an FDA-approved test), B.) Previously treated, locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 mutation (as detected by an FDA-approved test.), or C.) Acute myeloid leukemia (newly-diagnosed) with susceptible isocitrate dehydrogenase-1 mutation and meets one of the following: 1.) Patient is 75 years of age or older, or 2.) Patient has comorbidities that preclude intensive induction chemotherapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hematologist, hepatologist, or oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TOLVAPTAN

Products Affected

- *tolvaptan*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Diagnosis of Autosomal Dominant Polycystic Kidney Disease (ADPKD), B.) Urgent need to raise serum sodium acutely, C.) Inability to sense or appropriately respond to thirst, D.) Hypovolemic hyponatremia, E.) Concomitant use of strong CYP 3A Inhibitors (e.g. clarithromycin, ketoconazole, ritonavir), or F.) Anuria
Required Medical Information	Diagnosis of clinically significant hypervolemic or euvolemic hyponatremia (serum sodium less than 125 mEq/L or less marks hyponatremia that is symptomatic and has resisted correction with fluid restriction), including in patients with heart failure and syndrome of inappropriate antidiuretic hormone (SIADH)
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	1 month
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TOPICAL RETINOIDS

Products Affected

- *adapalene external cream*
- *adapalene external gel 0.3 %*
- AVITA
- *tretinoin external cream*
- *tretinoin external gel 0.01 %, 0.025 %*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of mild to moderate acne vulgaris
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TOREMIFENE

Products Affected

- *toremifene citrate*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Acquired or congenital long QT syndrome, B.) Uncorrected hypokalemia, C.) Uncorrected hypomagnesemia
Required Medical Information	Diagnosis of metastatic breast cancer and patient must have previous inadequate response or intolerance to tamoxifen
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	6 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TRELSTAR

Products Affected

- TRELSTAR MIXJECT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of advanced prostate cancer and used in palliative treatment
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TRIENTINE

Products Affected

- *trientine hcl*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of Wilson's disease in patients that are intolerant to penicillamine
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TRIKAFTA

Products Affected

- TRIKAFTA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of cystic fibrosis (CF) and patient has at least 1 F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene verified by an FDA-cleared CF mutation test
Age Restrictions	6 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TRUSELTIQ

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist, gastroenterologist or hepatologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TUKYSA

Products Affected

- TUKYSA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of advanced unresectable or metastatic HER2-positive breast cancer (including brain metastases) in patients who have received one or more prior anti-HER2-based regimens in the metastatic setting and drug is being used in combination with trastuzumab and capecitabine
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TURALIO

Products Affected
- TURALIO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TYMLOS

Products Affected

- TYMLOS

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of postmenopausal osteoporosis and one of the following A.) osteoporotic fracture or multiple risk factors for fracture, or B.) previous trial of/or contraindication to bisphosphonate
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	Initial: 12 months, Renewal: 12 months (Maximum 24 month treatment per patient lifetime)
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

UBRELVY

Products Affected

- UBRELVY

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin)
Required Medical Information	Diagnosis of migraine disorder with or without aura and patient has documented trial, inadequate response, or contraindication to at least 1 generic formulary triptan
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

VALCHLOR

Products Affected
- VALCHLOR

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of cutaneous T-cell lymphoma (stage IA and IB mycosis fungoides-type) and patient has received prior skin-directed therapy (e.g. Topical corticosteroids, phototherapy, or topical nitrogen mustard)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

VENCLEXTA

Products Affected

- VENCLEXTA
- VENCLEXTA STARTING PACK

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with strong CYP3A inhibitor during the initial and titration phase in patients with CLL or SLL
Required Medical Information	Diagnosis of one of the following A.) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), or B.) Newly-diagnosed acute myeloid leukemia (AML) and used in combination with azacitidine, decitabine or low-dose cytarabine in patients 75 years or older or who have comorbidities that preclude use of intensive induction chemotherapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

VERQUVO

Products Affected
- VERQUVO

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant use of other soluble guanylate cyclase (sGC) stimulators, or B.) Pregnancy
Required Medical Information	Diagnosis of chronic heart failure (HF), NYHA Class II to IV and all of the following 1.) Left ventricular ejection fraction less than 45%, 2.) Previous hospitalization for HF within 6 months or outpatient IV diuretic treatment for HF within 3 months
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

VERZENIO

Products Affected

- VERZENIO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of advanced or metastatic, HER2-negative, hormone receptor-positive breast cancer AND one of the following: A.) For men, and postmenopausal women must be used in combination with fulvestrant for the treatment of disease progression following endocrine therapy and patient has trial and failure or contraindication to Ibrance or Kisqali, B.) For premenopausal or perimenopausal women must be used in combination with fulvestrant for the treatment of disease progression following endocrine therapy and patient has trial and failure or contraindication to Ibrance, C.) Used as monotherapy for treatment of disease progression following endocrine therapy and patient has already received at least one prior chemotherapy regimen of Ibrance or Kisqali, D.) For men, and postmenopausal women used as initial endocrine-based treatment in combination with an aromatase inhibitor and patient has trial and failure or contraindication to Kisqali or Ibrance, E.) For premenopausal or perimenopausal women used as initial endocrine-based treatment in combination with an aromatase inhibitor and patient has trial and failure or contraindication to Kisqali, or F.) Used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor), for the adjuvant treatment of adult patients with hormone receptor-positive, human epidermal growth factor receptor 2-negative, node-positive, early breast cancer at high risk of recurrence and a Ki-67 score of at least 20% as determined by an FDA-approved test
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months

PA Criteria	Criteria Details
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

VIGABATRIN

Products Affected

- *vigabatrin*
- VIGADRONE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Infantile spasms, or B.) Refractory complex partial seizures and the drug is being used as adjunctive therapy in patients who have responded inadequately to two alternative treatments (i.e. valproic acid, primidone, carbamazepine, phenobarbital, and phenytoin)
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

VIJOICE

Products Affected

- VIJOICE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) in patients who require systemic therapy
Age Restrictions	2 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

VITRAKVI

Products Affected

- VITRAKVI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of metastatic or surgically unresectable neurotrophic receptor tyrosine kinase (NTRK) gene fusion positive solid tumors and used in patients with unsatisfactory alternative treatments or who have progressed following treatment
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

VIZIMPRO

Products Affected

- VIZIMPRO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of metastatic non-small cell lung cancer with confirmed epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

VONJO

Products Affected

- VONJO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of intermediate or high-risk primary or secondary myelofibrosis in adults AND a platelet count less than 50 X 10(9)/L
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

VORICONAZOLE

Products Affected

- *voriconazole intravenous*
- *voriconazole oral*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant use of carbamazepine, CYP3A4 substrates (e.g., terfenadine, astemizole, cisapride, pimozide, or quinidine), B.) Concomitant use with high-dose ritonavir (400mg every 12 hours), C.) Concomitant use with ergot alkaloids, D.) Concomitant use with long-acting barbiturates, E.) Conc0mitant use with rifabutin or rifampin, F.) Concomitant use with sirolimus, or G.) Concomitant use with efavirenz at standard doses of 400mg/day or higher
Required Medical Information	Diagnosis of one of the following A.) Invasive aspergillosis, B.) Candidemia, C.) Esophageal Candidiasis, D.) Invasive candidiasis of the skin and abdomen, kidney, bladder wall, and wounds, or E.) Serious fungal infection due to Scedosporium apiospermum or Fusarium species
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist
Coverage Duration	6 months
Other Criteria	IV formulation: B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

VOTRIENT

Products Affected

- VOTRIENT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Advanced renal cell carcinoma, or B.) Advanced soft tissue sarcoma and patient received at least one prior chemotherapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

VUMERITY

Products Affected

- VUMERITY

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

WELIREG

Products Affected

- WELIREG

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

XALKORI

Products Affected

- XALKORI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive or ROS1-positive as detected by an FDA-approved test, B.) Relapsed or refractory systemic anaplastic large cell lymphoma that is anaplastic lymphoma kinase (ALK) positive as detected by an FDA-approved test, or C.) Unresectable, recurrent, or refractory inflammatory myofibroblastic tumors that are anaplastic lymphoma kinase (ALK)-positive
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

XGEVA

Products Affected

- XGEVA

PA Criteria	Criteria Details
Exclusion Criteria	Hypocalcemia (calcium less than 8.0 mg/dL)
Required Medical Information	Diagnosis of one of the following A.) Bone metastases from a solid tumor and used for the prevention of skeletal related events, B.) Multiple myeloma and used for the prevention of skeletal related events, C.) Hypercalcemia of malignancy refractory to bisphosphonate therapy, or D.) Giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

XOLAIR

Products Affected

- XOLAIR

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Chronic idiopathic urticaria in patients who remain symptomatic despite H1 antihistamine therapy and patient will continue to receive concurrent H1 antihistamine therapy unless contraindicated or not tolerated, B.) Moderate to severe persistent asthma in patients with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms are inadequately controlled with inhaled corticosteroids or an alternative controller medication (i.e. long acting beta2-agonist, leukotriene modifier, or sustained-release theophylline) and patient has trial and failure, contraindication, or intolerance to one of the following based on patients age: Dupixent or Nucala, or C.) Nasal polyps in patients with inadequate response to nasal corticosteroids, requested drug will be used as adjunctive treatment, and patient has trial and failure, contraindication, or intolerance to Dupixent
Age Restrictions	6 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	B vs D determination required per CMS guidance
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

XOSPATA

Products Affected

- XOSPATA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

XPOVIO

Products Affected

- XPOVIO (100 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 50 MG
- XPOVIO (40 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 40 MG
- XPOVIO (40 MG TWICE WEEKLY) ORAL TABLET THERAPY PACK 40 MG
- XPOVIO (60 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 60 MG
- XPOVIO (60 MG TWICE WEEKLY)
- XPOVIO (80 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 40 MG
- XPOVIO (80 MG TWICE WEEKLY)

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Relapsed or refractory multiple myeloma being used in combination with dexamethasone in a patient who has received at least 4 prior therapies and is refractory to at least 2 proteasome inhibitors, at least 2 immunomodulatory agents, and an anti-CD38 monoclonal antibody, B.) Multiple myeloma being used in combination with bortezomib and dexamethasone in a patient who has received at least 1 prior therapy, C.) Relapsed or refractory diffuse large B-cell lymphoma not otherwise specified, or D.) Relapsed or refractory DLBCL arising from follicular lymphoma and patient has received at least 2 lines of systemic therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

XTANDI

Products Affected

- XTANDI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Castration-resistant prostate cancer, or B.) Metastatic, castration-sensitive prostate cancer
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

XYREM

Products Affected

- XYREM

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant treatment with sedative hypnotic agents, B.) Succinic semialdehyde dehydrogenase deficiency
Required Medical Information	Diagnosis of one of the following A.) Narcolepsy with excessive daytime drowsiness and has trial of/or contraindication to a central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, methylphenidate) or a CNS wakefulness promoting drug (e.g., armodafinil, modafinil), or B.) Cataplexy and narcolepsy
Age Restrictions	7 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

XYWAV

Products Affected

- XYWAV

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant treatment with sedative hypnotic agents, B.) Succinic semialdehyde dehydrogenase deficiency
Required Medical Information	Diagnosis of one of the following A.) Narcolepsy with excessive daytime drowsiness and has trial of/or contraindication to a central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, methylphenidate) or a CNS wakefulness promoting drug (e.g., armodafinil, modafinil), or B.) Cataplexy and narcolepsy, or C.) Idiopathic hypersomnia
Age Restrictions	7 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

YONSA

Products Affected
- YONSA

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of metastatic, castration-resistant prostate cancer and use in combination with methylprednisolone
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ZARXIO

Products Affected

- ZARXIO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Chemotherapy induced febrile neutropenia (prophylaxis), B.) Severe chronic neutropenia, C.) Patient is undergoing autologous peripheral-blood progenitor cell transplant to mobilize progenitor cells for collection by leukapheresis, or D.) Hematopoietic subsyndrome of acute radiation syndrome (H-ARS)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ZEJULA

Products Affected

- ZEJULA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Advanced or recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer and used as maintenance therapy in a patient who is in a complete or partial response to platinum-based chemotherapy, or B.) Advanced ovarian, fallopian tube, or primary peritoneal cancer and patient has been treated with 3 or more prior chemotherapy regimens, and cancer is associated with homologous recombination deficiency positive status defined by either a deleterious or suspected deleterious BRCA mutation, or genomic instability, and disease has progressed more than 6 months after response to the last platinum-based chemotherapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or gynecologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ZELBORAF

Products Affected

- ZELBORAF

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Unresectable or metastatic melanoma and patient has positive BRAF-V600E mutation documented by an FDA-approved test, or B.) Erdheim-Chester disease and patient has documented BRAF V600 mutation
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ZIEXTENZO

Products Affected

- ZIEXTENZO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of a non-myeloid malignancy and drug is being used as prophylaxis for chemotherapy-induced neutropenia
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ZOLINZA

Products Affected

- ZOLINZA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of primary cutaneous T-cell lymphoma (CTCL) in patients who have progressive, persistent or recurrent disease on or following two systemic therapies (e.g., bexarotene, romidepsin, etc)
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ZYDELIG

Products Affected

- ZYDELIG

PA Criteria	Criteria Details
Exclusion Criteria	History of toxic epidermal necrosis with any drug
Required Medical Information	Diagnosis of one of the following A.) Chronic lymphocytic leukemia, used in combination with rituximab and patient has relapsed on at least one prior therapy, B.) Non-Hodgkins lymphoma (Follicular, B-Cell) and the patient has relapsed on at least two prior systemic therapies, or C.) Small lymphocytic lymphoma and the patient has relapsed on at least two prior systemic therapies
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ZYKADIA

Products Affected
- ZYKADIA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

PART B VERSUS PART D

Products Affected

- ABELCET INTRAVENOUS SUSPENSION 5 MG/ML
- *acetylcysteine inhalation solution 10 %, 20 %*
- *acyclovir sodium intravenous solution 50 mg/ml*
- *albuterol sulfate inhalation nebulization solution (2.5 mg/3ml) 0.083%, 0.63 mg/3ml, 1.25 mg/3ml, 2.5 mg/0.5ml*
- AMBISOME INTRAVENOUS SUSPENSION RECONSTITUTED 50 MG
- *amphotericin b intravenous solution reconstituted 50 mg*
- *aprepitant oral capsule 125 mg, 40 mg, 80 & 125 mg, 80 mg*
- AZASAN ORAL TABLET 100 MG, 75 MG
- *azathioprine oral tablet 100 mg, 50 mg, 75 mg*
- *budesonide inhalation suspension 0.25 mg/2ml, 0.5 mg/2ml, 1 mg/2ml*
- *calcitonin (salmon) nasal solution 200 unit/act*
- *calcitriol oral capsule 0.25 mcg, 0.5 mcg*
- *calcitriol oral solution 1 mcg/ml*
- *cinacalcet hcl oral tablet 30 mg, 60 mg, 90 mg*
- CLINIMIX E/DEXTROSE (2.75/5) INTRAVENOUS SOLUTION 2.75 %
- CLINIMIX E/DEXTROSE (4.25/10) INTRAVENOUS SOLUTION 4.25 %
- CLINIMIX E/DEXTROSE (4.25/5) INTRAVENOUS SOLUTION 4.25 %
- CLINIMIX E/DEXTROSE (5/15) INTRAVENOUS SOLUTION 5 %
- CLINIMIX E/DEXTROSE (5/20) INTRAVENOUS SOLUTION 5 %
- CLINIMIX/DEXTROSE (4.25/10) INTRAVENOUS SOLUTION 4.25 %
- CLINIMIX/DEXTROSE (4.25/5) INTRAVENOUS SOLUTION 4.25 %
- CLINIMIX/DEXTROSE (5/15) INTRAVENOUS SOLUTION 5 %
- CLINIMIX/DEXTROSE (5/20) INTRAVENOUS SOLUTION 5 %
- CLINISOL SF INTRAVENOUS SOLUTION 15 %
- *cromolyn sodium inhalation nebulization solution 20 mg/2ml*
- *cyclophosphamide oral capsule 25 mg, 50 mg*
- *cyclophosphamide oral tablet 25 mg, 50 mg*
- *cyclosporine modified oral capsule 100 mg, 25 mg, 50 mg*
- *cyclosporine modified oral solution 100 mg/ml*
- *cyclosporine oral capsule 100 mg, 25 mg*
- *diphtheria-tetanus toxoids dt intramuscular suspension 25-5 lfu/0.5ml*
- ENGERIX-B INJECTION SUSPENSION 20 MCG/ML
- ENGERIX-B INJECTION SUSPENSION PREFILLED SYRINGE 10 MCG/0.5ML, 20 MCG/ML
- ENVARSUS XR ORAL TABLET EXTENDED RELEASE 24 HOUR 0.75 MG, 1 MG, 4 MG
- *everolimus oral tablet 0.25 mg, 0.5 mg, 0.75 mg, 1 mg*
- GENGRAF ORAL CAPSULE 100 MG, 25 MG
- GENGRAF ORAL SOLUTION 100 MG/ML
- *granisetron hcl oral tablet 1 mg*
- IMOVAX RABIES INTRAMUSCULAR SUSPENSION RECONSTITUTED 2.5 UNIT/ML
- INTRALIPID INTRAVENOUS EMULSION 20 %, 30 %
- *ipratropium bromide inhalation solution 0.02 %*

- *ipratropium-albuterol inhalation solution 0.5-2.5 (3) mg/3ml*
- ISOLYTE-P IN D5W INTRAVENOUS SOLUTION
- ISOLYTE-S PH 7.4 INTRAVENOUS SOLUTION
- *levalbuterol hcl inhalation nebulization solution 0.31 mg/3ml, 0.63 mg/3ml, 1.25 mg/0.5ml, 1.25 mg/3ml*
- *methotrexate oral tablet 2.5 mg*
- *methotrexate sodium (pf) injection solution 50 mg/2ml*
- *methotrexate sodium injection solution 50 mg/2ml*
- *methylprednisolone oral tablet 16 mg, 32 mg, 4 mg, 8 mg*
- *mycophenolate mofetil oral capsule 250 mg*
- *mycophenolate mofetil oral suspension reconstituted 200 mg/ml*
- *mycophenolate mofetil oral tablet 500 mg*
- *mycophenolate sodium oral tablet delayed release 180 mg, 360 mg*
- NUTRILIPID INTRAVENOUS EMULSION 20 %
- *ondansetron hcl injection solution 4 mg/2ml, 40 mg/20ml*
- *ondansetron hcl oral solution 4 mg/5ml*
- *ondansetron hcl oral tablet 4 mg, 8 mg*
- *ondansetron oral tablet dispersible 4 mg, 8 mg*
- *paricalcitol oral capsule 1 mcg, 2 mcg, 4 mcg*
- *pentamidine isethionate inhalation solution reconstituted 300 mg*
- PLASMA-LYTE 148 INTRAVENOUS SOLUTION
- PLASMA-LYTE A INTRAVENOUS SOLUTION
- PLENAMINE INTRAVENOUS SOLUTION 15 %
- *prednisolone oral solution 15 mg/5ml*
- *prednisolone sodium phosphate oral solution 10 mg/5ml, 20 mg/5ml, 25 mg/5ml, 6.7 (5 base) mg/5ml*
- *prednisolone sodium phosphate oral tablet dispersible 10 mg, 15 mg, 30 mg*
- PREDNISONE INTENSOL ORAL CONCENTRATE 5 MG/ML
- *prednisone oral solution 5 mg/5ml*
- *prednisone oral tablet 1 mg, 10 mg, 2.5 mg, 20 mg, 5 mg, 50 mg*
- *prehevbrio intramuscular suspension 10 mcg/ml*
- PREMASOL INTRAVENOUS SOLUTION 10 %
- PROGRAF ORAL PACKET 0.2 MG, 1 MG
- PROSOL INTRAVENOUS SOLUTION 20 %
- PULMOZYME INHALATION SOLUTION 2.5 MG/2.5ML
- RABAVERT INTRAMUSCULAR SUSPENSION RECONSTITUTED
- RECOMBIVAX HB INJECTION SUSPENSION 10 MCG/ML, 40 MCG/ML, 5 MCG/0.5ML
- RECOMBIVAX HB INJECTION SUSPENSION PREFILLED SYRINGE 10 MCG/ML, 5 MCG/0.5ML
- SANDIMMUNE ORAL SOLUTION 100 MG/ML
- *sirolimus oral solution 1 mg/ml*
- *sirolimus oral tablet 0.5 mg, 1 mg, 2 mg*
- *tacrolimus oral capsule 0.5 mg, 1 mg, 5 mg*
- TDVAX INTRAMUSCULAR SUSPENSION 2-2 LF/0.5ML
- TENIVAC INTRAMUSCULAR INJECTABLE 5-2 LFU, 5-2 LFU (INJECTION)
- *tobramycin inhalation nebulization solution 300 mg/5ml*
- TPN ELECTROLYTES INTRAVENOUS CONCENTRATE
- TRAVASOL INTRAVENOUS SOLUTION 10 %
- TREXALL ORAL TABLET 10 MG, 15 MG, 5 MG, 7.5 MG

- TROPHAMINE INTRAVENOUS SOLUTION 10 %
- VARUBI (180 MG DOSE) ORAL TABLET THERAPY PACK 2 X 90 MG
- XATMEP ORAL SOLUTION 2.5 MG/ML

Details

This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

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