MEDICATION(S)
ACTEMRA, ACTEMRA ACTPEN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Actemra therapy. Patient is not receiving Actemra in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]. Patient is not receiving Actemra in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RA (Initial): Prescribed by or in consultation with a rheumatologist.

COVERAGE DURATION
All indications (initial, reauth): 12 months

OTHER CRITERIA
RA (Reauth): Documentation of positive clinical response to Actemra therapy. Patient is not receiving Actemra in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]. Patient is not receiving Actemra in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].
MEDICATION(S)
ACTIMMUNE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of one of the following: 1) Chronic granulomatous disease (CGD), or 2) severe malignant osteopetrosis (SMO).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
ADAGEN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Excluded if patient has severe thrombocytopenia

REQUIRED MEDICAL INFORMATION
Adenosine deaminase (ADA) deficiency: Diagnosis of ADA deficiency in a patient with severe combined immunodeficiency disease (SCID) AND patient is not a suitable candidate for, or who has failed, bone marrow transplantation, hematopoietic stem cell transplant, or gene therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
ADAPALENE 0.1% CREAM, ADAPALENE 0.1% GEL, ADAPALENE 0.1% SOLUTION, ADAPALENE 0.3% GEL, ADAPALENE 0.3% GEL PUMP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of acne.

AGE RESTRICTION
PA applies to members 26 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
ADCIRCA, ALYQ, TADALAFIL 20 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.

COVERAGE DURATION
PAH: Initial: 6 months. Reauth: 12 months.

OTHER CRITERIA
PAH (Reauth): Documentation of positive clinical response to therapy.
MEDICATION(S)
DEXTROAMPHETAMINE-AMPHET ER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD)

AGE RESTRICTION
PA applies to members 19 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
ADEMPAS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH AND PAH is symptomatic AND One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. Chronic thromboembolic pulmonary hypertension (CTEPH) (Initial): One of the following: A) Both of the following: 1) Diagnosis of inoperable or persistent/recurrent CTEPH and 2) CTEPH is symptomatic OR B) Patient is currently on any therapy for the diagnosis of CTEPH.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PAH, CTEPH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.

COVERAGE DURATION
PAH, CTEPH: Initial: 6 months. Reauth: 12 months.

OTHER CRITERIA
PAH, CTEPH (Reauth): Documentation of positive clinical response to therapy.
AFINITOR

MEDICATION(S)
AFINITOR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Subependymal Giant Cell Astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC): Diagnosis of SEGA associated with TSC that requires therapeutic intervention but patient is not a candidate for curative surgical resection. Renal cell carcinoma: Diagnosis of advanced or metastatic renal cell carcinoma AND trial and failure, contraindication, or intolerance to SUTENT (sunitinib) or NEXAVAR (sorafenib). Neuroendocrine tumors of pancreatic origin (pNET): Diagnosis of progressive pNET that are unresectable, locally advanced, or metastatic. Renal angiomyolipoma: Diagnosis of renal angiomyolipoma and TSC AND Patient does not require immediate surgery. Breast Cancer: Patient is a postmenopausal woman AND Diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer AND trial and failure, contraindication, or intolerance to FEMARA (letrozole) or ARIMIDEX (anastrozole) AND Afinitor will be used in combination with AROMASIN (exemestane). Neuroendocrine tumors of gastrointestinal (GI) or lung origin: Diagnosis of progressive, well-differentiated, non-functional NET of GI or lung origin AND patient has unresectable, locally advanced or metastatic disease.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
All Indications: Prescribed by or in consultation with an oncologist

COVERAGE DURATION
All Indications: 12 months

OTHER CRITERIA
All Indications: Approve for continuation of prior therapy.
AFINITOR DISPERZ

MEDICATION(S)
AFINITOR DISPERZ

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Subependymal Giant Cell Astrocytoma (SEGA): Diagnosis of SEGA associated with tuberous sclerosis complex (TSC) that requires therapeutic intervention but patient is not a candidate for curative surgical resection.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist OR a neurologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
ALDURAZYME

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Mucopolysaccharidosis I: confirmed diagnosis of Hurler and Hurler-Scheie forms of Mucopolysaccharidosis I (MPS I), OR confirmed diagnosis of Scheie form of Mucopolysaccharidosis I (MPS I) who have moderate to severe symptoms.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
ALECENSA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Confirmed diagnosis of anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
ARALAST NP, GLASSIA, ZEMAIRA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Alpha-1 proteinase inhibitor (alpha-1 antitrypsin) deficiency: All of the following: A) Patient has an alpha-1 proteinase inhibitor (alpha-1 antitrypsin) deficiency AND B) Diagnosis of emphysema AND C) One of the following: 1) Patient has a high risk phenotype: PiZZ, PiZ(), or Pi()() OR 2) Patient has serum alpha-1 antitrypsin concentrations of less than 11 ??M/L (80 mg/dL), AND D) One of the following: FEV1 level is between 30% and 65% of predicted OR the patient has experienced a rapid decline in lung function (i.e., reduction of FEV1 more than 120 mL/year) that warrants treatment, AND E) Trial and failure, or intolerance to Prolastin-C.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
PROLASTIN C

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Alpha-1 proteinase inhibitor (alpha-1 antitrypsin) deficiency: All of the following: A) Patient has an alpha-1 proteinase inhibitor (alpha-1 antitrypsin) deficiency AND B) Diagnosis of emphysema AND C) One of the following: 1) Patient has a high risk phenotype: PiZZ, PiZ(), or Pi()() OR 2) Patient has serum alpha-1 antitrypsin concentrations of less than 11 ??M/L (80 mg/dL) AND D) One of the following: FEV1 level is between 30% and 65% of predicted OR the patient has experienced a rapid decline in lung function (i.e., reduction of FEV1 more than 120 mL/year) that warrants treatment.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
ALUNBRIG 30 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC. Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility. Trial and failure or intolerance to Xalkori (crizotinib).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
AMPYRA, DALFAMPRIDINE ER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Multiple Sclerosis (MS) (initial): Diagnosis of MS. Physician confirmation that patient has difficulty walking (eg, timed 25 foot walk test). One of the following: expanded disability status scale (EDSS) score less than or equal to 7, or not restricted to using a wheelchair (if EDSS is not measured).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
MS (Initial): Prescribed by or in consultation with a neurologist.

COVERAGE DURATION
MS (Initial): 6 months. (Reauth): 12 months.

OTHER CRITERIA
MS (Reauth): Physician confirmation that the patient's walking improved with Ampyra therapy. One of the following: EDSS score less than or equal to 7, or not restricted to using a wheelchair (if EDSS is not measured).
ANADROL-50

MEDICATION(S)
ANADROL-50

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Anemia (initial): Diagnosis of anemia caused by deficient red cell production AND trial and failure or intolerance to standard therapies for anemia (i.e., erythropoiesis-stimulating agents, immunosuppressants) AND Treatment will not replace other supportive measures (e.g., transfusion, correction of iron, folic acid, vitamin B12 or pyridoxine deficiency, antibacterial therapy, corticosteroids).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial and reauth: 12 months

OTHER CRITERIA
Anemia (reauth): patient has experienced an objective improvement in anemia (e.g., increased hemoglobin, increased reticulocyte count, reduction/elimination for need of blood transfusions)
MEDICATION(S)
APOKYN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
PD (Initial, reauth): Patient is using Apokyn with any 5-HT3 antagonist (eg, ondansetron, granisetron, dolasetron, palonosetron, alosetron)

REQUIRED MEDICAL INFORMATION
Parkinson’s disease (PD) (Initial): Diagnosis of advanced PD. Patient is experiencing acute intermittent hypomobility (defined as “off” episodes characterized by muscle stiffness, slow movements, or difficulty starting movements). Patient is receiving Apokyn in combination with other medications for the treatment of PD (e.g., carbidopa/levodopa, pramipexole, ropinirole, benztropine, etc.).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
PD (Initial, reauth): 12 months

OTHER CRITERIA
PD (Reauth): Patient is benefiting from therapy (eg, patient had an improvement in motor function).
MEDICATION(S)
ARANESP 10 MCG/0.4 ML SYRINGE, ARANESP 100 MCG/0.5 ML SYRINGE, ARANESP 100 MCG/ML VIAL, ARANESP 150 MCG/0.3 ML SYRINGE, ARANESP 200 MCG/0.4 ML SYRINGE, ARANESP 200 MCG/ML VIAL, ARANESP 25 MCG/0.42 ML SYRING, ARANESP 25 MCG/ML VIAL, ARANESP 300 MCG/0.6 ML SYRINGE, ARANESP 300 MCG/ML VIAL, ARANESP 40 MCG/0.4 ML SYRINGE, ARANESP 40 MCG/ML VIAL, ARANESP 500 MCG/1 ML SYRINGE, ARANESP 60 MCG/0.3 ML SYRINGE, ARANESP 60 MCG/ML VIAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Anemia with Chronic Kidney Disease (CKD) (Initial): Diagnosis (Dx) of CKD. Anemia by lab values (Hct less than 30% or Hgb less than 10 g/dL) collected within 30 days of request. One of the following: a) both of the following: Patient is on dialysis, patient is without ESRD OR b) all of the following: patient is not on dialysis, the rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion, and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal. Anemia with chemo (Initial): Other causes of anemia have been ruled out. Anemia by lab values (Hct less than 30%, Hgb less than 10 g/dL) collected within the prior 2 weeks of request. Cancer is a non-myeloid malignancy. Patient is concurrently on chemo, or will receive concomitant chemo for a minimum of 2 months, or anemia is caused by cancer chemo. Will not be approved if patient is not receiving cancer chemotherapy. Anemia in Myelodysplastic Syndrome (MDS) (Initial): Dx of MDS. Serum erythropoietin level is 500 mU/mL or less, or dx of transfusion-dependent MDS. CKD (init, reauth), Chemo (init), MDS (init): Verify iron evaluation for adequate iron stores.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A
COVERAGE DURATION
CKD (Init): 6 mo. CKD (reauth): 12 mo. Chemo(init, reauth): 3 mo. MDS: (init) 3 mo.,(reauth) 12 mo.

OTHER CRITERIA
Subject to ESRD review. CKD (Reauth): Dx of CKD. Most recent or average (avg) Hct over 3 mo is 33% or less OR most recent or avg Hgb over 3 months is 11 g/dL or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Chemo (Reauth): Anemia by lab values (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 weeks of request. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Patient is concurrently on chemo, or will receive concomitant chemo for a minimum of 2 months, or anemia is caused by cancer chemo. Will not be approved if patient is not receiving cancer chemotherapy. MDS (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Off-label uses (except MDS): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%.
MEDICATION(S)
ARCALYST

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Cryopyrin-Associated Periodic Syndromes (CAPS) (Initial): Diagnosis of CAPS, including Familial Cold Auto-inflammatory Syndrome (FCAS) and/or Muckle-Wells Syndrome (MWS). The medication will not be used in combination with another biologic.

AGE RESTRICTION
CAPS (Initial): 12 years of age or older

PRESCRIBER RESTRICTION
CAPS (Initial): Prescribed by or in consultation with an immunologist, allergist, dermatologist, rheumatologist, neurologist or other medical specialist.

COVERAGE DURATION
CAPS (initial, reauth): 12 months

OTHER CRITERIA
CAPS (Reauth): Patient has experienced disease stability or improvement in clinical symptoms while on therapy as evidence by one of the following: A) improvement in rash, fever, joint pain, headache, conjunctivitis, B) decreased number of disease flare days, C) normalization of inflammatory markers (CRP, ESR, SAA), D) corticosteroid dose reduction, OR E) improvement in MD global score or active joint count.
**MEDICATION(S)**
ARIKAYCE

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
Patients with non-refractory MAC lung disease. Amikacin oral inhalation has only been studied in patients with refractory MAC lung disease defined as patients who did not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy.

**REQUIRED MEDICAL INFORMATION**
Treatment of Mycobacterium avium complex (MAC) lung disease in adults who have limited or no alternative treatment options, as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy. Limitation of use: Amikacin oral inhalation has only been studied in patients with refractory MAC lung disease defined as patients who did not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy. The use of amikacin is not recommended for patients with non-refractory MAC lung disease.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
12 months

**OTHER CRITERIA**
Subject to Part B vs. Part D review
MEDICATION(S)
AUBAGIO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
AVASTIN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months
Avastin may be approved for Diabetic macular edema, Established neovascular wet AMD, Macular edema from branch retinal vein occlusion, Macular edema from central retinal vein occlusion, Neovascular glaucoma, Pseudoxanthoma elasticum, radiation retinopathy, Retinopathy of prematurity, diabetic retinopathy with or w/o diabetic macular edema, or Other rare causes of choroidal neovascularization for one or more of the following conditions: angioid streaks or choroiditis (including, but not limited to histoplasmosis induced choroiditis) or degenerative myopia, idiopathic or retinal dystrophies or trauma. For metastatic Colon, Rectal, or small bowel adenocarcinoma, Avastin is used in combination with 5FU based chemotherapy irinotecan or oxaliplatin and has not progressed on more than 2 lines of bevacizumab containing regimen. For NSCLC, Avastin is being used in combination with both platinum based therapies with a taxane or pemetrexed with ECOG status of 0-1 with no hx of hemoptysis for the first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic nonsquamous NSCLC. Maintenance therapy for NSCLC is approved when Avastin was prev used as a first-line combination regimen AND used as a single agent AND can be used until disease progression. For Metastatic Breast Carcinoma, HER2-negative disease, Avastin is being used as first-line therapy in combination with paclitaxel or paclitaxel protein bound. For Metastatic Clear Cell Renal Carcinoma, Avastin is being used as first-line therapy in combination with interferon or as a single agent for relapsed or medically unresectable stage IV disease with predominant clear cell histology in individuals who have progressed on prior cytokine therapy. For primary central nervous system tumors who have failed radiation therapy, bevacizumab will be used in a single line of therapy AND tumor to be treated is a WHO Grade III/IV glioma (includes but is not limited to): Anaplastic astrocytoma, Progressive or recurrent ependymoma that has failed radiation therapy, Anaplastic glioma, High-grade glioma, Recurrent, Glioblastoma, OR Glioblastoma multiforme. For recurrent, metastatic epithelial ovarian cancer, fallopian tube cancer, or recurrent primary peritoneal cancer, bevacizumab will be used in a single line of therapy AND used for relapsed or refractory disease and used as a single agent or in combination with other chemotherapy. For malignant mesothelioma, in combination with cisplatin or carboplatin and pemetrexed and ECOG status of 0-2 with no history of bleeding or thrombosis. For maintenance therapy, Bevacizumab was previously administered as an agent in a first-line combination chemotherapy regimen and used as a single agent until disease progression.
MEDICATION(S)
BELEODAQ

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Peripheral T-cell lymphoma (PTCL): Diagnosis of PTCL. Trial and failure, contraindication, or intolerance to at least one prior therapy (e.g., conventional chemotherapy).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hematologist/oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
**MEDICATION(S)**
BENLYSTA

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Systemic lupus erythematosus (SLE) (init): Diagnosis of active SLE. Autoantibody positive (ie, anti-nuclear antibody [ANA] titer greater than or equal to 1:80 or anti-dsDNA level greater than or equal to 30 IU/mL). Currently receiving at least one standard of care treatment for active SLE (eg, antimalarials [eg, Plaquinil (hydroxychloroquine)], corticosteroids [eg, prednisone], or immunosuppressants [eg, methotrexate, Imuran (azathioprine), CellCept (mycophenolate mofetil)]).

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
SLE (init): Prescribed by or in consultation with a rheumatologist

**COVERAGE DURATION**
SLE (init, reauth): 6 months

**OTHER CRITERIA**
SLE (reauth): Documentation of positive clinical response to Benlysta therapy
BERINERT

MEDICATION(S)
BERINERT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks (eg, Firazyr, Kalbitor, or Ruconest).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
HAE: Prescribed by an immunologist, allergist, or rheumatologist

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
BOSULIF

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Confirmed diagnosis of newly-diagnosed chronic phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) or treatment of chronic, accelerated, or blast phase Ph+ CML with resistance or intolerance to prior therapy with one of the following tyrosine kinase inhibitors (TKI): Gleevec [imatinib], Tasigna [nilotinib], Sprycel [dasatinib] AND Patient has received mutation testing AND does not have the T315I or V299L mutation OR B) Ph+ CML with intolerance to prior therapy with one of the following tyrosine kinase inhibitors (TKI): Gleevec [imatinib], Tasigna [nilotinib], Sprycel [dasatinib]

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist or hematologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
BOTOX

MEDICATION(S)
BOTOX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Neuromuscular Disorders (init): Strabismus, blepharospasm associated with dystonia (eg, benign essential blepharospasm), treatment of upper or lower limb spasticity, VII cranial nerve disorders (hemifacial spasms), cervical dystonia Hyperhidrosis(HH): (Init) Dx of primary axillary HH. Score of 3 or 4 on the Hyperhidrosis Disease Severity Scale (HDSS) or skin maceration with secondary infection. Trial and failure, contraindication, or intolerance (TF/C/I) to topical prescription strength drying agents [eg, Drysol, Hypercare, Xerac AC (aluminum chloride hexahydrate)]. Migraine:(Init) Dx of chronic migraines (greater than or equal to 15 migraine headache days per month with headache lasting 4 hours a day or longer). TF/C/I to prophylactic therapy with at least two of the following agents, each given for a trial of at least two months: antidepressants [ie, Effexor (venlafaxine)], antiepileptics [ie, Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], beta-blockers [eg, atenolol, Inderal (propranolol), nadolol, timolol, Toprol XL (metoprolol)] Achalasia:(Init) High risk of complication from or failure to pneumatic dilation or myotomy, or prior dilation caused esophageal perforation, or patient has an epiphrenic diverticulum or hiatal hernia. Anal Fissure (AF)(Init): Dx of chronic AF. At least 2 months of either nocturnal pain and bleeding or postdefecation pain. Chronic Back Pain (CBP):(Init) Dx of low back pain lasting greater than or equal to six months. Urinary incont (UI):(init) Neurogenic detrusor overactivity associated with a neurologic condition (eg, spinal cord injury [SCI], multiple sclerosis) or detrusor sphincter dyssynergia with SCI. Overactive bladder (OAB): (init) Dx of OAB. One of the following symptoms: urge urinary incontinence, urgency, frequency.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Migraine (Initial): Prescribed by a neurologist or pain specialist. CBP (Initial): Prescribed by a neurologist, neurosurgeon, orthopedist, or pain specialist. UI, OAB (initial): Prescribed by a neurologist, neurosurgeon, or urologist.
COVERAGE DURATION
Achalasia: 6mo CBP: 1 tx (series of injxs) UI: 3mo (1 dose, 200 units) Other: 3mo

OTHER CRITERIA
UI, OAB, CBP, Neuromuscular Disorders: (Reauth) Confirmed improvement in symptoms with initial Botox treatment. At least 3 months have or will have elapsed since the last treatment with Botox HH: (Reauth) At least a 2-point improvement in HDSS. Migraine: (Reauth) Reduction in headache frequency or intensity. Confirmation of decreased utilization of pain medications (eg, narcotic analgesics, NSAIDs) or triptans, or a reduction in the number of ER visits. Achalasia: (Reauth) Documentation of improvement or reduction in symptoms of achalasia (ie, dysphagia, regurgitation, chest pain). At least 6 months have or will have elapsed since last series of injections AF: (Reauth) Incomplete healing of fissure or recurrence of fissure. Improved symptoms with prior treatment with Botox.
MEDICATION(S)
BRAFTOVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Encorafenib is not indicated for treatment of wild-type BRAF melanoma.

REQUIRED MEDICAL INFORMATION
Melanoma, unresectable or metastatic Treatment of unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with binimetinib, as detected by an FDA-approved test. Limitations of use: Encorafenib is not indicated for treatment of wild-type BRAF melanoma.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
CABLIVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Treatment of acquired thrombotic thrombocytopenic purpura (aTTP) in adults, in combination with plasma exchange and immunosuppressive therapy

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
CABOMETYX

MEDICATION(S)
CABOMETYX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Renal cell carcinoma (RCC): Diagnosis of RCC. RCC is advanced. Trial and failure, contraindication, or intolerance to at least one prior anti-angiogenic therapy [e.g., Nexavar (sorafenib), Sutent (sunitinib)].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
CAPRELSA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Thyroid Cancer: Diagnosis of medullary thyroid cancer (MTC)

AGE RESTRICTION
N/A

PREScriber restriction
Prescribed by or in consultation with oncologist or endocrinologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
CARISOPRODOL

MEDICATION(S)
CARISOPRODOL 350 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
The drug is being prescribed for an FDA-approved indication. If the patient is 65 years of age or older, the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
**CAYSTON**

**MEDICATION(S)**
CAYSTON

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Cystic fibrosis (CF) (Initial, Reauth): Diagnosis of CF AND Patient has evidence of Pseudomonas aeruginosa in the lungs

**AGE RESTRICTION**
CF (Initial): 7 years of age or older

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
CF (Initial, reauth): 12 months

**OTHER CRITERIA**
CF (Reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations)
MEDICATION(S)
CERDELGA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Gaucher disease (Initial): Diagnosis of Gaucher disease type 1. Patient is an extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) of cytochrome P450 enzyme (CYP) 2D6 as detected by an FDA-cleared test.

AGE RESTRICTION
Gaucher disease (initial): 18 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Gaucher disease (initial, reauth): 12 months

OTHER CRITERIA
Gaucher disease (Reauth): Patient’s condition has not progressed, as defined by ALL of the following: A) Hemoglobin level decreased greater than 1.5 g/dL from baseline, AND B) Platelet count decreased greater than 25% from baseline, AND C) Spleen volume increased greater than 25% from baseline, AND D) Liver volume increased greater than 20% from baseline.
MEDICATION(S)
CEREZYME 400 UNITS VIAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Gaucher disease: Diagnosis of type 1 Gaucher disease. Patient has evidence of symptomatic disease (e.g., moderate to severe anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Gaucher disease: 12 months

OTHER CRITERIA
N/A
MEDICATION(S)
EMGALITY 100 MG/ML SYR (1 OF 3), EMGALITY 300 MG (100 MG X3SYR)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For migraine PROPHYLAXIS to be approved if: Patient must have at least 4 migraine days per month or one or more severe migraines lasting for greater than 12 hours despite use of abortive therapy (e.g. triptan or NSAIDs) AND There is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least one drug from two categories below for at least 4 weeks EACH, at minimum effective doses: Beta-adrenergic blockers, Topiramate or divalproex ER or DR, Amitriptyline or venlafaxine, Frovatriptan, zolmitriptan or naratriptan (for menstrual migraine prophylaxis),

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBER MUST BE A NEUROLOGIST

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
CHOLBAM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Bile acid synthesis disorders due to single enzyme defects (BAS) (initial): diagnosis of a bile acid synthesis disorder due to a single enzyme defect. Peroxisomal disorders (PD) (initial): All of the following: 1) diagnosis of peroxisomal disorder, 2) patient exhibits at least one of the following: a) liver disease (eg, jaundice, elevated serum transaminases), OR b) steatorrhea, OR c) complications from decreased fat-soluble vitamin absorption (eg, poor growth), AND 3) Cholbam will be used as an adjunctive treatment.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
All uses (initial): Prescribed by a hepatologist, medical geneticist, pediatric gastroenterologist, OR other specialist that treats inborn errors of metabolism.

COVERAGE DURATION
All uses (initial, reauth): 12 months

OTHER CRITERIA
All uses (reauth): documentation of positive clinical response to Cholbam therapy
MEDICATION(S)
CHORIONIC GONAD 10,000 UNIT VL, NOVAREL 10,000 UNITS VIAL, PREGNYL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Prepubertal Cryptorchidism: Diagnosis of prepubertal cryptorchidism not due to anatomical obstruction.
Male Hypogonadotropic Hypogonadism (MHH) (initial): Diagnosis of male hypogonadism secondary to pituitary deficiency, and low testosterone (below normal reference value provided by the physician's laboratory) and one of the following: a) low LH (below normal reference value provided by the physician’s laboratory) or b) low FSH (below normal reference value provided by the physician’s laboratory).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Prepubertal Cryptorchidism: 6 wks. MHH (initial, reauth): 12 months.

OTHER CRITERIA
Excluded if used to promote fertility. MHH (Reauth): Documentation of positive clinical response to therapy.
CIMZIA

MEDICATION(S)
CIMZIA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Rheumatoid Arthritis (RA, initial): Diagnosis (dx) of moderately to severely active RA. TF/C/I to Enbrel and Humira OR for continuation of prior Cimzia therapy. Crohn's Disease (CD, initial): Dx of moderately to severely active CD. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine (Purinethol), Azathioprine (Imuran), Corticosteroid (eg, prednisone, methylprednisolone), Methotrexate (Rheumatrex, Trexall). TF/C/I to Humira OR for continuation of prior Cimzia therapy. Psoriatic Arthritis (PsA, initial): Dx of active PsA. TF/C/I to Cosentyx and either Humira or Enbrel OR for continuation of prior Cimzia therapy. Ankylosing Spondylitis (AS, initial): Dx of active AS. TF/C/I to Enbrel and Humira OR for continuation of prior Cimzia therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
CD (init): Prescribed by or in consultation with a gastroenterologist. RA, AS (init): Prescribed by or in consultation with a rheumatologist. PsA (init): Prescribed by or in consultation with a dermatologist or rheumatologist.

COVERAGE DURATION
OTHER CRITERIA
Reauthorization (all indications): Documentation of positive clinical response to Cimzia therapy. All indications (initial and reauth): Patient is not receiving Cimzia in combination with either of the following: Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab), Orencia (abatacept)] or Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].
MEDICATION(S)
CINRYZE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Prophylaxis of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For prophylaxis against HAE attacks. For continuation of prior therapy or Trial and failure, contraindication, or intolerance of one of the following: 17-alpha alkylated androgen (eg, danazol, oxandrolone) or antifibrinolytics (eg, aminocaproic acid, tranexamic acid).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
HAE (prophylaxis, treatment): Prescribed by an immunologist, allergist, or rheumatologist

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
COMETRIQ

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Medullary thyroid cancer (MTC): Diagnosis of Metastatic MTC. Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC and positive for RET gene rearrangements.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
MTC: Prescribed by or in consultation with an oncologist/hematologist or endocrinologist. NSCLC: Prescribed by or in consultation with an oncologist/hematologist.

COVERAGE DURATION
All uses: 12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
COPIKTRA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chronic lymphocytic leukemia/small lymphocytic lymphoma, relapsed or refractory Treatment of relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) in adult patients after at least two prior therapies. Follicular lymphoma, relapsed or refractory Treatment of relapsed or refractory follicular lymphoma (FL) in adult patients after at least two prior systemic therapies.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
**MEDICATION(S)**
CORLANOR 5 MG TABLET, CORLANOR 7.5 MG TABLET

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
CHF (initial, reauth): BP less than 90/50, severe hepatic impairment, a. fib.

**REQUIRED MEDICAL INFORMATION**
Chronic heart failure (CHF) (initial): Diagnosis of CHF with NYHA Class II, III, or IV symptoms. Left ventricular ejection fraction less than or equal to 35%. Patient is in sinus rhythm with a resting heart rate of greater than or equal to 70 BPM and has been hospitalized for worsening HF in the previous 12 months. Trial and failure, intolerance, or contraindication to maximally tolerated doses of at least one beta-blocker with proven mortality benefit (i.e., carvedilol, bisoprolol, sustained-release metoprolol) AND trial and failure, intolerance, or contraindication to maximally tolerated doses of an ACE inhibitor or ARB.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
CHF (initial): Prescribed by or in consultation with a cardiologist

**COVERAGE DURATION**
CHF (initial, reauth): 12 months

**OTHER CRITERIA**
CHF (reauth): patient does not have contraindications/exclusions to therapy.
MEDICATION(S)
COSENTYX (2 SYRINGES), COSENTYX PEN, COSENTYX PEN (2 PENS), COSENTYX SYRINGE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: Trial and failure, contraindication, or intolerance to Enbrel (etanercept) OR Humira (adalimumab), OR for continuation of prior Cosentyx therapy. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: Trial and failure, contraindication, or intolerance to Enbrel (etanercept) or Humira (adalimumab), OR for continuation of prior Cosentyx therapy. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. One of the following: Trial and failure, contraindication, or intolerance to Enbrel (etanercept) or Humira (adalimumab), OR for continuation of prior Cosentyx therapy. All indications (Initial, reauth): Patient is not receiving Cosentyx in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Plaque psoriasis (Initial): Prescribed by or in consultation with a dermatologist. PsA (Initial): Prescribed by or in consultation with a rheumatologist or dermatologist. AS (Initial): Prescribed by or in consultation with a rheumatologist.

COVERAGE DURATION
All indications (Initial, reauth): 12 months

OTHER CRITERIA
All indications (Reauth): Documentation of positive clinical response to Cosentyx therapy.
COTELLIC

**MEDICATION(S)**
COTELLIC

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Melanoma: Diagnosis of unresectable or metastatic melanoma. Patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test (e.g., cobas 4800 BRAF V600 Mutation Test) or performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with vemurafenib.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
Prescribed by or in consultation with an oncologist

**COVERAGE DURATION**
12 months

**OTHER CRITERIA**
Approve for continuation of prior therapy.
MEDICATION(S)
CRINONE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
All indications: Excluded if for fertility uses.

REQUIRED MEDICAL INFORMATION
Secondary amenorrhea: Diagnosis of secondary amenorrhea (the absence of menses in women who have already started menstruation who are not pregnant, breastfeeding, or in menopause).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
CYRAMZA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Gastric cancer: All of the following: 1) diagnosis of one of the following: a) gastric adenocarcinoma, OR b) gastro-esophageal junction (GEJ) adenocarcinoma, AND 2) disease is one of the following: a) locally advanced, OR b) metastatic, AND 3) disease has progressed on or after one of the following first-line therapies: a) fluoropyrimidine-containing chemotherapy (eg, fluorouracil, capecitabine), OR b) platinum-containing chemotherapy (eg, cisplatin, carboplatin, oxaliplatin). Non-small cell lung cancer: All of the following: 1) diagnosis of metastatic non-small cell lung cancer, AND 2) used in combination with docetaxel, AND 3) disease has progressed on or after platinum-based chemotherapy (eg, cisplatin, carboplatin, oxaliplatin). Metastatic colorectal cancer (mCRC): 1) Diagnosis of metastatic CRC AND 2) Patient had disease progression on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
CYSTARAN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Cystinosis: Diagnosis of cystinosis, confirmed by elevated leukocyte cystine levels (LCL), genetic analysis of the CTNS gene or corneal cystine crystal accumulation AND Patient is concomitantly receiving treatment with oral cysteamine

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
DECITABINE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of myelodysplastic syndrome.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hematologist/oncologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
DALIRESP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chronic Obstructive Pulmonary Disease (COPD): (Initial) Diagnosis of severe COPD. Patient has chronic bronchitis. Trial and failure, intolerance, or contraindication to two prior therapies for COPD.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
COPD (init, reauth): 12 months

OTHER CRITERIA
COPD (reauth): Documentation of positive clinical response to Daliresp therapy.
MEDICATION(S)
DARAPRIM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Toxoplasmosis: 1) Patient is using Daraprim for the treatment of toxoplasmic encephalitis, secondary prophylaxis of toxoplasmic encephalitis, or treatment of congenital toxoplasmosis OR 2) Patient is using Daraprim for the primary prophylaxis of toxoplasmic encephalitis, patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX), and one of the following: patient has been re-challenged with TMP-SMX using a desensitization protocol and is still unable to tolerate, or evidence of life-threatening reaction to TMP-SMX in the past (eg, toxic epidermal necrolysis, Stevens-Johnson syndrome). Malaria: Patient is using Daraprim for the treatment of acute malaria or chemoprophylaxis of malaria. Patient does not have megaloblastic anemia due to folate deficiency. The provider acknowledges that Daraprim is not recommended by the Centers for Disease Control and Prevention (CDC) for the treatment and/or prophylaxis of malaria.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an infectious disease specialist

COVERAGE DURATION
12 months

OTHER CRITERIA
Toxoplasmosis only: Approve for continuation of prior therapy.
MEDICATION(S)
DARZALEX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Multiple Myeloma (MM): Diagnosis of MM. One of the following: A) Patient has received at least three prior treatment regimens which included both a proteasome inhibitor (eg, bortezomib [Velcade], carfilzomib [Kyprolis]) and an immunomodulatory agent (eg, lenalidomide [Revlimid], thalidomide [Thalomid]) or patient is double-refractory to a proteasome inhibitor and an immunomodulatory agent. OR B) Patient has received at least one prior therapy. Darzalex will be used in combination with either 1) lenalidomide and dexamethasone or 2) bortezomib and dexamethasone

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist/hematologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy
DEFERASIROX

MEDICATION(S)
DEFERASIROX, EXJADE, JADENU

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chronic Iron Overload Due to Blood Transfusions (Initial): Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis). Patient has a baseline ferritin level more than 1,000 mcg/L. Patient has required the transfusion of at least 100 mL/kg packed red blood cells.
Myelodysplastic Syndrome (MDS) (Initial): Diagnosis of MDS. Patient has Low or Intermediate-1 disease or is a potential transplant patient. Patient has received more than 20 red blood cell transfusions. Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT) (Initial): Diagnosis of chronic iron overload due to NTDT. Liver iron concentration (LIC) 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) or higher. Serum ferritin level greater than 300 mcg/L.

AGE RESTRICTION
Iron Overload Due to Blood Transfusions (initial): 2 years of age or older. NTDT (initial): 10 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Iron Overload Due to Blood Transfusions, MDS (initial, reauth): 12 mo. NTDT (initial, reauth): 6 mo.

OTHER CRITERIA
Iron Overload Due to Blood Transfusions, MDS (Reauth): Patient experienced a reduction from baseline in serum ferritin level or LIC. NTDT (Reauth): Patient has LIC 3 mg Fe/g dw or higher. Patient experienced a reduction from baseline in serum ferritin level or LIC.
DEXMETHYLPHENIDATE

MEDICATION(S)
DEXMETHYLPHENIDATE HCL, DEXMETHYLPHENIDATE ER 10 MG CP, DEXMETHYLPHENIDATE ER 15 MG CP, DEXMETHYLPHENIDATE ER 20 MG CP, DEXMETHYLPHENIDATE ER 25 MG CP, DEXMETHYLPHENIDATE ER 30 MG CP, DEXMETHYLPHENIDATE ER 35 MG CP, DEXMETHYLPHENIDATE ER 40 MG CP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD)

AGE RESTRICTION
PA applies to members 19 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
DEXTROAMPHETAMINE 10 MG TAB, DEXTROAMPHETAMINE 5 MG TAB, DEXTROAMPHETAMINE SULFATE ER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD), OR c) diagnosis of narcolepsy as confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

AGE RESTRICTION
PA applies to members 19 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
DICLOFENAC SODIUM 3% GEL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Dx of Actinic Keratosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
DUOBRII

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of Plaque Psoriasis. Patient has tried and failed the combination of the individual generic components of the product (halobetasol and tazarotene) and other topical products indicated for the treatment of plaque psoriasis such as calcipotriene/betamethasone or its generic components.

AGE RESTRICTION
Patient must be 18 years of age or greater.

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a dermatologist or rheumatologist.

COVERAGE DURATION
Initial Auth: 6 months

OTHER CRITERIA
Reauth: Documentation of positive clinical response to therapy. 12 months.
**MEDICATION(S)**
DUPIXENT 200 MG/1.14 ML SYRING

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Asthma: Add-on maintenance treatment of moderate to severe asthma in adults and pediatric patients equal to or greater than 12 years of age with an eosinophilic phenotype or with corticosteroid dependent asthma. Limitations of use: Not indicated for the relief of acute bronchospasm or status asthmaticus. Atopic dermatitis: Treatment of moderate to severe atopic dermatitis in adults whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable

**AGE RESTRICTION**
ASTHMA: equal to or greater than 12 years of age, ATOPIC DERMATITIS: ADULTS

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
12 months

**OTHER CRITERIA**
N/A
MEDICATION(S)
EGRIFTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
HIV-associated lipodystrophy (initial): All of the following: 1) diagnosis of HIV-associated lipodystrophy, 2) one of the following: a) waist-circumference of greater than or equal to 95 cm (37.4 inches) in men, OR b) waist-circumference of greater than or equal to 94 cm (37 inches) for women, 3) one of the following: a) Waist-to-hip ratio of greater than or equal to 0.94 for men, OR b) waist-to-hip ratio of greater than or equal to 0.88 for women, 4) body mass index (BMI) greater than 20 kg/m², AND 5) fasting blood glucose (FBG) levels less than or equal to 150 mg/dL (8.33 mmol/L), AND 6) patient has been on a stable regimen of antiretrovirals (eg, NRTIs, NNRTI, Protease Inhibitors, Integrase Inhibitors) for at least 8 weeks.

AGE RESTRICTION
(Initial): 18 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
(initial, reauth): 6 months

OTHER CRITERIA
(reauth): documentation of clinical improvement (eg, improvement in visceral adipose tissue [VAT], decrease in waist circumference, belly appearance, etc) while on Egrifta therapy.
**MEDICATION(S)**
ELAPRASE

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Diagnosis of Hunter Syndrome (Mucopolysaccharidosis II (MPS II))

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
12 months

**OTHER CRITERIA**
N/A
MEDICATION(S)
ELIGARD

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Prostate Cancer: Diagnosis of advanced or metastatic prostate cancer. Trial and failure, contraindication, or intolerance to Lupron Depot (7.5 mg, 22.5 mg, 30 mg, and 45 mg).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
**MEDICATION(S)**
EMPLICITI

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Multiple myeloma: Diagnosis of multiple myeloma. Patient has received at least one prior therapy for multiple myeloma [eg, Revlimid (lenalidomide), Thalomid (thalidomide), Velcade (bortezomib)].

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
Prescribed by or in consultation with a hematologist/oncologist.

**COVERAGE DURATION**
12 months

**OTHER CRITERIA**
Approve for continuation of prior therapy.
MA J2KJ003

ENBREL

MEDICATION(S)
ENBREL, ENBREL MINI, ENBREL SURECLICK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Failure, contraindication, or intolerance to one disease-modifying antirheumatic drug (DMARD) [eg, methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)]. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Trial and failure, contraindication, or intolerance to one of the following DMARDs: Arava (leflunomide) or methotrexate (Rheumatrex/Trexall). Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Trial and failure, contraindication, or intolerance to two NSAIDs. All indications (Initial, reauth): Patient is not receiving Enbrel in combination with a biologic DMARD [eg, Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)]. Patient is not receiving Enbrel in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RA (Initial), PJIA (Initial), AS (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with a rheumatologist or dermatologist. Plaque Psoriasis (Initial): Prescribed by or in consultation with a dermatologist.

COVERAGE DURATION
All indications (Initial, reauth): 12 months

OTHER CRITERIA
All indications (Reauth): Documentation of positive clinical response to Enbrel therapy.
MEDICATION(S)
EPCLUSA, SOFOSBUVIR-VELPATASVIR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria will be applied consistent with current AASLD/IDSA guideline. Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C virus. Patient is not receiving Epclusa in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir). One of the following: a) genotypes 2, 3, 5, or 6, or b) genotypes 1 or 4: trial and failure, contraindication, or intolerance to Harvoni and Zepatier or, for patients with decompensated cirrhosis, trial and failure, contraindication, or intolerance to Harvoni, or c) for continuation of prior Epclusa therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine

COVERAGE DURATION
12 to 24 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.

OTHER CRITERIA
N/A
**MEDICATION(S)**
EPIDIOLEX

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) in patients equal to or greater than 2 years of age. Patient has failed or has developed intolerable side effects to conventional treatment. Conventional treatment includes medications from the following Anticonvulsant Therapeutic Classes: Calcium Channel Modifying Agents, Gamma-aminobutyric Acid (GABA) Augmenting Agents, Glutamate Reducing Agents, Sodium Channel Agents, Anticonvulsants, Other. Dravet syndrome -patient is taking at least 1 concomitant antiepileptic medication AND The patient is refractory on current therapy (i.e. patient has experienced a convulsive seizure [i.e. tonic, atonic, tonic clonic] in the past 28 days). Lennox Gastaut Syndrome -patient has an EEG which has shown a pattern of slow (greater than 2.5 Hz) spike and wave complexes AND The member is taking at least 1 concomitant antiepileptic medication AND The member is refractory on current therapy (e.g. has experienced a drop seizure in the past 28 days, i.e. tonic, atonic, tonic clonic, that led to or could have led to a fall or injury)

**AGE RESTRICTION**
Equal to or greater than 2 years of age.

**PRESCRIBER RESTRICTION**
Prescribed by a neurologist.

**COVERAGE DURATION**
12 months

**OTHER CRITERIA**
N/A
EPOETIN ALFA

MEDICATION(S)
PROCRIT, RETACRIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Anemia with Chronic Kidney Disease (CKD) (Initial): Diagnosis (Dx) of CKD. Anemia by lab values (Hct less than 30% or Hgb less than 10 g/dL) collected within 30 days of request. One of the following: a) both of the following: Patient is on dialysis, patient is without ESRD OR b) all of the following: patient is not on dialysis, the rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion, and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal. Anemia with HIV (Initial): Anemia by lab values (Hgb less than 12 g/dL or Hct less than 36%) collected within 30 days of request. Serum erythropoietin level less than or equal to 500 mU/mL. Receiving zidovudine therapy or dx of HIV. Anemia with chemo (Initial): Other causes of anemia have been ruled out. Anemia by lab values (Hct less than 30%, Hgb less than 10 g/dL) collected within the prior 2 weeks of request. Cancer is a non-myeloid malignancy. Patient is concurrently on chemo, or will receive concomitant chemo for a minimum of 2 mos, or anemia is caused by cancer chemo. Will not be approved if patient is not receiving cancer chemotherapy. Preoperative for reduction of allogeneic blood transfusion: Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery. Hgb is greater than 10 to less than or equal to 13 g/dL. Patient is at high risk for perioperative transfusions. Patient is unwilling or unable to donate autologous blood pre-operatively. Anemia in hepatitis C virus (HCV)-infected pts due to ribavirin in combination with interferon or peg-interferon (Initial): Dx of HCV infection. Anemia by labs (Hct less than 30% or Hgb less than 10 g/dL) collected within 30 days of request. Patient is receiving ribavirin and one of the following: interferon alfa or peginterferon alfa. Anemia in Myelodysplastic Syndrome (MDS) (Initial): Dx of MDS. Serum erythropoietin level is 500 mU/mL or less, or dx of transfusion-dependent MDS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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**COVERAGE DURATION**

**OTHER CRITERIA**
Subject to ESRD review. CKD (Reauth): Dx of CKD. Most recent or average (avg) Hct over 3 months is 33% or less OR most recent or avg Hgb over 3 months is 11 g/dL or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. HIV (Reauth): Most recent or avg Hct over 3 months is below 36% or most recent or avg Hgb over 3 months is below 12 g/dL. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Chemo (Reauth): Anemia by lab values (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 weeks of request. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Patient is concurrently on chemo, or will receive concomitant chemo for a minimum of 2 months, or anemia is caused by cancer chemo. Will not be approved if patient is not receiving cancer chemotherapy. HCV (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. If patient has demonstrated response to therapy, authorization will be issued for the full course of ribavirin therapy. MDS (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Off-label uses (except MDS): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%. CKD (init, reauth), HIV (init), Chemo (init), Preop, MDS (init), HCV (init): Verify iron evaluation for adequate iron stores.
MEDICATION(S)
ERBITUX 100 MG/50 ML VIAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Head and Neck Cancer: Diagnosis of locally or regionally advanced squamous cell head and neck cancer and used in combination with radiation therapy, or diagnosis of recurrent or metastatic squamous cell head and neck cancer and 1 of the following: trial and failure of platinum-based chemotherapy, or used in combination with 1 of the following: cisplatin (Platinol AQ), carboplatin (Paraplatin), cisplatin (Platinol AQ) plus 5-FU (Adrucil), or carboplatin (Paraplatin) plus 5-FU (Adrucil).
Colorectal Cancer: Diagnosis of metastatic carcinoma of the colon or rectum. One of the following: Used in combination with either FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or FOLFIRI (fluorouracil, leucovorin, and irinotecan), OR trial and failure or intolerance to irinotecan-based chemotherapy, oxaliplatin-based chemotherapy, or intensive therapy (eg, FOLFOX or FOLFIRI), OR used as monotherapy in patients not appropriate for intensive therapy. Tumor expresses wild-type KRAS gene and wild type NRAS gene.
Non-Small Cell Lung Cancer (NSCLC): Diagnosis of recurrent or metastatic NSCLC stage IIIB or IV. One of the following: Used in combination with vinorelbine (Navelbine) and cisplatin (Platinol AQ), OR used as a single-agent for continuation maintenance therapy and Erbitux was given first-line with chemotherapy. ECOG performance status 0-2. Epidermal growth factor receptor (EGFR) expression by immunohistochemistry.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months.
OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
ERIVEDGE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Basal cell carcinoma: One of the following: A) Diagnosis of metastatic basal cell carcinoma OR B) Both of the following: 1) Diagnosis of locally advanced basal cell carcinoma AND 2) One of the following: a) Disease recurred following surgery or b) Patient is not a candidate for surgery and radiation.

AGE RESTRICTION
18 years of age or older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist or dermatologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
**ESBRIET**

**MEDICATION(S)**
ESBRIET 267 MG CAPSULE, ESBRIET 801 MG TABLET

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Idiopathic pulmonary fibrosis (IPF) (initial): Both of the following: 1) diagnosis of IPF as documented by all of the following: a) exclusion of other known causes of interstitial lung disease (ILD) (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity), AND b) one of the following: i) in patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF, AND 2) not used in combination with Ofev (nintedanib).

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
IPF (initial): Prescribed by a pulmonologist

**COVERAGE DURATION**
initial, reauth: 12 months

**OTHER CRITERIA**
IPF (reauth): Documentation of positive clinical response to Esbriet therapy
EXONDYS 51

MEDICATION(S)
EXONDYS 51

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of Duchenne muscular dystrophy (DMD). Documentation of a confirmed mutation of the dystrophin gene amenable to exon 51 skipping. Patient is ambulatory. Initial/Reauth: Exondys 51 dosing for DMD is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 30 mg/kg infused once weekly.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
(initial, reauth): Prescribed by or in consultation with a neurologist who has experience treating children

COVERAGE DURATION
Initial: 6 months, Reauth: 12 months

OTHER CRITERIA
Reauth: One of the following: 1) All of the following: Patient has been on therapy for less than 12 months, patient is maintaining ambulatory status, and patient is tolerating therapy, OR 2) All of the following: Patient has been on therapy for 12 months or more, Patient is maintaining ambulatory status, patient has experienced a benefit from therapy (e.g., disease amelioration compared to untreated patients), and patient is tolerating therapy.
MEDICATION(S)
EYLEA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Patient must not have an active ocular or periocular infection.

REQUIRED MEDICAL INFORMATION
Diagnosis of Diabetic Macular Edema (DME) and has tried and failed or had an intolerance to Avastin OR Diagnosis of Macular Degeneration- Neovascular (wet) age-related macular degeneration and has tried and failed or had an intolerance to Avastin OR Diagnosis of diabetic retinopathy OR Diagnosis of Macular Edema following retinal vein occlusion (RVO).

AGE RESTRICTION
Patient must be 18 years of age or older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an ophthalmologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
FABRAZYME 35 MG VIAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Fabry Disease: Diagnosis of Fabry disease.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Fabry Disease: 12 months

OTHER CRITERIA
N/A
MEDICATION(S)
FARYDAK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Multiple Myeloma (MM): Diagnosis of MM. Used in combination with both of the following: Velcade (bortezomib) and dexamethasone. Patient has received at least two prior treatment regimens which included both of the following: Velcade (bortezomib) and an immunomodulatory agent [eg, Revlimid (lenalidomide), Thalomid (thalidomide)].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist/hematologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
FENTANYL

MEDICATION(S)
FENTANYL CIT OTFC 1,200 MCG, FENTANYL CITRATE OTFC 200 MCG, FENTANYL CITRATE OTFC 600 MCG, FENTANYL CITRATE OTFC 800 MCG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For the management of breakthrough cancer pain. Patient is currently taking a long-acting opioid around the clock for cancer pain. Patient must have at least a one week history of ONE of the following medications to demonstrate tolerance to opioids: Morphine sulfate at doses of greater than or equal to 60 mg/day, Fentanyl transdermal patch at doses greater than or equal to 25 ??g/hr, Oxycodone at a dose of greater than or equal to 30 mg/day, Oral hydromorphone at a dose of greater than or equal to 8 mg/day, Oral oxymorphone at a dose of greater than or equal to 25 mg/day, or an alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with one of the following: Pain specialist, Oncologist, Hematologist, Hospice care specialist, or Palliative care specialist.

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
FERRIPROX 100 MG/ML SOLUTION, FERRIPROX 500 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Transfusional iron overload due to thalassemia syndromes (Initial): Patient has a diagnosis of transfusional iron overload due to thalassemia syndromes. Absolute neutrophil count (ANC) greater than 1.5 x 10⁹/L. One of the following: A) Patient has failed prior chelation therapy (e.g., Exjade) [failure defined as serum ferritin greater than 2,500 mcg/L] OR B) Patient has a contraindication or intolerance to Desferal (deferroxamine) or Exjade (deferasirox).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
All uses (initial, reauth): 12 months

OTHER CRITERIA
All uses (reauth): Patient has experienced greater than or equal to 20% decline in serum ferritin levels from baseline. ANC greater than 0.5 x 10⁹/L.
MEDICATION(S)
FIRAZYR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks (eg, Berinert, Kalbitor, or Ruconest).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
HAE: Prescribed by an immunologist, allergist, or rheumatologist

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
FIRMAGON

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of advanced or metastatic prostate cancer.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
DICLOFENAC EPOLAMINE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of acute mild pain or moderate pain due to minor strains, sprains, and contusions (initial auth): (Reauthorization): Documentation of clinical benefit from ongoing therapy with Flector Patch (diclofenac epolamine topical).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 months

OTHER CRITERIA
N/A
MEDICATION(S)
FOLOTYN 40 MG/2 ML VIAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Peripheral T-cell lymphoma: Diagnosis of relapsed or refractory PTCL

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
Forteo

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Postmenopausal Osteoporosis or men with primary or hypogonadal osteoporosis (initial): Set I) Both of the following: A) Diagnosis of osteoporosis defined as bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) either 1) patient has a history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) patient has a trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia (denosumab)). Set II) Both of the following: A) Diagnosis of osteopenia defined by bone mineral density (BMD) T-score of between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site), AND B) One of the following: 1) patient has a history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) both of the following: i) Trial and failure, contraindication, or intolerance to at least one prior osteoporosis therapy (e.g., alendronate, risedronate, zoledronic acid, Prolia (denosumab)) and ii) One of the following FRAX 10-year probabilities: a) Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions, or b) Hip fracture is 3% or more in the U.S., or the country-specific threshold in other countries or regions.

Postmenopausal Osteoporosis or men with primary or hypogonadal osteoporosis (reauth): Documentation of a positive clinical response to Forteo (teriparatide) therapy and total duration has not exceeded a total of 24 months during the patient's lifetime. Glucocorticoid-Induced Osteoporosis: See Other Criteria section.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A
COVERAGE DURATION
All indications: 12 months, max 2 years of therapy.

OTHER CRITERIA
Glucocorticoid-Induced Osteoporosis: Diagnosis of glucocorticoid-induced osteoporosis. History of prednisone or its equivalent at a dose of greater than or equal to 5mg/day for greater than or equal to 3 months. One of the following: A) BMD T score of -2.0 or less based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) or B) Both of the following: 1) BMD T score between -1.0 and -2.0 (BMD T-score greater than -2.0 and less than or equal to -1.0) based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) and 2) either history of one of the following fx resulting from minimal trauma (vertebral compression fx, fx of the hip, or fx of the distal radius) or trial and failure, contraindication, or intolerance (TF/C/I) to one bisphosphonate [e.g., Fosamax (alendronate)] or C) Both of the following: 1) history of one of the following fractures resulting from minimal trauma (vertebral compression fx, fx of the hip, or fx of the distal radius) and 2) TF/C/I to one bisphosphonate [e.g., Fosamax (alendronate)]. Treatment duration has not exceeded a total of 24 months during the patient's lifetime.
MEDICATION(S)
GALAFOLD

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Galactosidase alpha gene (GLA) variant based on in vitro assay data.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
GAMASTAN S-D

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication).

REQUIRED MEDICAL INFORMATION
Immune globulin is being used intramuscularly. The immune globulin will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. Patient requires immunization for hepatitis A, measles, rubella, or varicella.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 months (Approve one dose only)

OTHER CRITERIA
Subject to Part B vs D review.
MEDICATION(S)
GATTEX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Short Bowel Syndrome (SBS) (Initial) Diagnosis of SBS. Patient is dependent on parenteral nutrition/intravenous (PN/IV) support for at least 12 consecutive months.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
SBS (Init): 6 months. SBS (Reauth): 12 months.

OTHER CRITERIA
SBS (Reauth): Documentation of positive clinical response to Gattex therapy.
MEDICATION(S)
GiLENYA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
GILOTRIF

MEDICATION(S)
GILOTRIF

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Confirmed diagnosis of 1) First-line treatment of metastatic non-small cell lung cancer (NSCLC) whose tumor has nonresistant epidermal growth factor receptor (EGFR) mutations as detected by a Food and Drug Administration-approved test. OR 2) Treatment of previously treated metastatic squamous cell NSCLC that has progressed following platinum-based chemotherapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
GLATIRAMER ACETATE

MEDICATION(S)
COPAXONE, GLATOPA 20 MG/ML SYRINGE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
GLEEVEC

MEDICATION(S)
IMATINIB MESYLATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For adults 18 years of age or older, One of the following: A) Diagnosis of Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) AND Patient is found to be Ph+ or BCR-ABL positive as detected by bone marrow cytogenetics, FISH or PCR OR B) Ph+ acute lymphoblastic leukemia (ALL) OR C) Gastrointestinal stromal tumor (GIST) AND one of the following: 1) Patient has documented c-KIT (CD117) positive unresectable or metastatic malignant GIST, OR 2) Patient had resection of c-KIT (CD117) positive GIST and imatinib will be used as adjuvant therapy OR D) Dermatofibrosarcoma protuberans that is unresectable, recurrent, or metastatic OR E) Hypereosinophilic syndrome or chronic eosinophilic leukemia OR F) Myelodysplastic syndrome (MDS) or myeloproliferative disease associated with platelet-derived growth factor receptor gene rearrangements OR G) Aggressive systemic mastocytosis without the D816V c-KIT mutation or with c-KIT mutational status unknown. For Pediatric patients younger than 18 years of age, One of the following: A) Diagnosis of Ph+ CML that is newly diagnosed in the chronic phase OR B) Diagnosis of newly diagnosed Ph+ALL.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
All uses: Prescribed by or in consultation with an oncologist or hematologist

COVERAGE DURATION
All uses: 12 months

OTHER CRITERIA
All uses: Approve for continuation of prior therapy.
**MEDICATION(S)**
GRANIX

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Primary prophylaxis of chemotherapy-induced febrile neutropenia (CFN): One of the following: 1) patient is receiving chemotherapy regimens associated with a greater than 20% incidence of FN, OR 2) both of the following: a) patient receiving chemotherapy regimen associated with 10-20% incidence of FN, AND b) one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia. Secondary prophylaxis of FN: Both of the following: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm^3), AND 2) patients with a history of FN during a previous course of chemotherapy. All indications: History of failure or intolerance to Zarxio (filgrastim-sndz).

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
All uses: Prescribed by or in consultation with a hematologist/oncologist or infectious disease specialist

**COVERAGE DURATION**
CFN, secondary prophylaxis of FN: 3mo or duration of tx

**OTHER CRITERIA**
N/A
MEDICATION(S)
GENOTROPIN, HUMATROPE, NORDITROPIN FLEXPRO, NORDITROPIN NORDIFLEX, NUTROPIN AQ NUSPIN, OMNITROPE 10 MG/1.5 ML CRTG, OMNITROPE 5 MG/1.5 ML CRTG, SAIZEN 5 MG VIAL, SAIZEN 8.8 MG VIAL, SAIZEN-SAIZENPREP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
PGHD(initial):less than 4mo w/GD, or hx neonatal hypoglycemia assoc w/pituitary dz, or panhypopituitarism dx, or all of the following: PGHD dx [confrmd by ht (utilizing age and gender grwth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.25SD below population(pop) mean (below 1.2 percentile for age and gender), or growth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg, delayed more than 2yrs compared w/chronological age)], and ped GH dosing used as defined by PI. PWS(reauth):evidence of positive response to tx(eg, incr in total LBM, decr in fat mass), or ht incr at least 2cm/yr over previous yr of tx (doc by previous ht and date and current ht and date) and expctd adult ht not attained and doc of expctd adult ht goal. GFSGA(initial):SGA dx based on catchup grwth failure in 1st 24mo of life using 0-36mo grwth chart confirmd by birth wt or length below 3rd percentile for gestational age (more than 2SD below pop mean) and ht remains at or below 3rd percentile (more than 2SD below pop mean). TS,NS(initial):ped grwth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on grwth charts for age and gender. SHOX(initial):ped grwth failure dx w/SHOX gene deficiency confirmed by genetic testing. GFCRI(initial): ped grwth failure dx assoc w/CRI. ISS(initial):ISS dx, diagnostic eval excluded other causes assoc w/short stature (eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender, doc growth velocity less than 25th percentile for bone age. PGHD,NS,SHOX,GFCRI,ISS (initial): doc male w/bone age less than 16yrs or female w/bone age less than 14yrs. PGHD,GFSGA,TS/NS,SHOX,GFCRI,ISS(reauth): ht incr of at least 2 cm/yr over previous yr of tx (doc by previous ht and date and current ht and date) and expctd adult ht not attained and doc of expctd adult ht goal.

AGE RESTRICTION
N/A
PRESCRIBER RESTRICTION
PGHD, PWS, GFGSA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist.
GFCRI: prescribed by endocrinologist or nephrologist

COVERAGE DURATION
All indications (initial, reauth): 12 months

OTHER CRITERIA
All(init): No prerequisites needed for Genotropin and Nutropin. All others: trial and failure or intolerance to Genotropin and Nutropin. AGHD(initial): dx of AGHD with clin records supporting dx of childhood-onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg, damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1GH stim test (insulin tolerance test [ITT], arginine/GHRH, glucagon, arginine) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L]) or doc deficiency of 3 anterior pituitary hormones (prolactin, ACTH, TSH, FSH/LH) and IGF-1/somatomedinC below age and gender adjsnt nrml range as provided by physicians lab. AGHD(init, reauth): panhypopituitarism OR other dx and not used in combo w/aromatase inhibitors (eg, anastrazole, letrozole) or androgens (eg, testosterone cypionate), and adult dosing used as def by PI. AGHD, IGHDA(reauth): monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level. TransitionPhaseAdolescent Pts(TPAP)(initial): adult GH dosing used as def by PI/AACE 2009 tx GL, attained expctl adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones:ACTH, TSH, prolactin, FSH/LH), w/IGF-1/somatomedinC below age and gender adjsnt nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], or at low risk of severe GHD (eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/ corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L]. TPAP(reauth): evidence of positive response to therapy (eg, incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3), and cont adult GH dosing used as def by PI/AACE 2009 tx GL. IGHDA(initial): doc GHD by failure to produce peak serum GH greater than 5 mcg/L after 2 provocative pharmacol stim tests (insulin, L-ARG, glucagon).
MEDICATION(S)
ACTHAR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Infantile Spasm (West Syndrome): Diagnosis of infantile spasms (West Syndrome). Multiple Sclerosis (MS): Acute exacerbations of MS. Rheumatic disorders: As adjunctive therapy for short-term administration in: psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), ankylosing spondylitis. Collagen diseases: During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis). Dermatologic diseases: Severe erythema multiforme, Stevens-Johnson syndrome. Allergic states: Serum sickness. Ophthalmic diseases: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa, such as: keratitis, iritis and iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation. Respiratory diseases: Symptomatic sarcoidosis. Edematous state: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus. All indications except for infantile spasms: Trial and failure, contraindication, or intolerance to treatment with two corticosteroids.

AGE RESTRICTION
Infantile spasms: less than 2 years old

PRESCRIBER RESTRICTION

COVERAGE DURATION
Infantile Spasms: 4 weeks. MS: 3 weeks. All other FDA-approved uses: 3 months.
OTHER CRITERIA
N/A
HALAVEN

MEDICATION(S)
HALAVEN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Breast Cancer: Diagnosis of recurrent or metastatic breast cancer. Previous treatment with both of the following: one anthracycline [eg, doxorubicin, Ellence (epirubicin)] and one taxane [eg, paclitaxel, Taxotere (docetaxel)]. Liposarcoma: Diagnosis of unresectable or metastatic liposarcoma. Previous treatment with one anthracycline-containing regimen.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
All Uses: prescribed by or in consultation with an oncologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
HARVONI, LEDIPASVIR-SOFOSBUVIR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria will be applied consistent with current AASLD/IDSA guideline. ALL (including patients with genotype 5 or 6 infection AND decompensated cirrhosis): A) Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C (CHC) virus AND B) Patient is not receiving Harvoni in combination with another HCV direct acting antiviral agent [eg, Sovaldi (sofosbuvir)]. For the following: 1) genotype 1, with cirrhosis, ribavirin ineligible, and with prior failure to HCV protease inhibitor triple therapy OR with prior failure to peginterferon plus ribavirin (except in 1) patients 12 to 17 years of age or 2) both of the following: a) patients weighing at least 35 kg and b) less than 18 years of age) OR 2) genotype 4, treatment-experienced, with cirrhosis, and ribavirin ineligible: trial and failure, intolerance or contraindication to Epclusa OR for continuation of prior Harvoni therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine

COVERAGE DURATION
12 to 24 wks. Criteria will be applied consistent with current AASLD/IDSA guideline

OTHER CRITERIA
N/A
MEDICATION(S)
HERCEPTIN 440 MG VIAL, HERCEPTIN HYLECTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Breast cancer: Diagnosis of human epidermal growth factor receptor 2 (HER2)-overexpressing breast cancer. One of the following treatment regimens: a) As adjuvant treatment, b) metastatic disease and one of the following: 1) used in combination with a taxane (eg, docetaxel, paclitaxel), or 2) used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease, or c) used in combination with Perjeta (pertuzumab). Gastric Cancer: Diagnosis of HER2-overexpressing gastric or gastroesophageal junction adenocarcinoma (locally advanced, recurrent, or metastatic). Used in combination with one of the following treatment regimens: a) Adrucil (5-fluorouracil), or b) Platinol (cisplatin) and Xeloda (capecitabine).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
All uses: Prescribed by or in consultation with an oncologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
HETLIOZ

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Non-24-Hour Sleep-Wake Disorder (Non-24) (initial): Both of the following: 1) Diagnosis of non-24-hour sleep-wake disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernychthemeral syndrome), AND 2) patient is totally blind (has no light perception).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Non-24 (initial): Prescribed by or in consultation with a specialist in sleep disorders or neurologist

COVERAGE DURATION
Non-24 (initial): 6 mo. (reauth): 12 mo

OTHER CRITERIA
Non-24 (reauth): Documentation of positive clinical response to Hetlloz therapy.
MEDICATION(S)
GUANFACINE HCL, GUANFACINE HCL ER, METHYLDOPA, METHYLDOPA-
HYDROCHLOROTHIAZIDE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
The drug is being prescribed for an FDA-approved indication AND the patient has tried and failed at least one non-HRM alternative (listed in OTHER CRITERIA) unless alternative(s) is/are inappropriate or would not be applicable for the indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.

AGE RESTRICTION
PA applies to patients 65 years or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Requires trial of at least one Non-HRM alternative: Low dose thiazide or a second generation calcium channel blocker OR ACE inhibitor, ARB, beta-blocker or combination product based on specific chronic conditions
**MEDICATION(S)**
CHLORPROMAZINE 10 MG TABLET, CHLORPROMAZINE 100 MG TABLET, CHLORPROMAZINE 200 MG TABLET, CHLORPROMAZINE 25 MG TABLET, CHLORPROMAZINE 50 MG TABLET, THIORIDAZINE HCL

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
The drug is being prescribed for an FDA-approved indication AND the patient has tried and failed at least one non-HRM alternative (listed in OTHER CRITERIA) unless alternative(s) is/are inappropriate or would not be applicable for the indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.

**AGE RESTRICTION**
PA applies to patients 65 years or older

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
12 months

**OTHER CRITERIA**
Applies to New Starts only. Requires trial of at least one Non-HRM alternative: haloperidol, atypical antipsychotic
MEDICATION(S)
ARALAST NP 500 MG VIAL, DIGITEK 250 MCG TABLET, DIGOXIN 0.05 MG/ML SOLUTION, DIGOXIN 0.25 MG TABLET, DIGOXIN 0.25 MG/ML SYRINGE, DIGOXIN 250 MCG TABLET, DISOPYRAMIDE PHOSPHATE, LANOXIN 187.5 MCG TABLET, LANOXIN 250 MCG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.

AGE RESTRICTION
PA applies to patients 65 years or older

PREScriber RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
**MEDICATION(S)**
MEGESTROL 20 MG TABLET, MEGESTROL 40 MG TABLET, MEGESTROL 625 MG/5 ML SUSP, MEGESTROL ACET 40 MG/ML SUSP, MEGESTROL ACET 400 MG/10 ML

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.

**AGE RESTRICTION**
PA applies to patients 65 years or older

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
12 months

**OTHER CRITERIA**
Applies to New Starts only.
MEDICATION(S)
MENEST 0.3 MG TABLET, MENEST 0.625 MG TABLET, MENEST 1.25 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.

AGE RESTRICTION
PA applies to patients 65 years or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of therapy.
MEDICATION(S)
AMABELZ, BIJUVA, CLIMARA PRO, COMBIPATCH, ESTRADIOL 0.025 MG PATCH, ESTRADIOL 0.0375 MG PATCH, ESTRADIOL 0.0375 MG/DAY PATCH, ESTRADIOL 0.05 MG PATCH, ESTRADIOL 0.06 MG/DAY PATCH, ESTRADIOL 0.075 MG PATCH, ESTRADIOL 0.075 MG/DAY PATCH, ESTRADIOL 0.1 MG PATCH, ESTRADIOL 0.1 MG/DAY PATCH, ESTRADIOL 0.5 MG TABLET, ESTRADIOL 1 MG TABLET, ESTRADIOL 2 MG TABLET, ESTRADIOL TDS 0.025 MG/DAY, ESTRADIOL TDS 0.0375 MG/DAY, ESTRADIOL TDS 0.05 MG/DAY, ESTRADIOL TDS 0.06 MG/DAY, ESTRADIOL TDS 0.075 MG/DAY, ESTRADIOL TDS 0.1 MG/DAY, ESTRADIOL-NORETHINDRONE ACETAT, FYAVOLV, JINTELI, MIMVEY, MIMVEY LO, NORETHIN-ETH ESTRAD 1 MG-5 MCG, NORETHIND-ETH ESTRAD 0.5-2.5, PREMARIN 0.3 MG TABLET, PREMARIN 0.45 MG TABLET, PREMARIN 0.625 MG TABLET, PREMARIN 0.9 MG TABLET, PREMARIN 1.25 MG TABLET, PREMPHASE, PREMPRO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication. Breast cancer (estradiol tablets and Premarin only): Dx of breast cancer. Disease is metastatic. Used for palliative treatment. Prostatic carcinoma (estradiol tablets and Premarin only): Dx of advanced androgen-dependent carcinoma of the prostate. Used for palliative treatment.

AGE RESTRICTION
PA applies to patients 65 years or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months
OTHER CRITERIA
Breast cancer and prostatic carcinoma (estradiol tablets and Premarin only): Approve for continuation of therapy.
**MEDICATION(S)**

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
The drug is being prescribed for an FDA-approved indication AND the patient has tried and failed at least one non-HRM alternative (listed in OTHER CRITERIA) unless alternative(s) is/are inappropriate or would not be applicable for the indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.

**AGE RESTRICTION**
PA applies to patients 65 years or older

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
12 months

**OTHER CRITERIA**
Requires trial of at least one Non-HRM alternative: Mild pain: acetaminophen, codeine. Moderate to severe pain: short-term NSAIDs, tramadol, tramadol/APAP, morphine sulfate, hydrocodone/APAP, oxycodone, oxycodone/APAP, fentanyl.
MEDICATION(S)
PHENOBARBITAL 100 MG TABLET, PHENOBARBITAL 15 MG TABLET, PHENOBARBITAL 16.2 MG TABLET, PHENOBARBITAL 20 MG/5 ML ELIX, PHENOBARBITAL 20 MG/5 ML SOLN, PHENOBARBITAL 30 MG TABLET, PHENOBARBITAL 32.4 MG TABLET, PHENOBARBITAL 60 MG TABLET, PHENOBARBITAL 64.8 MG TABLET, PHENOBARBITAL 97.2 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Verify the medication is being used for an FDA-approved diagnosis AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.

AGE RESTRICTION
PA applies to patients 65 years or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of therapy.
MEDICATION(S)
ZALEPLON, ZOLPIDEM TARTRATE, ZOLPIDEM TARTRATE ER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) when used longer than 90 days and wishes to proceed with the originally prescribed medication.

AGE RESTRICTION
PA applies to patients 65 years or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
CHLORZOXAZONE 375 MG TABLET, CHLORZOXAZONE 500 MG TABLET, CHLORZOXAZONE 750 MG TABLET, CYCLOBENZAPRINE 10 MG TABLET, CYCLOBENZAPRINE 5 MG TABLET, ORPHENADRINE CITRATE ER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.

AGE RESTRICTION
PA applies to patients 65 years or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
GLYBURIDE 1.25 MG TABLET, GLYBURIDE 2.5 MG TABLET, GLYBURIDE 5 MG TABLET, GLYBURIDE MICRONIZ E, GLYBURIDE-METFORMIN HCL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
The drug is being prescribed for an FDA-approved indication AND the patient has tried and failed at least one non-HRM alternative (listed in OTHER CRITERIA) unless alternative(s) is/are inappropriate or would not be applicable for the indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.

AGE RESTRICTION
PA applies to patients 65 years or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Requires trial of at least one Non-HRM alternative: glimepiride, glipizide
MEDICATION(S)
AMITRIPTYLINE HCL 10 MG TAB, AMITRIPTYLINE HCL 100 MG TAB, AMITRIPTYLINE HCL 150 MG TAB, AMITRIPTYLINE HCL 25 MG TAB, AMITRIPTYLINE HCL 50 MG TAB, AMITRIPTYLINE HCL 75 MG TAB, CHLORDIAZEPoxide-AMITRIPTYLINE, CLOMIPRAMINE 25 MG CAPSULE, CLOMIPRAMINE 50 MG CAPSULE, CLOMIPRAMINE 75 MG CAPSULE, DOXEPIN 10 MG CAPSULE, DOXEPIN 10 MG/ML ORAL CONC, DOXEPIN 100 MG CAPSULE, DOXEPIN 150 MG CAPSULE, DOXEPIN 25 MG CAPSULE, DOXEPIN 50 MG CAPSULE, DOXEPIN 75 MG CAPSULE, IMIPRAMINE HCL 10 MG TABLET, IMIPRAMINE HCL 25 MG TABLET, IMIPRAMINE HCL 50 MG TABLET, IMIPRAMINE PAMOATE, PERPHENAZINE-AMITRIPTYLINE, TRIMIPRAMINE MALEATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.

AGE RESTRICTION
PA applies to patients 65 years or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Applies to New Starts only.
HYDROXYPROGESTERONE

MEDICATION(S)
HYDROXYPROGEST 250 MG/ML VIAL, HYDROXYPROGESTERONE 1.25 G/5ML

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
All uses (initial): Pregnant patients.

REQUIRED MEDICAL INFORMATION
Amenorrhea: Diagnosis of primary or secondary amenorrhea. Amenorrhea is due to hormonal imbalance in the absence of organic pathology (e.g., submucous fibroids or uterine cancer) Secretory endometrium and desquamation: Used for production of secretory endometrium and desquamation in patients with endometrial disorder. Adenocarcinoma: Diagnosis of Stage III or IV adenocarcinoma of the uterine corpus. Estrogen production test: Used for the testing of endogenous estrogen production.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Adenocarcinoma (initial): Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
IBRANCE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Breast Cancer: Diagnosis of breast cancer. Disease is a) locally advanced or metastatic, b) estrogen-receptor (ER)-positive, and c) human epidermal growth factor receptor 2 (HER2)-negative. One of the following: a) used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) and patient is a postmenopausal woman, OR b) all of the following: used in combination with Faslodex (fulvestrant), disease has progressed following endocrine therapy, and one of the following: 1) patient is a postmenopausal woman OR 2) both of the following: patient is a premenopausal or perimenopausal woman and patient is receiving a luteinizing hormone-releasing hormone (LHRH) agonist [eg, Zoladex (goserelin)].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
**MEDICATION(S)**
ICLUSIG

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Chronic myelogenous leukemia: Diagnosis of chronic myelogenous leukemia AND One of the following: A) Trial and failure, resistance, relapse, contraindication, or intolerance to at least TWO other tyrosine kinase inhibitors (i.e., Gleevec [imatinib], Sprycel, Tasigna, and Bosulif) or B) Patient has the T315I mutation. Acute Lymphoblastic Leukemia: Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) AND One of the following: A) Trial and failure, resistance relapse, contraindication, or intolerance to at least TWO other FDA-approved tyrosine kinase inhibitors (i.e., Gleevec [imatinib], Sprycel), or B) Patient has the T315I mutation.

**AGE RESTRICTION**
All Uses: 18 years of age or older

**PRESCRIBER RESTRICTION**
All Uses: Prescribed by or in consultation with an oncologist or hematologist

**COVERAGE DURATION**
All uses: 12 months

**OTHER CRITERIA**
All uses: Approve for continuation of prior therapy.
**MEDICATION(S)**
IMBRUVICA 140 MG CAPSULE, IMBRUVICA 420 MG TABLET, IMBRUVICA 560 MG TABLET

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Mantle cell lymphoma (MCL): Diagnosis of MCL AND patient has relapsed or is refractory to at least one prior therapy for the treatment of MCL. Chronic lymphocytic leukemia (CLL): Diagnosis of CLL. Waldenström's macroglobulinemia: Diagnosis of Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma. Small lymphocytic lymphoma (SLL): Diagnosis of SLL. Marginal zone lymphoma (MZL): Diagnosis of MZL AND patient has received at least one prior anti-CD20-based therapy for MZL [e.g., Rituxan (rituximab), Zevalin (ibritumomab), Gazyva (obinutuzumab, etc.)].

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
All uses: Prescribed by or in consultation with an oncologist, hematologist or transplant specialist.

**COVERAGE DURATION**
All Uses: 12 months

**OTHER CRITERIA**
All Uses: Approve for continuation of prior therapy.
MEDICATION(S)
IMFINZI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Urothelial carcinoma: 1) Diagnosis of locally advanced or metastatic urothelial carcinoma AND 2) One of the following: a) Patient has experienced disease progression during or following platinum-containing chemotherapy OR b) Patient has experienced disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy
MEDICATION(S)
INBRIJA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Patient has developed OFF periods due to disease progression despite optimal treatment with oral doses of carbidopa/levodopa.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
INFLECTRA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Crohn's Disease (CD) and Fistulizing Crohn's Disease (FCD) (initial): Dx of moderately to severely active CD or FCD. Ulcerative colitis (UC) (initial): Dx of moderately to severely active UC. Rheumatoid arthritis (RA) (initial): Diagnosis (Dx) of moderately to severely active RA. Ankylosing spondylitis (AS) (initial): Dx of active AS. Psoriatic arthritis (PsA) (initial): Dx of active PsA. Plaque psoriasis (initial): Dx of chronic severe (ie, extensive and/or disabling) plaque psoriasis. CD, FCD (initial): Trial and failure, contraindication or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine (Purinethol), azathioprine (Imuran), corticosteroids (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex, Trexall). UC (initial): TF/C/I to one of the following conventional therapies: corticosteroids, aminosalicylate [eg, mesalamine (Asacol/Pentasa/Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine/Sulfazine)], azathioprine (Imuran), 6-mercaptopurine (Purinethol). RA (initial): Receiving concurrent therapy with methotrexate (Rheumatrex/Trexall), or TF/C/I to methotrexate. AS (initial): TF/C/I to two or more NSAIDs. All indications (initial): One of the following: 1) Trial and failure or intolerance to Remicade or 2) For continuation of prior Inflectra therapy. All indications (Initial): Excluded if patient is receiving infliximab in combination with a Biologic Disease Modifying Antirheumatic Drug (DMARD) [eg, Enbrel (etanercept), Orencia (abatacept), Rituxan (rituximab), Kineret (anakinra), Cimzia (certolizumab)] or Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RA, AS: Prescribed or recommended by a rheumatologist. PsA: Prescribed or recommended by rheumatologist or dermatologist. Crohn's Disease, Fistulizing Crohn's Disease, UC: Prescribed or recommended by a gastroenterologist. Plaque Psoriasis: Prescribed or recommended by a dermatologist.
COVERAGE DURATION
All indications (initial, reauth): 12 months

OTHER CRITERIA
Reauthorization for all indications: Documentation of positive clinical response to infliximab therapy. All indications (re-auth): Excluded if patient is receiving infliximab in combination with a Biologic Disease Modifying Antirheumatic Drug (DMARD) [eg, Enbrel (etanercept), Orencia (abatacept), Rituxan (rituximab), Kineret (anakinra), Cimzia (certolizumab)] or Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].
MEDICATION(S)
INGREZZA, INGREZZA INITIATION PACK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Must not be taken with other VMAT2 inhibitors, such as Xenazine (tetrabenazine) and must not be taken with a monoamine oxidase inhibitor (MAOI) or reserpine (must be greater than 20 days post discontinuing therapy).

REQUIRED MEDICAL INFORMATION
Initial Auth: Clinically diagnosed with tardive dyskinesia, If tardive dyskinesia is related to drug use, and if appropriate for this patient, the causative drug must be discontinued or tried at a lower dose, Failure/intolerance/contraindication to a benzodiazepine, such as clonazepam (Klonopin) or tetrabenazine (Xenazxine), Baseline evaluation of TD using one of the following: Abnormal Involuntary Movement Scale (AIMS) greater than or equal to 10 or Clinical Global Impression of Severity (CGI-S) score greater than or equal to 4. Reauth: Patients therapy has been re-evaluated within the last 12 month AND Patient is tolerating treatment AND Patient has disease stabilization or improvement in disease as defined by one of the following scores: AIMS decrease from baseline by at least 2 points Clinical Global Impression of Severity (CGI-S) score less than or equal to 2.

AGE RESTRICTION
Patient must be 18 years of age or older

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a neurologist or psychiatrist

COVERAGE DURATION
3 months, Reauth 12 months

OTHER CRITERIA
N/A
MEDICATION(S)
INLYTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Renal cell cancer (RCC): Diagnosis of RCC. One of the following: (1) disease has relapsed or (2) both of the following: medically or surgically unresectable tumor and diagnosis of stage IV disease.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
INTRON A 10 MILLION UNITS VIAL, INTRON A 18 MILLION UNIT/3 ML, INTRON A 50 MILLION UNITS VIAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chronic hepatitis B: Diagnosis of chronic hepatitis B infection, and patient is without decompensated liver disease. Chronic Hepatitis C: Diagnosis of chronic hepatitis C, patient without decompensated liver disease, patient has not previously been treated with interferon, and one of the following - 1) used in combination with ribavirin or 2) contraindication or intolerance to ribavirin. Metastatic renal cell carcinoma (RCC): diagnosis of metastatic RCC, used in combination with Avastin (bevacizumab). Other: diagnosis of condylomata acuminata (genital or perianal), diagnosis of hairy cell leukemia, diagnosis of AIDS-related Kaposi??s sarcoma, diagnosis of malignant melanoma, diagnosis of Stage III or IV follicular Non-Hodgkin??s Lymphoma, as maintenance therapy for the treatment of multiple myeloma.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RCC: Prescribed by or in consultation with an oncologist.

COVERAGE DURATION
HepB, HepC: 48 wks. Condylomata acuminata (genital or perianal): 6 wks. Other: 12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
IRESSA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC AND Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
**MEDICATION(S)**
CLARAVIS, MYORISAN, ZENATANE

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Acne (initial): Diagnosis of acne. Trial and failure, contraindication or intolerance to an adequate trial (at least 6 weeks) on both of the following conventional therapy regimens: a) topical retinoid or retinoid-like agent [eg, Retin-A/Retin-A Micro (tretinoin)] AND b) combination therapy with benzoyl peroxide and one of the following: 1) oral antibiotic [eg, Ery-Tab (erythromycin), Minocin (minocycline)] OR 2) topical antibiotic with or without benzoyl peroxide [eg, Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl peroxide/erythromycin)].

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
Acne (Initial): Prescribed by a dermatologist

**COVERAGE DURATION**
Acne (initial, reauth): 5 months

**OTHER CRITERIA**
Acne (reauth): One of the following: A) After more than 2 months off therapy, persistent or recurring severe recalcitrant nodular acne is still present, OR B) the total cumulative dose is less than 150 mg/kg (will be approved up to a total of 150 mg/kg).
MEDICATION(S)
ISTODAX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Cutaneous T-cell lymphoma (CTCL): Diagnosis of CTCL. Patient has tried and had an inadequate response, intolerance or contraindication to at least one prior therapy (eg, retinoids, corticosteroids).
Peripheral T-cell lymphoma (PTCL): Diagnosis of PTCL. Patient has tried and had an inadequate response, intolerance or contraindication to at least one prior therapy (eg, conventional chemotherapy such as CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone), CHOEP (cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone), Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin), HyperCVAD (cyclophosphamide, vincristine, doxorubicin, dexamethasone) alternating with high-dose methotrexate and cytarabine).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
CTCL, PTCL: Prescribed by or in consultation with an oncologist/hematologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
**MEDICATION(S)**
BIVIGAM, CARIMUNE NF 6 GM VIAL, FLEBOGAMMA DIF 10% VIAL, GAMMAGARD LIQUID, GAMMAGARD S-D, GAMMAKED 1 GRAM/10 ML VIAL, GAMMAKED 10 GRAM/100 ML VIAL, GAMMAKED 20 GRAM/200 ML VIAL, GAMMAKED 5 GRAM/50 ML VIAL, GAMMAPLEX 10 GRAM/200 ML VIAL, GAMMAPLEX 20 GRAM/400 ML VIAL, GAMMAPLEX 5 GRAM/100 ML VIAL, GAMUNEX-C, OCTAGAM, PANZYGA, PRIVIGEN

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
All uses (initial, reauth): Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication). Privigen only: Hyperprolinemia. Octagam only: Allergy to corn. Gammaplex only: Hereditary intolerance to fructose. Infants for whom sucrose or fructose tolerance has not been established.

**REQUIRED MEDICAL INFORMATION**
Initial: Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. For IVIG ?? Ig is being used intravenously (IV) AND One of the following diagnoses: [A] Primary Immunodeficiency 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patient??s age at the time of diagnosis and the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). [B] Secondary Acquired Antibody Deficiency 1) B-cell chronic lymphocytic leukemia with an Ig level less than 500 mg/dL OR history of recurrent bacterial infections. 2) HIV infection with an Ig level less than 400 mg/dL OR Patient has active bleeding or a platelet count less than 10 x 109/L. 3) Multiple myeloma in plateau phase and patient has hypogammaglobulinemia. [C] Hematological Autoimmune Disorders 1) Acquired (pure) red cell aplasia (PRCA) that is immunologic and patient had a trial and failure, contraindication, or intolerance (TF/C/I) to a corticosteroid and an immunosuppressant (i.e., cyclophosphamide, cyclosporine) OR patient has viral PRCA caused by parvovirus B19. 2) Fetal alloimmune thrombocytopenia. 3) Hemolytic disease of the newborn and the patient has established hyperbilirubinemia. 4) Idiopathic thrombocytopenic purpura and patient had a TF/C/I to a corticosteroid OR a platelet count less than 30,000 cells/mm3. 5) Post-transfusion purpura. Continued in Other Criteria Section.
AGE RESTRICTION
HIV (initial): patient is less than or equal to 12 years of age.

PRESCRIBER RESTRICTION
All uses (initial, reauth): Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist, etc.).

COVERAGE DURATION
4 months: Solid organ transplant. 12 months: all other diagnoses.

OTHER CRITERIA
[D] Neuromuscular Autoimmune Disorders 1) Chronic inflammatory demyelinating polyneuropathy. 2) Guillain-Barré syndrome. 3) Inflammatory myopathies (dermatomyositis and polymyositis) AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, methotrexate, cyclosporine A, cyclophosphamide, or tacrolimus). 4) Lambert-Eaton myasthenic syndrome AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (e.g., azathioprine). 5) Multifocal motor neuropathy. 6) Myasthenia gravis with severe exacerbations or myasthenic crises AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, cyclophosphamide, cyclophosphamide, or mycophenolate mofetil). 7) Stiff person syndrome AND Patient had a TF/C/I to at least 2 standard therapies (i.e., benzodiazepines, muscle relaxants, or anti-convulsants). [E] Other Disorders 1) Autoimmune blistering disease AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., cyclophosphamide, dapsone, methotrexate, azathioprine, or mycophenolate mofetil). 2) Kawasaki syndrome. 3) Solid organ transplant and IVIG is being used for CMV prophylaxis, or patient is a kidney transplant recipient and has donor specific antibodies, or patient has steroid-resistant rejection and had a TF/C/I to standard therapies. For SCIG (Gamunex-C, Gammagard Liquid, Gammaked only)- Immune globulin is being used subcutaneously AND One of the following PI diagnoses: 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patient’s age at the time of diagnosis and patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). All products: Subject to Part B vs. Part D review. For non-oncology renewal, the patient has experienced an objective improvement on immune globulin therapy and the immune globulin will be administered at the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both strategies) for maintenance therapy.
MEDICATION(S)
JAKAFI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Myelofibrosis: Diagnosis of primary myelofibrosis, OR post-polycythemia vera myelofibrosis, OR post-essential thrombocythemia myelofibrosis. Polycythemia vera: Diagnosis of polycythemia vera, AND trial and failure, contraindication, or intolerance to hydroxyurea.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hematologist/oncologist

COVERAGE DURATION
Myelofibrosis, Polycythemia vera: 12 months.

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
JEVTANA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Prostate Cancer: Diagnosis of castration-resistant metastatic prostate cancer AND patient has been previously treated with a docetaxel-containing regimen AND patient is receiving concurrent prednisone

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
REQUIRED MEDICAL INFORMATION
Homozgous familial hypercholesterolemia (HoFH) (initial): Submission of medical records (eg, chart notes, laboratory values) documenting diagnosis of HoFH as confirmed by one of the following: a) genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (ie, LDLRAP1 or ARH), or b) both of the following: 1) either untreated LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL AND 2) either xanthoma before 10 years of age or evidence of heterozygous FH in both parents. Patient has been receiving at least 12 consecutive weeks of ONE LDL-C lowering prescription therapy and will continue to receive an LDL-C lowering prescription therapy. Trial and failure after 12 consecutive weeks or intolerance to Repatha therapy. One of the following LDL-C values while on maximally tolerated lipid-lowering regimen within the last 30 days: LDL-C greater than or equal to 100 mg/dL with ASCVD OR LDL-C greater than or equal to 130 mg/dL without ASCVD. Not used in combination with Kynamro (mipomersen). Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. Patient is not pregnant. Patient does not have moderate or severe hepatic impairment (ie, Child-Pugh category B or C) or active liver disease including unexplained persistent abnormal liver function tests. Patient is not concomitantly on moderate or strong CYP 3A4 inhibitors (eg, clarithromycin).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
HoFH (initial, reauth): Prescribed by a cardiologist, endocrinologist, or lipid specialist.

COVERAGE DURATION
HoFH (initial): 6 months. (reauth): 12 months
OTHER CRITERIA
HoFH (reauthorization): Patient continues to receive statin at the maximally tolerated dose (or other LDL-C lowering prescription therapy if patient is unable to take a statin). Submission of medical records (eg, laboratory values) documenting a sustained LDL-C reduction from pre-treatment baseline (ie, prior Juxtapid therapy) while on Juxtapid therapy. Not used in combination with Kynamro (mipomersen). Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. Patient is not pregnant. Patient does not have moderate or severe hepatic impairment (ie, Child-Pugh category B or C) or active liver disease including unexplained persistent abnormal liver function tests. Patient is not concomitantly on moderate or strong CYP 3A4 inhibitors (eg, clarithromycin).
MEDICATION(S)
JYNARQUE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Use is contraindicated in patients who are anuric. Use is contraindicated in patients with significant hepatic impairment or disease (or a history of). Concurrent use of strong CYP3A4 inhibitors (eg, ketoconazole, clarithromycin, ritonavir, saquinavir)

REQUIRED MEDICAL INFORMATION
Diagnosis of Autosomal dominant polycystic kidney disease

AGE RESTRICTION
Patient must be 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 Months

OTHER CRITERIA
N/A
MEDICATION(S)
KADCYLA 100 MG VIAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Breast cancer: A) Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive recurrent or metastatic breast cancer AND B) Patient has been previously treated with Herceptin (trastuzumab) and a taxane (eg, docetaxel, paclitaxel).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
**MEDICATION(S)**
KALYDECO

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Confirmed diagnosis of Cistic Fibrosis (CF) in patients ≥12 months of age who have 1 mutation in the CF transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data. If the patient’s genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bidirectional sequencing when recommended by the mutation test instructions for use.

**AGE RESTRICTION**
CF (Initial): 2 years of age or older

**PRESCRIBER RESTRICTION**
CF (Initial): Prescribed by or in consultation with a specialist affiliated with a CF care center or a pulmonologist.

**COVERAGE DURATION**
CF (initial, reauth): 12 months

**OTHER CRITERIA**
CF (Reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations).
MEDICATION(S)
KANUMA

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Lysosomal acid lipase deficiency: Diagnosis of lysosomal acid lipase deficiency (LAL-D). Diagnosis was confirmed by an enzymatic blood (e.g., dried blood spot test) or genetic test.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a specialist experienced in the treatment of inborn errors of metabolism, gastroenterologist, or lipidologist

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
KEVEYS

MEDICATION(S)
KEVEYS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
All Uses (Initial and Reauth): Hepatic insufficiency (e.g., Child-Pugh class A). Severe pulmonary
disease [e.g., severe chronic obstructive pulmonary disease]. Concomitant use with high dose aspirin
(i.e., greater than 100 mg per day).

REQUIRED MEDICAL INFORMATION
Periodic paralysis (Initial): Diagnosis of one of the following: Primary hyperkalemic periodic paralysis,
Primary hypokalemic periodic paralysis, or Paramyotonia Congenita with periodic paralysis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
All uses (Initial): Prescribed by or in consultation with a neurologist

COVERAGE DURATION
All uses (Initial): 3 months. (Reauth): 12 months

OTHER CRITERIA
All uses (Reauth): Documentation of positive clinical response to Keveyis therapy.
KEYTRUDA

MEDICATION(S)
KEYTRUDA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Melanoma: Diagnosis (dx) of melanoma and disease is unresectable or metastatic. Non-Small Cell Lung Cancer (NSCLC): Dx of metastatic NSCLC. One of the following: A) Tumors express high PD-L1 [Tumor Proportion Score (TPS) greater than or equal to 50%]) as determined by an FDA-approved test, absence of epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations, and used as first-line treatment. OR B) Tumors express PD-L1 [Tumor Proportion Score (TPS) greater than or equal to 1%] as determined by an FDA-approved test, patient had a trial and failure, contraindication, or intolerance to platinum-containing therapy (eg, cisplatin, carboplatin), AND one of the following: 1) absence of EGFR mutation or ALK rearrangement, OR 2) both of the following: presence of EGFR or ALK genomic tumor aberrations AND trial and failure, contraindication, or intolerance to FDA-approved therapy for these aberrations [e.g., Gilotrif (afatinib), Iressa (gefitinib), Tarceva (erlotinib), Xalkori (crizotinib)]. Recurrent or metastatic head and neck squamous cell carcinoma (HNSCC): Patient has a diagnosis of recurrent or metastatic HNSCC AND patient has disease progression on or after platinum-containing therapy. Classical Hodgkin lymphoma: Diagnosis of classical Hodgkin lymphoma AND One of the following: A) disease is refractory or B) disease has relapsed after 3 or more prior lines of therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist.

COVERAGE DURATION
12 months
OTHER CRITERIA
Approve for continuation of prior therapy.
KINERET

MEDICATION(S)
KINERET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Kineret therapy. Neonatal-Onset Multisystem Inflammatory Disease (NOMID) (initial): Diagnosis of NOMID AND dx of NOMID has been confirmed by one of the following: NLRP-3 (nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3] gene (also known as Cold-Induced Auto-inflammatory Syndrome-1 [CIAS1]) mutation OR evidence of active inflammation including both of the following: clinical symptoms (eg, rash, fever, arthralgia) and elevated acute phase reactants (eg, ESR, CRP). All Uses (initial, reauth): Patient is not receiving Kineret in combination with a biologic disease modifying antirheumatic drug (DMARD) [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]. Patient is not receiving Kineret in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RA (initial): Prescribed by or in consultation with a rheumatologist. NOMID (initial): Prescribed by or in consultation with allergist/immunologist or rheumatologist or pediatrician.

COVERAGE DURATION
All Uses (initial, reauth): 12 months

OTHER CRITERIA
All Uses (Reauth): Documentation of positive clinical response to Kineret therapy.
MEDICATION(S)
KISQALI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of advanced or metastatic breast cancer: Patient has hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer (in combination with an aromatase inhibitor) in pre/perimenopausal or postmenopausal women as initial endocrine-based therapy. Treatment of HR-positive, HER2-negative advanced or metastatic breast cancer (in combination with fulvestrant) in postmenopausal women as initial endocrine-based therapy or following disease progression on endocrine therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy
KISQALI-FEMARA PACK

MEDICATION(S)
KISQALI FEMARA CO-PACK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of Breast cancer, advanced or metastatic as initial endocrine-based therapy for the treatment of hormone receptor-positive, human epidermal growth factor receptor 2-negative in pre/perimenopausal or postmenopausal women.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy
MEDICATION(S)
KORLYM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Cushing's syndrome (Initial): Diagnosis of endogenous Cushing's syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids). Diagnosis of either type 2 diabetes mellitus or diagnosis of glucose intolerance. Patient has either failed surgery or patient is not a candidate for surgery. Patient is not pregnant.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Initial: Prescribed by or in consultation with an endocrinologist.

COVERAGE DURATION
Initial, reauth: 6 months

OTHER CRITERIA
Reauthorization: Documentation of one of the following: patient has improved glucose tolerance while on Korlym therapy or patient has stable glucose tolerance while on Korlym therapy.
MEDICATION(S)
KUVAN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Phenylketonuria (PKU) (initial): Diagnosis of PKU. Patient is a new start to Kuvan (sapropterin dihydrochloride). Patient will have blood Phe levels measured after 1 week of therapy and periodically for up to 2 months of therapy to determine response.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
PKU (Init): 2 months (Reauth): 12 months

OTHER CRITERIA
PKU (reauth): Patient is currently on therapy with Kuvan (sapropterin dihydrochloride). Patient has had an objective response to therapy, defined as a 30% or greater reduction in phenylalanine (Phe) blood levels from baseline. Patient will continue to have blood Phe levels measured periodically during therapy.
MEDICATION(S)
KYNAMRO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Homozygous familial hypercholesterolemia (HoFH) (initial): Submission of medical records (eg, chart notes, laboratory values) documenting diagnosis of HoFH as confirmed by one of the following: a) genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (ie, LDLRAP1 or ARH), or b) both of the following: 1) either untreated LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL AND 2) either xanthoma before 10 years of age or evidence of heterozygous FH in both parents. Patient has been receiving at least 12 consecutive weeks of ONE LDL-C lowering prescription therapy and will continue to receive an LDL-C lowering prescription therapy. Trial and failure after 12 consecutive weeks or intolerance to Repatha therapy. One of the following LDL-C values while on maximally tolerated lipid-lowering regimen within the last 30 days: LDL-C greater than or equal to 100 mg/dL with ASCVD OR LDL-C greater than or equal to 130 mg/dL without ASCVD. Not used in combination with Juxtapid (lomitapide). Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. Patient does not have moderate or severe hepatic impairment (ie, Child-Pugh category B or C) or active liver disease including unexplained persistent abnormal liver function tests.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
HoFH (initial, reauth): Prescribed by a cardiologist, endocrinologist, or lipid specialist.

COVERAGE DURATION
HoFH (initial): 6 months. (reauth): 12 months
OTHER CRITERIA
HoFH (reauthorization): Patient continues to receive statin at the maximally tolerated dose (or other LDL-C lowering prescription therapy if patient is unable to take a statin). Submission of medical records (eg, laboratory values) documenting a sustained LDL-C reduction from pre-treatment baseline (ie, prior Juxtapid therapy) while on Kynamro therapy. Not used in combination with Juxtapid (lomitapide). Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. Patient does not have moderate or severe hepatic impairment (ie, Child-Pugh category B or C) or active liver disease including unexplained persistent abnormal liver function tests.
**MEDICATION(S)**
KYPROLIS

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Multiple Myeloma (MM): Diagnosis of MM. Disease is relapsed or refractory. Patient has received at least one prior therapy for MM.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
Prescribed by or in consultation with an oncologist/hematologist

**COVERAGE DURATION**
12 months

**OTHER CRITERIA**
Approve for continuation of prior therapy.
MEDICATION(S)
LARTRUVO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Soft Tissue Sarcoma (STS): Diagnosis of STS. All of the following: A) One of the following: 1) Disease is not amenable to curative treatment with radiotherapy or 2) Disease is not amenable to curative treatment with surgery AND B) Used in combination with doxorubicin for the first 8 cycles of treatment

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy
MEDICATION(S)
LENVIMA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Differentiated thyroid cancer (DTC): Diagnosis of DTC. Disease is locally recurrent or metastatic. Patient has symptomatic or progressive disease. Disease is refractory to radioactive iodine treatment.
Renal Cell Carcinoma (RCC): Diagnosis of advanced RCC following one prior anti-angiogenic therapy. Used in combination with everolimus.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
AMBRISENTAN, LETAIRIS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.

COVERAGE DURATION
PAH (Initial): 6 months. PAH (Reauth): 12 months

OTHER CRITERIA
PAH (Reauth): Documentation of positive clinical response to therapy.
LEUKINE

MEDICATION(S)
LEUKINE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Bone marrow/stem cell transplant (BMSCT): One of the following: 1) patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic BMT, OR 2) for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis, OR 3) for peripheral stem cell transplant (PSCT) patients who have received myeloablative chemotherapy. Acute myeloid leukemia (AML): patients with AML following induction or consolidation chemotherapy, AND age greater than or equal to 55 years. Primary prophylaxis of chemotherapy-induced febrile neutropenia (CFN): One of the following: 1) patient is receiving chemotherapy regimens associated with a greater than 20% incidence of FN, OR 2) both of the following: a) patient receiving chemotherapy regimen associated with 10-20% incidence of FN, AND b) one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia. Secondary prophylaxis of FN: Both of the following: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm^3), AND 2) patients with a history of FN during a previous course of chemotherapy. Neutropenia associated with dose-dense chemotherapy (NDDC): One of the following: 1) Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, OR 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown. Treatment of FN (off-label): Both of the following: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm^3), AND 2) patients with FN at high risk for infection-associated complications.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
(Initial): Prescribed by hematologist/oncologist except HIVN: Prescribed by hematologist/oncologist or infectious disease specialist

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COVERAGE DURATION
BMSCT, AML, CFN, FN (prophylaxis), NDDC: 3mo or duration of tx. HIVN: 6mo. FN (treatment): 1 mo.

OTHER CRITERIA
HIV-related neutropenia (HIVN) (off-label): Patients infected with HIV, and ANC less than or equal to 1000 (cells/mm$^3$).
LIDOCAINE

MEDICATION(S)
LIDOCAINE 5% OINTMENT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 Months

OTHER CRITERIA
N/A
MEDICATION(S)
LIDOCAINE 5% PATCH

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of post-herpetic neuralgia

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
**LINEZOLID**

**MEDICATION(S)**
LINEZOLID

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Confirmed vancomycin-resistant enterococcus faecium (VRE) infection. Confirmed methicillin-resistant S. aureus (MRSA) infection AND individual has had a trial and inadequate response or intolerance to or has contraindications to an alternative antibiotic that the organism is susceptible to (depending on manifestation, severity of infection and culture or local sensitivity patterns, examples of alternative antibiotics may include, but are not limited to: vancomycin, TMP-SMX, clindamycin, doxycycline, tetracycline (Based on 2011 IDSA MRSA guideline recommendations)). Individual started treatment with LINEZOLID in the hospital and requires continued outpatient therapy. Isolates of MRSA have a vancomycin minimum inhibitory concentration (MIC) of greater than 2.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
12 months

**OTHER CRITERIA**
N/A
MEDICATION(S)
LONSURF

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Colorectal Cancer: Diagnosis of metastatic colorectal cancer AND trial and failure, contraindication, or intolerance to at least one component in the following: fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI) AND trial and failure, contraindication, or intolerance to at least one anti-VEGF therapy (e.g., Avastin) AND One of the following: A) patient has KRAS wild-type tumors and trial and failure, contraindication, or intolerance to at least one anti-EGFR therapy (e.g., Vectibix, Erbitux) OR Patient has KRAS mutant tumors.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
LORBRENA

MEDICATION(S)
LORBRENA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Non-small cell lung cancer, metastatic treatment of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) in patients whose disease has progressed on crizotinib and at least one other ALK inhibitor for metastatic disease, or progressed on alectinib as the first ALK inhibitor therapy for metastatic disease, or progressed on ceritinib as the first ALK inhibitor therapy for metastatic disease.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
ALOSETRON HCL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Severe Diarrhea-Predominant Irritable Bowel Syndrome (IBS) in Women (initial): All of the following: 1) diagnosis of severe diarrhea-predominant IBS, 2) symptoms for at least 6 months, 3) female patient, AND 4) trial and failure, contraindication, or intolerance to an antidiarrheal agent [eg, loperamide].

AGE RESTRICTION
Initial: 18 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
IBS (initial): 12 weeks. IBS (reauth): 6 mo.

OTHER CRITERIA
IBS (reauthorization): Symptoms of IBS continue to persist, AND documentation of positive clinical response to alosetron therapy.
MEDICATION(S)
LUCEMYRA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Congenital long QT syndrome, severe coronary insufficiency, recent myocardial infarction, cerebrovascular disease, chronic renal failure.

REQUIRED MEDICAL INFORMATION
Diagnosis of covered use.

AGE RESTRICTION
18 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
14 days

OTHER CRITERIA
N/A
MEDICATION(S)
LUCENTIS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Patient must not have an active ocular or periocular infection.

REQUIRED MEDICAL INFORMATION
Diagnosis of Diabetic Macular Edema (DME) and has tried and failed or had an intolerance to Avastin OR Diagnosis of Macular Degeneration- Neovascular (wet) age-related macular degeneration and has tried and failed or had an intolerance to Avastin OR Diagnosis of diabetic retinopathy OR Diagnosis of Myopic choroidal neovascularization OR Diagnosis of Macular Edema following retinal vein occlusion (RVO).

AGE RESTRICTION
Patient must be 18 years of age or older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an ophthalmologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
LUMIZYME

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Pompe disease: Diagnosis of Pompe disease [acid alpha-glucosidase (GAA) deficiency].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
LUPANETA PACK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Endometriosis (initial): Diagnosis of endometriosis. One of the following: Patient has had surgical ablation to prevent recurrence, or trial and failure, contraindication, or intolerance to one NSAID or one oral contraceptive. Trial and failure, contraindication, or intolerance to Lupron Depot (7.5 mg, 22.5 mg, 30 mg, and 45 mg).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Endomet (init, reauth): 6 months

OTHER CRITERIA
Endometriosis (reauthorization): Patient is experiencing recurrence of symptoms after an initial course of therapy.
MEDICATION(S)
LEUPROLIDE 2WK 1 MG/0.2 ML KT, LEUPROLIDE 2WK 14 MG/2.8 ML KT, LEUPROLIDE 2WK 14 MG/2.8 ML VL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Prostate Cancer: Diagnosis of advanced or metastatic prostate cancer. Central Precocious Puberty (CPP) (initial): Diagnosis of CPP (idiopathic or neurogenic). Early onset of secondary sexual characteristics in females less than age 8 or males less than age 9. Advanced bone age of at least one year compared with chronologic age. One of the following: a) patient has undergone gonadotropin-releasing hormone agonist (GnRHa) testing AND Peak luteinizing hormone (LH) level above pre-pubertal range, or b) patient has a random LH level in the pubertal range.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
CPP (initial, reauth): Prescribed by or in consultation with a pediatric endocrinologist.

COVERAGE DURATION
CPP (initial, reauth), Prostate CA: 12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
LUPRON DEPOT, LUPRON DEPOT (LUPANETA), LUPRON DEPOT-PED 11.25 MG 3MO, LUPRON DEPOT-PED 7.5 MG KIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Prostate Cancer (7.5 mg, 22.5 mg, 30 mg, 45 mg): Diagnosis of advanced or metastatic prostate cancer. Endometriosis (3.75 mg, 11.25 mg) (initial): Diagnosis of endometriosis. One of the following: Patient has had surgical ablation to prevent recurrence, or trial and failure, contraindication, or intolerance to one NSAID and one oral contraceptive. Uterine Leiomyomata (UL) (3.75 mg, 11.25 mg): a) For use prior to surgery to reduce size of fibroids to facilitate a surgical procedure (eg, myomectomy, hysterectomy) OR b) all of the following: treatment of anemia, anemia is caused by uterine leiomyomata (fibroids), and for use prior to surgery.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Prostate CA: 12 mo. Endomet (init, reauth):6mo. UL (anemia):3 mo (fibroids):4 mo

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
LUPRON DEPOT-PED 11.25 MG KIT, LUPRON DEPOT-PED 15 MG KIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Central Precocious Puberty (CPP) (initial): Diagnosis of CPP (idiopathic or neurogenic). Early onset of secondary sexual characteristics in females less than age 8 or males less than age 9. Advanced bone age of at least one year compared with chronologic age. One of the following: a) patient has undergone gonadotropin-releasing hormone agonist (GnRHa) testing AND Peak luteinizing hormone (LH) level above pre-pubertal range, or b) patient has a random LH level in the pubertal range.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
CPP (initial, reauth): Prescribed by or in consultation with a pediatric endocrinologist.

COVERAGE DURATION
CPP (init, reauth): 12 months

OTHER CRITERIA
CPP (reauthorization): LH levels have been suppressed to pre-pubertal levels.
MEDICATION(S)
LYNPARZA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Ovarian Cancer: Diagnosis of advanced ovarian cancer. Presence of deleterious or suspected deleterious germline BRCA-mutations as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility. Trial and failure, contraindication, or intolerance to three or more prior lines of chemotherapy (e.g., paclitaxel with cisplatin).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
MAKENA 250 MG/ML VIAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Preterm birth prophylaxis: Patient had a previous singleton (single offspring) spontaneous preterm birth. Patient is having a singleton pregnancy. Therapy will be started between 16 weeks, 0 days and 20 weeks, 6 days of gestation. Therapy will be continued until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Preterm birth prophylaxis: Prescribed by a specialist in obstetrics and gynecology

COVERAGE DURATION
Preterm birth prophylaxis: 21 weeks

OTHER CRITERIA
N/A
**MEDICATION(S)**
DRONABINOL

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Nausea and Vomiting Associated with Cancer Chemotherapy (CINV): Patient is receiving cancer chemotherapy. Trial and failure, contraindication, or intolerance to one 5HT-3 receptor antagonist (eg, Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]). Trial and failure, contraindication, or intolerance to one of the following: Compazine (prochlorperazine), Decadron (dexamethasone), Haldol (haloperidol), Zyprexa (olanzapine). AIDS anorexia: Diagnosis of anorexia with weight loss in patients with AIDS. Patient is on antiretroviral therapy.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
CINV: 6 months. AIDS anorexia: 3 months.

**OTHER CRITERIA**
Subject to Part B vs. Part D review. CINV: Approve for continuation of therapy for treatment covered under Part B when patient is receiving cancer chemotherapy.
**MAYZENT**

**MEDICATION(S)**
MAYZENT 0.25 MG TABLET, MAYZENT 2 MG TABLET

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
A CYP2C9<sup>*</sup>3/*3 genotype— Patient must not have experienced in the last 6 months experienced myocardial infarction, unstable angina, stroke, transient ischemia attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure — Patient must not have presence of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker

**REQUIRED MEDICAL INFORMATION**
Inadequate response, or intolerance, to first-line agents such as fingolimod (GILENYA) and dimethyl fumarate (TECFIDERA).

**AGE RESTRICTION**
Patient must be 18 years of age or older

**PRESCRIBER RESTRICTION**
Must be prescribed by a neurologist or in consultation with a neurologist.

**COVERAGE DURATION**
Initial Auth: 12 months

**OTHER CRITERIA**
Reauth: Documentation of positive clinical response to therapy. 12 months.
MEDICATION(S)
MEKINIST

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma. Cancer is BRAFV600 mutant type (MT) as detected by an FDA-approved test (THxID-BRAF Kit) or performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
MEKTOVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
CRITERIA: Melanoma, unresectable or metastatic Treatment of unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with encorafenib, as detected by an FDA-approved test.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
METADATE ER, METHYLPHENIDATE ER 10 MG TAB, METHYLPHENIDATE ER 20 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD), OR c) diagnosis of narcolepsy as confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

AGE RESTRICTION
PA applies to members 19 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
METHYLPHENIDATE 10 MG CHEW TAB, METHYLPHENIDATE 2.5 MG CHEW TB, METHYLPHENIDATE 5 MG CHEW TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD), OR c) diagnosis of narcolepsy as confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

AGE RESTRICTION
PA applies to members 19 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
METHYLPHENIDATE

MEDICATION(S)
METHYLPHENIDATE 10 MG TABLET, METHYLPHENIDATE 10 MG/5 ML SOL, METHYLPHENIDATE 20 MG TABLET, METHYLPHENIDATE 5 MG TABLET, METHYLPHENIDATE 5 MG/5 ML SOLN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD), OR c) diagnosis of narcolepsy as confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

AGE RESTRICTION
PA applies to members 19 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
METHYLPHENIDATE ER

MEDICATION(S)
METHYLPHENIDATE ER 18 MG TAB, METHYLPHENIDATE ER 27 MG TAB, METHYLPHENIDATE ER 36 MG TAB, METHYLPHENIDATE ER 54 MG TAB, METHYLPHENIDATE ER(LA) 30MG CP, METHYLPHENIDATE HCL CD, METHYLPHENIDATE HCL ER (CD), METHYLPHENIDATE LA 30 MG CAP, METHYLPHENIDATE LA 60 MG CAP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD)

AGE RESTRICTION
PA applies to members 19 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
METHYLTESTOSTERONE

**MEDICATION(S)**
METHYLTESTOSTERONE 10 MG CAP

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following:
1) Two pre-treatment serum total testosterone (T) levels less than reference range for the lab OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome). Delayed puberty (DP): Dx of DP AND male patient at birth. Breast cancer (BC): Dx of inoperable BC AND used for palliative treatment AND female patient at birth. Gender Identity Disorder (GID) (off-label): Dx of GID. Patient is a female-to-male transsexual.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
OTHER CRITERIA
HG (Reauth): 1) Total serum T level within or below the normal limits of the reporting lab, or 2) Total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one of the following: Calculated free or bioavailable T level within or below the normal limits of the reporting lab, or calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted.
MIRVASO

MEDICATION(S)
MIRVASO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Rosacea (init): Diagnosis of rosacea. Patient has moderate to severe persistent (nontransient) facial erythema.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Rosacea (init, reauth): 12 months

OTHER CRITERIA
Rosacea (reauth) Documentation of positive clinical response to Mirvaso therapy.
MEDICATION(S)
MOTEGRITY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Patient must have a diagnosis of chronic idiopathic constipation, Patient must have experienced an inadequate response after a 14-day trial of lactulose or polyethylene glycol (PEG-3350) at a maximum tolerated dose, OR have a documented intolerance or contraindication to both lactulose and polyethylene glycol (PEG-3350), Patient must not have a known or suspected mechanical gastrointestinal obstruction.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Precribed by or in consultation with a gastroenerologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
MOZOBIL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Hematopoietic Stem Cell (HSC) Mobilization: Patient with non-Hodgkin's lymphoma (NHL) or multiple myeloma (MM) who will be undergoing autologous HSC transplantation. Used in combination with granulocyte-colony stimulating factor (G-CSF).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hematologist/oncologist

COVERAGE DURATION
One course of therapy up to 4 days

OTHER CRITERIA
N/A
MEDICATION(S)
AVONEX, AVONEX PEN, BETASERON 0.3 MG KIT, PLEGRIDY 125 MCG/0.5 ML SYRING, PLEGRIDY PEN, REBIF, REBIF REBIDOSE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
MYALEPT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Lipodystrophy (initial): Diagnosis of congenital or acquired generalized lipodystrophy AND Patient is refractory to current standards of care for lipid and diabetic management AND One or more of the following metabolic abnormalities are present: A) Insulin resistance (defined as requiring more than 200 units per day), B) Hypertriglyceridemia, or C) Diabetes

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Initial: Prescribed by or in consultation with an endocrinologist

COVERAGE DURATION
Initial and reauth: 12 months

OTHER CRITERIA
Lipodystrophy (reauth): Patient has experienced an objective response to therapy, such as A) Sustained reduction in hemoglobin A1c (HbA1c) level from baseline OR B) Sustained reduction in triglyceride (TG) levels from baseline
MEDICATION(S)
NAGLAZYME

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Mucopolysaccharidosis (MPS VI): Diagnosis of MPS VI (Maroteaux-Lamy Syndrome)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
MPS VI: 12 months

OTHER CRITERIA
N/A
MEDICATION(S)
MEMANTINE 5-10 MG TITRATION PK, MEMANTINE HCL 10 MG TABLET, MEMANTINE HCL 2 MG/ML SOLUTION, MEMANTINE HCL 5 MG TABLET, MEMANTINE HCL ER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Members that are 50 years of age or older are NOT subject to the prior authorization requirements. Prior Authorization applies to members that are 49 years of age or younger.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Individual has a diagnosis of moderate to severe dementia of the Alzheimer's type.
MEDICATION(S)
NATPARA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Hypocalcemia (Initial): Diagnosis of hypocalcemia due to chronic hypoparathyroidism. NATPARA is not being used in the setting of acute post-surgical hypoparathyroidism. Patient does not have a known calcium-sensing receptor mutation. Patient is not at an increased risk for osteosarcoma.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Hypocalcemia (Initial): Prescribed by or in consultation with an endocrinologist.

COVERAGE DURATION
Initial: 4 months. Reauth: 12 months

OTHER CRITERIA
N/A
REQUIRED MEDICAL INFORMATION
Primary prophylaxis of chemotherapy-induced febrile neutropenia (CFN): One of the following: 1) patient is receiving chemotherapy regimens associated with a greater than 20% incidence of FN, OR 2) both of the following: a) patient receiving chemotherapy regimen associated with 10-20% incidence of FN, AND b) one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia. Secondary prophylaxis of FN: Both of the following: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm$^3$), AND 2) patients with a history of FN during a previous course of chemotherapy. Neutropenia associated with dose-dense chemotherapy (NDDC): One of the following: 1) patient is receiving National Cancer Institute’s Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, OR 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown. Treatment of FN (off-label): Both of the following: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm$^3$), AND 2) patients with FN at high risk for infection-associated complications. Acute radiation syndrome (ARS): Patient was acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
All uses (initial): Prescribed by a hematologist/oncologist

COVERAGE DURATION
FN (treatment), ARS: 1 mo. CFN, NDDC, FN (prophylaxis): 3 mo or duration of tx.
MEDICATION(S)
NEUPOGEN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Bone marrow/stem cell transplant (BMSCT): One of the following: 1) pts with non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic BMT, OR 2) for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis, OR 3) for peripheral stem cell transplant (PSCT) pts who have received myeloablative chemotherapy. Acute myeloid leukemia (AML): patients with AML following induction or consolidation chemotherapy. Primary prophylaxis of chemotherapy-induced febrile neutropenia (CFN): One of the following: 1) Pt is receiving chemotherapy regimens associated with a greater than 20% incidence of FN, OR 2) both of the following: a) Pt receiving chemotherapy regimen associated with 10-20% incidence of FN, AND b) one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia. Secondary prophylaxis of FN: Both of the following: 1) Pts receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm^3), AND 2) Pts with a history of FN during a previous course of chemotherapy. Neutropenia associated with dosedense chemotherapy (NDDC): One of the following: 1) Pt is receiving National Cancer Institute’s Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, OR 2) Pt is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown. Severe chronic neutropenia (SCN): Pts with SCN (ie, congenital, cyclic, and idiopathic neutropenias with chronic ANC less than or equal to 500 cells/mm^3). Treatment of FN (off-label): Both of the following: 1) Pts receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm^3), AND 2) Pts with FN at high risk for infection-associated complications. Acute radiation syndrome (ARS): Pt is/was acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrom

AGE RESTRICTION
N/A
PRESCRIBER RESTRICTION
Prescribed by hematologist/oncologist except HIVN: Prescribed by hematologist/oncologist or infectious disease specialist

COVERAGE DURATION
BMSCT, AML, CFN, secondary ppx of FN, NDDC: 3mo or tx duration. SCN: 12mo. HIVN: 6mo. ARS, FN Tx: 1 mo.

OTHER CRITERIA
HIV-related neutropenia (HIVN)(off-label): Patients infected with HIV, and ANC less than or equal to 1000 (cells/mm^3).
MEDICATION(S)
NEXAVAR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Renal cell carcinoma (RCC): Diagnosis of RCC. One of the following: Relapsed disease OR both medically/surgically unresectable tumor and dx of Stage IV disease. Hepatocellular carcinoma (HCC): Diagnosis of HCC. One of the following: patient has metastatic disease, or patient has extensive liver tumor burden, or patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only), or both of the following: patient is not a transplant candidate and disease is unresectable. Differentiated thyroid carcinoma (DTC): Diagnosis of DTC (ie, follicular carcinoma, Hurthle cell carcinoma, or papillary carcinoma). One of the following: locally recurrent disease or metastatic disease. One of the following: patient has symptomatic disease or patient has progressive disease. Disease is refractory to radioactive iodine (RAI) treatment. Medullary thyroid carcinoma (MTC): Diagnosis of MTC. Patient has symptomatic disease. Trial and failure, contraindication, or intolerance to Caprelsa (vandetanib) or Cometriq (cabozantinib).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RCC, DTC, MTC: Prescribed by or in consultation with an oncologist. HCC: Prescribed by or in consultation with an oncologist, hepatologist, or gastroenterologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
NINLARO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Multiple myeloma: Diagnosis of multiple myeloma. Used in combination with Revlimid (lenalidomide) and dexamethasone. Patient has received at least one prior therapy for multiple myeloma [eg, Revlimid (lenalidomide), Thalomid (thalidomide), Velcade (bortezomib)].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hematologist/oncologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
NIVESTYM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Acute myeloid leukemia following induction or consolidation chemotherapy - To reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy in adults with acute myeloid leukemia (AML) Bone marrow transplantation To reduce the duration of neutropenia and neutropenia-related events (eg, neutropenic fever) in patients with nonmyeloid malignancies receiving myeloablative chemotherapy followed by bone marrow transplantation.Ref Myelosuppressive chemotherapy recipients with nonmyeloid malignancies To decrease the incidence of infection (neutropenic fever) in patients with nonmyeloid malignancies receiving myelosuppressive chemotherapy associated with a significant incidence of severe neutropenia with fever. Peripheral blood progenitor cell collection and therapy Mobilization of autologous hematopoietic progenitor cells into the peripheral blood for apheresis collection. Severe chronic neutropenia Long-term administration to reduce the incidence and duration of neutropenic complications (eg, fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia. All indications: History of failure or intolerance to Zarxio (filgrastim-sndz).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
NON-PREFERRED TIRF

MEDICATION(S)
ABSTRAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For the management of breakthrough cancer pain. Patient is currently taking a long-acting opioid around the clock for cancer pain. Patient must have at least a one week history of ONE of the following medications to demonstrate tolerance to opioids: Morphine sulfate at doses of greater than or equal to 60 mg/day, Fentanyl transdermal patch at doses greater than or equal to 25 ??g/hr, Oxycodone at a dose of greater than or equal to 30 mg/day, Oral hydromorphone at a dose of greater than or equal to 8 mg/day, Oral oxymorphone at a dose of greater than or equal to 25 mg/day, or an alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day). Trial and failure or intolerance to generic fentanyl lozenge.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with one of the following: Pain specialist, Oncologist, Hematologist, Hospice care specialist, or Palliative care specialist.

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
NORTHERA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Neurogenic orthostatic hypotension (NOH) (init): Diagnosis of symptomatic NOH. NOH is caused by one of the following conditions: primary autonomic failure (e.g., Parkinson’s disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, non-diabetic autonomic neuropathy. Trial and failure, contraindication, or intolerance to one of the following agents: fludrocortisone acetate, midodrine.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
NOH (init): Prescribed by or in consultation with a cardiologist, neurologist, or nephrologist

COVERAGE DURATION
NOH (init): 1 month (reauth): 12 months

OTHER CRITERIA
NOH (reauth): Documentation of positive clinical response to therapy
NOVANTRONE

MEDICATION(S)
MITOXANTRONE HCL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Multiple Sclerosis (MS) (init): Diagnosis (dx) of one of the following: secondary progressive MS: gradually worsening disability with or without superimposed relapses, progressive relapsing MS: progression of disability from the onset with superimposed relapses, or worsening relapsing-remitting MS: neurological status remains significantly abnormal in between MS relapses. Disease progression despite one of the following therapies: Avonex, Aubagio, Betaseron, Copaxone, Glatopa, Extavia, Gilenya, Lemtrada, Rebif, Tecfidera, Tysabri. Left ventricular ejection fraction (LVEF) greater than or equal to 50%. Neutrophil count greater than or equal to 1500 cell/mm^3. Lifetime cumulative dose less than 140 mg/m^2. Prostate Cancer (PC) (init): Dx of advanced hormone-refractory (castration-resistant) PC. Used in combination with corticosteroids (eg, prednisone, methylprednisolone). LVEF greater than or equal to 50%. Neutrophil count greater than or equal to 1500 cell/mm^3. Acute Non-Lymphocytic Leukemia (ANLL) (init): Dx of ANLL (eg, myelogenous, promyelocytic, monocytic, and erythroid). Used in combination with other medications used for the treatment of ANLL. LVEF greater than or equal to 50%.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
All Uses: 12 weeks

OTHER CRITERIA
Approve for continuation of prior therapy.
NOXAFIL DR 100MG TABLET

MEDICATION(S)
NOXAFIL 40 MG/ML SUSPENSION, NOXAFIL DR 100 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
NP HUMAN GROWTH HORMONE

MEDICATION(S)
ZOMACTON

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
PGHD(initial): less than 4mo w/GD, or hx neonatal hypoglycemia assoc w/pituitary dz, or panhypopituitarism dx, or all of the following: PGHD dx [confrmd by ht (utilizing age and gender growth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.25SD below population(pop) mean (below 1.2 percentile for age and gender), or growth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg, delayed more than 2yrs compared w/chronological age)].
PWS(reauth): evidence of positive response to tx (eg, incr in total LBM, decr in fat mass) and expctd adult ht not attained and doc of expctd adult ht goal. GFSGA(initial): SGA dx based on catchup growth failure in 1st 24mo of life using 0-36mo growth chart conf rm by birth wt or length below 3rd percentile for gestational age (more than 2SD below pop mean) and ht remains at or below 3rd percentile (more than 2SD below pop mean). TS, NS(initial): ped growth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on growth charts for age and gender.
SHOX(initial): ped growth failure dx w/SHOX gene deficiency confirmed by genetic testing.
GFCRI(initial): ped growth failure dx assoc w/CRI. ISS(initial): ISS dx, diagnostic eval excluded other causes assoc w/short stature (eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender, doc growth velocity less than 25th percentile for bone age. PGHD, NS, SHOX, GFCRI, ISS (initial): doc male w/bone age less than 16yrs or female w/bone age less than 14yrs. PGHD, GFSGA, TS/NS, SHOX, GFCRI, ISS(reauth): expctd adult ht not attained and doc of expctd adult ht goal.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist.
GFCRI: prescribed by endocrinologist or nephrologist
COVERAGE DURATION
All indications (initial, reauth): 12 months

OTHER CRITERIA
Trial and failure or intolerance to Genotropin and Nutropin. AGHD(initial): dx of AGHD with clin records supporting dx of childhood-onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg, damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1 GH stim test (insulin tolerance test [ITT], arginine/GHRH, glucagon, arginine) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L]) or doc deficiency of 3 anterior pituitary hormones (prolactin, ACTH, TSH, FSH/LH) and IFG-1/somatomedinC below age and gender adj std nrml range as provided by physicians lab. AGHD(init, reauth): panhypopituitarism OR other dx and not used in combo w/aromatase inhibitors (eg, anastrozole, letrozole) or androgens (eg, testosterone cypionate).
AGHD, IGHDA(reauth): monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level. TransitionPhase Adolescent Pts (TPAP)(initial): attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones: ACTH, TSH, prolactin, FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/peak GH value ([ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], or at low risk of severe GHD (eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value ([ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L]). TPAP(reauth): evidence of positive response to therapy (eg, incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3). IGHDA(initial): doc GHD by failure to produce peak serum GH greater than 5 mcg/L after 2 provocative pharmacol stim tests (insulin, L-ARG, glucagon).
MEDICATION(S)
NUDEXTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Pseudobulbar affect (PBA) (initial): Diagnosis of PBA. (Reauthorization): Documentation of clinical benefit from ongoing therapy with Nuedexta.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 months

OTHER CRITERIA
N/A
MEDICATION(S)
NULOJIX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Kidney transplant: The medication is being used for prevention of kidney transplant organ rejection
AND The patient is immune to the Epstein-Barr virus (i.e. EBV seropositive) AND The patient is
prescribed concurrent therapy with mycophenolate and corticosteroids

AGE RESTRICTION
Kidney transplant: 18 years of age or older

PRESCRIBER RESTRICTION
Kidney transplant: Prescriber is experienced in immunosuppressive therapy and management of
transplant patients

COVERAGE DURATION
12 months

OTHER CRITERIA
Subject to Part B vs. Part D review. Approve for continuation of prior therapy.
MEDICATION(S)
NUPLAZID

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Parkinson's disease psychosis: Diagnosis of Parkinson's disease. Patient has at least one of the following: hallucinations or delusions.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
NUVIGIL

MEDICATION(S)
ARMODAFINIL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Obstructive sleep apnea/hypopnea syndrome (OSAHS) (Initial): Diagnosis (dx) of OSAHS defined by one of the following: a) 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), or b) both of the following: 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), AND 1 of the following symptoms: unintentional sleep episodes during wakefulness, daytime sleepiness, unrefreshing sleep, fatigue, insomnia, waking up breath holding/gasping/choking, loud snoring, or breathing interruptions during sleep. Shift-work sleep disorder (SWSD) (Initial): Dx of SWSD confirmed by symptoms of excessive sleepiness or insomnia for at least 3 months, which is associated with a work period (usually night work) that occurs during the normal sleep period, or sleep study demonstrating loss of a normal sleep-wake pattern (ie, disturbed chronobiologic rhythmicity). No other medical condition or medication accounts for the symptoms. Narcolepsy (initial): Dx of narcolepsy as confirmed by sleep study (unless prescriber provides justification confirming that a sleep study is not feasible).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
OSAHS (Initial): 3 months (Reauth): 12 months. SWSD (Initial, Reauth): 3 months. Other:12 months
OTHER CRITERIA
OSAHS (Reauth): Documentation of positive clinical response to prior therapy. SWSD (Reauth): Documentation of positive clinical response to prior therapy. Patient still requires treatment for SWSD. Narcolepsy (reauth): Documentation of positive clinical response to prior therapy.
**OCALIVA**

**MEDICATION(S)**
OCALIVA

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUARED MEDICAL INFORMATION**
Primary Biliary Cholangitis (PBC) (initial): Diagnosis of PBC (aka primary biliary cirrhosis). One of the following: a) patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal (ULN) after at least 12 consecutive months of treatment with ursodeoxycholic acid (UDCA) (e.g., Urso, Urso Forte, ursodiol) AND used in combination with UDCA, OR b) contraindication or intolerance to UDCA.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
PBC (initial): Prescribed by or in consultation with a hepatologist or gastroenterologist.

**COVERAGE DURATION**
PBC (initial): 6 months, (reauth): 12 months

**OTHER CRITERIA**
PBC (reauthorization): Submission of medical records (eg, laboratory values) documenting a reduction in ALP level from pre-treatment baseline (ie, prior Ocaliva therapy) while on Ocaliva therapy.
MEDICATION(S)
ODOMZO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Basal cell carcinoma: Diagnosis of locally advanced basal cell carcinoma AND One of the following: 1) Cancer has recurred following surgery or radiation therapy or 2) Patient is not a candidate for surgery or radiation therapy

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist or dermatologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
OFEV

MEDICATION(S)
OFEV

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Idiopathic pulmonary fibrosis (IPF) (initial): Both of the following: 1) diagnosis of IPF as documented by all of the following: a) exclusion of other known causes of interstitial lung disease (ILD) (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity) AND b) one of the following: i) in patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF, AND 2) not used in combination with Esbriet (pirfenidone).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
IPF (initial): Prescribed by a pulmonologist

COVERAGE DURATION
Initial, reauth: 12 months

OTHER CRITERIA
IPF (reauth): Documentation of positive clinical response to Ofev therapy.
**ONMEL**

**MEDICATION(S)**
ONMEL

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
All of the following: 1) Diagnosis of onychomycosis of the toenail as confirmed by one of the following: a) positive potassium hydroxide (KOH) preparation, OR b) culture, OR c) histology, AND 2) patient’s condition is causing debility or a disruption in their activities of daily living, AND 3) patient has had a trial and inadequate response, intolerance or hypersensitivity to oral terbinafine.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
3 months

**OTHER CRITERIA**
N/A
**MEDICATION(S)**
OPDIVO 100 MG/10 ML VIAL, OPDIVO 40 MG/4 ML VIAL

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Melanoma: Diagnosis (dx) of melanoma and disease is unresectable or metastatic. Non-small cell lung cancer (NSCLC): Dx of NSCLC, disease is metastatic, trial and failure, contraindication, or intolerance to platinum-based chemotherapy (eg, cisplatin, carboplatin), and one of the following: 1) absence of epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) rearrangement, OR 2) presence of EGFR or ALK genomic tumor aberrations AND trial and failure, contraindication, or intolerance to FDA-approved therapy for these aberrations [e.g., Gilotrif (afatinib), Iressa (gefitinib), Tarceva (erlotinib), Xalkori (crizotinib)]. Renal cell carcinoma (RCC): Dx of renal cell carcinoma. Disease is advanced, relapsed, or surgically unresectable Stage IV. Trial and failure, contraindication, or intolerance to at least one anti-angiogenic or tyrosine kinase inhibitor therapy (eg, axitinib, pazopanib, sorafenib, sunitinib). Classical Hodgkin Lymphoma (cHL): Dx of cHL. One of the following: A) Patient has had relapse or progression after autologous hematopoietic stem cell transplantation and post-transplantation Adcetris (brentuximab vedotin) therapy. OR B) Used as palliative therapy and patient is greater than 60 years of age. Head and Neck Squamous Cell Carcinoma (HNSCC): Dx of recurrent or metastatic HNSCC. Patient has disease progression on or after platinum-containing therapy.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
Prescribed by or in consultation with an oncologist.

**COVERAGE DURATION**
12 months
OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
OPSUMIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.

COVERAGE DURATION
PAH: Initial: 6 months. Reauth: 12 months.

OTHER CRITERIA
PAH (Reauth): Documentation of positive clinical response to therapy.
ORENCEIA IV

MEDICATION(S)
ORENCEIA 250 MG VIAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. All indications (Initial, reauth): One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Orencia IV therapy. Patient is not receiving Orencia in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]. Patient is not receiving Orencia in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RA, JIA (Initial): Prescribed by or in consultation with a rheumatologist.

COVERAGE DURATION
All indications (Initial, reauth): 12 months

OTHER CRITERIA
All indications (Reauth): Documentation of positive clinical response to Orencia therapy.
ORENCIA SC

MEDICATION(S)
ORENCIA 125 MG/ML SYRINGE, ORENCIA 50 MG/0.4 ML SYRINGE, ORENCIA 87.5 MG/0.7 ML SYRINGE, ORENCIA CLICKJECT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Ocrecia SC therapy, OR prior maintenance therapy of at least 4 weeks with Ocrecia IV. Patient is not receiving Ocrecia in combination with a biologic disease modifying antirheumatic drug (DMARD) [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]. Patient is not receiving Ocrecia in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RA (Initial): Prescribed by or in consultation with a rheumatologist.

COVERAGE DURATION
RA (Initial, reauth): 12 months

OTHER CRITERIA
RA (Reauth): Documentation of positive clinical response to Ocrecia therapy. Patient is not receiving Ocrecia in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]. Patient is not receiving Ocrecia in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].
ORENITRAM

MEDICATION(S)
ORENITRAM ER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.

COVERAGE DURATION
PAH: Initial: 6 months. Reauth: 12 months.

OTHER CRITERIA
PAH (Reauth): Documentation of positive clinical response to therapy.
ORKAMBI

MEDICATION(S)
ORKAMBI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Cystic Fibrosis (CF) (Initial): Diagnosis of CF. Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene. The presence of the mutation was documented by an FDA-cleared cystic fibrosis mutation test or Clinical Laboratory Improvement Amendments-approved facility.

AGE RESTRICTION
CF (Initial): Patient is 2 years of age or older

PRESCRIBER RESTRICTION
CF (Initial): Prescribed by or in consultation with a specialist affiliated with a CF care center or a pulmonologist.

COVERAGE DURATION
CF (initial, reauth): 12 months

OTHER CRITERIA
CF (Reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations)
**MEDICATION(S)**
OTEZLA 28 DAY STARTER PACK, OTEZLA 30 MG TABLET

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Psoriatic arthritis (PsA, initial): Diagnosis of active PsA. Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. PsA, plaque psoriasis (initial): Trial and failure, contraindication, or intolerance to both Humira and Enbrel, OR for continuation of prior Otezla therapy.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
PsA (init): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque psoriasis (init): Prescribed by or in consultation with a dermatologist.

**COVERAGE DURATION**
Initial, Reauth: 12 months

**OTHER CRITERIA**
Reauthorization (all indications): Documentation of positive clinical response to Otezla therapy.
OXANDRIN

MEDICATION(S)
OXANDROLONE 10 MG TABLET, OXANDROLONE 2.5 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Promote weight gain (initial): Medication will be used as an adjunct therapy to promote weight gain AND One of the following: Extensive surgery, Chronic infections, Severe trauma, Failure to gain or maintain at least 90% of ideal body weight without definite pathophysiologic reasons. Counterbalance protein catabolism (initial): Oxandrin will be used to counterbalance protein catabolism associated with chronic corticosteroid administration. Bone pain (initial): Diagnosis of bone pain associated with osteoporosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
bone pain (initial, reauth): 1 month. Others (initial, reauth): 3 months

OTHER CRITERIA
All diagnoses (reauth): patient has experienced an objective improvement (i.e. weight gain, increase in lead body mass, or reduction in muscle pain/weakness)
MEDICATION(S)
OXERVATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis Neurotrophic Keratitis.

AGE RESTRICTION
Greater than or equal to 2 years.

PRESCRIBER RESTRICTION
Must be prescribed by an ophthalmologist

COVERAGE DURATION
Initial: 8 weeks. Re Auth: Documentation supports positive response to therapy Duration 8 weeks

OTHER CRITERIA
N/A
MEDICATION(S)
PALYNZIK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Labs showing uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR

OTHER CRITERIA
N/A
MEDICATION(S)
ABELCET, ACETYLCYSTEINE 10% VIAL, ACETYLCYSTEINE 20% VIAL, ACYCLOVIR 1,000 MG/20 ML VIAL, ACYCLOVIR 500 MG/10 ML VIAL, ALBUTEROL 15 MG/3 ML SOLUTION, ALBUTEROL 2.5 MG/0.5 ML SOL, ALBUTEROL 20 MG/4 ML SOLUTION, ALBUTEROL 5 MG/ML SOLUTION, ALBUTEROL SUL 0.63 MG/3 ML SOL, ALBUTEROL SUL 1.25 MG/3 ML SOL, ALBUTEROL SUL 2.5 MG/3 ML SOLN, AMBISOME, AMINOSYN II 10% IV SOLUTION, AMINOSYN II 7% IV SOLUTION, AMINOSYN II WITH ELECTROLYTES, AMINOSYN WITH ELECTROLYTES, AMINOSYN-HBC, AMINOSYN-PF, AMINOSYN-RF, AMPHOTERICIN B 50 MG VIAL, APREPITANT, ASTAGRAF XL, AZASAN, AZATHIOPRINE 50 MG TABLET, BETHKIS, BROVANA, BUDESONIDE 0.25 MG/2 ML SUSP, BUDESONIDE 0.5 MG/2 ML SUSP, BUDESONIDE 1 MG/2 ML INH SUSP, CINACALCET HCL, CLINIMIX 2.75%-5% SOLUTION, CLINIMIX 4.25%-10% SOLUTION, CLINIMIX 4.25%-20% SOLUTION, CLINIMIX 4.25%-25% SOLUTION, CLINIMIX 4.25%-5% SOLUTION, CLINIMIX 5%-15% SOLUTION, CLINIMIX 5%-25% SOLUTION, CLINIMIX 5%-25% SOLUTION, CLINIMIX E, CROMOLYN 20 MG/2 ML NEB SOLN, CYCLOPHOSPHAMIDE 25 MG CAPSULE, CYCLOPHOSPHAMIDE 50 MG CAPSULE, CYCLOSPORINE 100 MG CAPSULE, CYCLOSPORINE 25 MG CAPSULE, CYCLOSPORINE MODIFIED, EMEND 125 MG POWDER PACKET, ENGERIX-B 20 MCG/ML SYRN, ENGERIX-B PEDI 10 MCG/0.5 SYRN, FLUOROURACIL 1,000 MG/20 ML VL, FLUOROURACIL 2,500 MG/50 ML VL, FLUOROURACIL 2.5 GM/50 ML BTL, FLUOROURACIL 2.5 GM/50 ML VIAL, FLUOROURACIL 500 MG/10 ML VIAL, FREAMINE HBC, GENGRAF, GRANISETRON HCL 1 MG TABLET, HEPATAMINE, IMOVAX RABIES VACCINE, INTRALIPID 20% IV FAT EMUL, IPRATROPIUM BR 0.02% SOLN, IPRATROPIUM-ALBUTEROL, LEVALBUTEROL CONCENTRATE, LEVALBUTEROL HCL, LIORESAL IT 0.05 MG/1 ML AMP, MIACALCIN 200 UNIT/ML VIAL, MIACALCIN 400 UNIT/2 ML VIAL, MYCOPHENOLATE 200 MG/ML SUSP, MYCOPHENOLATE 250 MG CAPSULE, MYCOPHENOLATE 500 MG TABLET, MYCOPHENOLIC ACID, NEBUPENT, NEPHRAMINE, NUTRILIPID, ONDANSETRON 4 MG/5 ML SOLUTION, ONDANSETRON HCL 24 MG TABLET, ONDANSETRON HCL 4 MG TABLET, ONDANSETRON HCL 8 MG TABLET, ONDANSETRON ODT, PAMIDRONATE 30 MG/10 ML VIAL, PAMIDRONATE 60 MG/10 ML VIAL, PAMIDRONATE 90 MG/10 ML VIAL, PARICALCITOL 1 MCG CAPSULE, PARICALCITOL 2 MCG CAPSULE, PARICALCITOL 4 MCG CAPSULE, PERFOROMIST, PLENAMINE, PREMASOL, PROCALAMINE, PROGRAF 0.2 MG GRANULE PACKET, PROGRAF 1 MG GRANULE PACKET, PROSOL, RABAVERT, RAPAMUNE 1 MG/ML ORAL SOLN, RECOMBIVAX HB 10 MCG/ML SYR, RECOMBIVAX HB 10 MCG/ML VIAL, RECOMBIVAX HB 40 MCG/ML VIAL, RECOMBIVAX HB 5 MCG/0.5 ML SYR, SANDIMMUNE 100 MG/ML SOLN, SIROLIMUS 0.5 MG TABLET, SIROLIMUS 1 MG TABLET, SIROLIMUS 1 MG/ML SOLUTION, SIROLIMUS 2 MG TABLET, TACROLIMUS 0.5 MG CAPSULE, TACROLIMUS 1 MG CAPSULE, TACROLIMUS 5 MG CAPSULE, TOBRAMYCIN 300 MG/5 ML AMPULE, TRAVASOL, TREANDA 100 MG VIAL, TRIMETHOBENZAMIDE 300 MG CAP, TROPHAMINE 10% IV SOLUTION
DETAILS
This drug may be covered under Medicare Part B or D depending on the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.
MEDICATION(S)
PEGASYS, PEGASYS PROCLICK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chronic hepatitis B: Diagnosis of chronic hepatitis B infection, and patient is without decompensated liver disease. Chronic Hepatitis C: Criteria will be applied consistent with current AASLD-IDSA guidance

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

OTHER CRITERIA
N/A
MEDICATION(S)
DICLOFENAC 1.5% TOPICAL SOLN, KLOFENSAID II

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Initial, reauth: History of severe allergic-type reactions after taking aspirin or other non-steroidal anti-inflammatory (NSAIDs), including urticaria and asthma (aspirin-sensitive asthma).

REQUIRED MEDICAL INFORMATION
Osteoarthritis of the knees (initial): Diagnosis of osteoarthritis of the knees and diclofenac will not be used in the treatment of peri-operative pain in the setting of coronary artery bypass graft surgery. Patient meets one of the following: 1) Treatment failure with at least two prescription strength oral non-steroidal anti-inflammatory drugs (NSAIDs) OR 2) Documented swallowing disorder OR 3) History of peptic ulcer disease/gastrointestinal bleed OR 4) Patient is older than 65 years of age with one additional risk factor for gastrointestinal adverse events (e.g. use of anticoagulants, chronic corticosteroids).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial, reauth: 12 months

OTHER CRITERIA
Osteoarthritis of the knees (reauth): Patient has experienced a response to therapy (e.g., improvement in pain symptoms of osteoarthritis).
PERJETA

MEDICATION(S)
PERJETA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Metastatic breast cancer: Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive metastatic breast cancer. One of the following: a) patient has not received prior anti-HER2 therapy or chemotherapy for metastatic disease AND used in combination with Herceptin (trastuzumab) and a taxane (eg, docetaxel, paclitaxel), OR b) patient was previously treated with chemotherapy and Herceptin (trastuzumab) without Perjeta AND used in combination with Herceptin (trastuzumab). Non-metastatic breast cancer: One of the following diagnoses: HER2-positive early stage breast cancer, HER2-positive locally advanced breast cancer, or HER2-positive inflammatory breast cancer. Used in combination with both Herceptin (trastuzumab) and a taxane (eg, docetaxel, paclitaxel).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
All Uses: Prescribed by or in consultation with an oncologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
POLIVY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Treatment of adults with relapsed or refractory diffuse large B-cell lymphoma (in combination with bendamustine and a rituximab product) not otherwise specified, after at least two prior therapies.

AGE RESTRICTION
Patient must be 18 years of age or older

PRESCRIBER RESTRICTION
Must be prescribed by an oncologist or in consultation with an oncologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
POMALYST

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Multiple Myeloma (MM): Diagnosis of MM. Used in combination with dexamethasone. Patient has received two prior therapies, including Revlimid (lenalidomide) and a proteasome inhibitor [eg, Velcade (bortezomib) or Kyprolis (carfilzomib)] or has a contraindication or intolerance to Revlimid and proteasome inhibitors. Patient has experienced disease progression on or within 60 days of completion of last therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist/hematologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
PRALUENT PEN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Submission of medical records (eg, chart notes, laboratory values) documenting one of the following diagnoses: Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following: (1) Documented assessment of patient using Dutch Lipid Clinic Network diagnostic criteria with a cumulative score greater than or equal to 9 points (ie, definite FH), (2) Presence of tendinous xanthomas in patient, first degree relative, or second degree relative, AND Untreated/pre-treatment LDL-C greater than 190 mg/dL in an adult, (3) Genetic confirmation of a mutation in the LDL receptor, ApoB, or PCSK9. OR Atherosclerotic cardiovascular disease (ASCVD) as confirmed by acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin. One of the following LDL-C values while on maximally tolerated lipid-lowering regimen within the last 30 days: (1) LDL-C greater than or equal to 100 mg/dL with ASCVD. (2) LDL-C greater than or equal to 130 mg/dL without ASCVD.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Initial, reauth: Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist

COVERAGE DURATION
Initial: 6 months. Reauth: 12 months
OTHER CRITERIA
HeFH/ASCVD: Initial: One of the following: (1) Patient has been receiving at least 12 consecutive weeks of one high-intensity statin therapy and will continue to receive a HIGH-INTENSITY statin [ie, atorvastatin 40-80 mg, Crestor (rosuvastatin) 20-40 mg] at maximally tolerated dose, OR (2) Both of the following: A) Patient is unable to tolerate high-intensity statin as evidenced by intolerable and persistent (ie, more than 2 weeks) myalgia (muscle symptoms without CK elevations) or myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN]), AND B) One of the following: a) Patient has been receiving at least 12 consecutive weeks of one moderate-intensity or low-intensity statin therapy and will continue to receive a MODERATE-INTENSITY or LOW-INTENSITY statin [ie, atorvastatin 10-20 mg, Crestor (rosuvastatin) 5-10 mg, simvastatin 10-40 mg, pravastatin 10-80 mg, lovastatin 20-40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1-4 mg] at maximally tolerated dose, OR b) Patient is unable to tolerate moderate-intensity or low-intensity statin as evidenced by intolerable and persistent (ie, more than 2 weeks) myalgia (muscle symptoms without CK elevations) or myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN]), OR (3) Submission of medical records documenting patient has a labeled contraindication to all statins, OR (4) Patient has experienced rhabdomyolysis on one statin therapy. Reauth: Patient continues to receive statin at the maximally tolerated dose (unless patient has documented inability to take statins). Submission of medical records (eg, laboratory values) documenting a sustained LDL-C reduction from pre-treatment baseline (ie, prior to Praluent therapy) while on Praluent therapy. Initial, reauth: Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor.
PROCYSBI

MEDICATION(S)
PROCYSBI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Nephropathic cystinosis: Diagnosis of nephropathic cystinosis, confirmed by elevated leukocyte cystine levels (LCL) or genetic analysis of the CTNS gene AND Trial and failure or intolerance to therapy with Cystagon (immediate-release cysteamine bitartrate).

AGE RESTRICTION
2 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
PROLIA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Postmenopausal osteoporosis (PMO) (initial): Diagnosis (dx) of PMO. History (hx) of vertebral compression fractures (fx), or fx of the hip, or distal radius resulting from minimal trauma, or bone mineral density score (BMD) indicative of osteoporosis (OP): T-score less than or equal to -2.5 (2.5 standard deviations [SD] or greater below the mean for young adults). PMO, prophylaxis (initial): For prevention of PMO. BMD scan indicative of osteopenia: T-score -1.0 to -2.5. Nonmetastatic prostate cancer (NMPC) bone loss (initial): Dx of NMPC. Pt is 70 years or older, or less than 70 years old with BMD T-score below -1.0 (1.0 SD or greater below the mean for young adults) or hx of vertebral compression fx or fx of the hip or distal radius resulting from minimal trauma. NMPC (reauth): No evidence of metastases. Breast cancer (BC) bone loss (initial): Dx of BC. BMD T-score below -1.0 (1.0 SD or greater below the mean for young adults) or hx of vertebral compression fx or fx of the hip or distal radius resulting from minimal trauma. OP in men (initial): Pt is a male with OP. Hx of vertebral compression fx or fx of the hip or distal radius resulting from minimal trauma, or BMD indicative of OP: T-score less than or equal to -2.0 (2.0 SD or greater below the mean for young adults). Treatment of glucocorticoid-induced osteoporosis in patients at high risk of fracture who are initiating or continuing systemic glucocorticoids at a daily dose equivalent to ±7.5 mg of prednisone for an anticipated duration of at least 6 months (high risk defined as osteoporotic fracture history, multiple risk factors for fracture, or failure of or intolerance to other available osteoporosis therapy).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A
COVERAGE DURATION
All uses (initial, reauth): 12 months

OTHER CRITERIA
NMPC bone loss (initial and reauth): Receiving androgen deprivation therapy (ADT) from luteinizing hormone/gonadotropin releasing hormone (LHRH/GnRH) agonist [e.g., Eligard/Lupron (leuprolide), Trelstar (triptorelin), Vantas (histrelin), Zoladex (goserelin)] or bilateral orchiectomy (i.e., surgical castration). BC bone loss (initial and reauth): Pt is receiving aromatase inhibitor (AI) therapy [e.g., Arimidex (anastrozole), Aromasin (exemestane), Femara (letrozole)]. All indications except NMPC (initial): One of the following A) Patient has a documented trial and therapeutic failure with a bisphosphonate, where therapeutic failure is defined as new fractures in compliant patients on therapy for at least 6 months, failure to produce a clinically significant change in a biochemical marker(s) of bone turnover, or significant loss of bone mineral density on follow-up scans after 12 to 24 months of therapy or B) Patient has a documented contraindication or intolerance to bisphosphonate therapy, or is unable to comply with appropriate administration recommendations for oral or injectable bisphosphonate therapy. All indications (renewal): The patient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, or improved biochemical markers, etc.)
MEDICATION(S)
MODAFINIL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Obstructive sleep apnea/hypopnea syndrome (OSAHS) (Initial): Diagnosis (dx) of OSAHS defined by
one of the following: 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep
study (unless prescriber provides justification confirming that a sleep study is not feasible), or both of
the following: 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study
(unless prescriber provides justification confirming that a sleep study is not feasible), and 1 of the
following symptoms: unintentional sleep episodes during wakefulness, daytime sleepiness,
unrefreshing sleep, fatigue, insomnia, waking up breath holding/gasping/choking, loud snoring, or
breathing interruptions during sleep. Shift-work sleep disorder (SWSD) (Initial): Dx of SWSD confirmed
by symptoms of excessive sleepiness or insomnia for at least 3 months, which is associated with a
work period (usually night work) that occurs during the normal sleep period, or sleep study
demonstrating loss of a normal sleep-wake pattern (ie, disturbed chronobiologic rhythmicity). No other
medical condition or medication accounts for the symptoms. Narcolepsy (initial): Dx of narcolepsy as
confirmed by sleep study (unless prescriber provides justification confirming that a sleep study is not
feasible). MS Fatigue (initial): Dx of multiple sclerosis (MS). Patient is experiencing fatigue. Depression
(initial): Treatment-resistant depression defined as diagnosis of major depressive disorder (MDD) or
bipolar depression, AND trial and failure, contraindication, or intolerance to at least two
antidepressants from different classes (eg, SSRIs, SNRIs, bupropion). Used as adjunctive therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A
COVERAGE DURATION
OSAHS/MS/dep(init), SWSD (init,reauth): 3 mo. OSAHS/dep(reauth): 12 mo. MS (reauth): 6 mo. Other: 12 mo

OTHER CRITERIA
MEDICATION(S)
PULMOZYME

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Cystic Fibrosis (CF) (Initial, Reauth): Diagnosis of CF

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
CF (initial, reauth): 12 months

OTHER CRITERIA
Part B vs D determination applies. CF (reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations).
QUALAQUIN

MEDICATION(S)
QUININE SULFATE 324 MG CAPSULE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Malaria: Diagnosis of uncomplicated malaria. One of the following: 1) Treatment in areas of chloroquine-sensitive malaria, and trial and failure, contraindication, or intolerance to chloroquine or hydroxychloroquine, OR 2) Treatment in areas of chloroquine-resistant malaria. Not used for the treatment or prevention of nocturnal leg cramps.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
7 days

OTHER CRITERIA
N/A
QUETIAPINE ER

MEDICATION(S)
QUETIAPINE FUMARATE ER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
For schizophrenia, 13 years of age or older. For bipolar disorder, 10 years of age or older. For MDD, 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
For schizophrenia/bipolar use, the individual has had a trial of one of the following generic oral atypical antipsychotic: Risperidone, Olanzapine, Quetiapine fumarate, Paliperidone or Ziprasidone.
RAVICTI

MEDICATION(S)
RAVICTI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Urea cycle disorders (UCDs) (Initial): Diagnosis of UCDs.

AGE RESTRICTION
UCDs (Initial): Age greater than 2 months

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
UCDs (Initial, reauth): 12 months

OTHER CRITERIA
UCDs (reauth): Documentation of positive clinical response to Ravigiti therapy.
REGRANEX

MEDICATION(S)
REGRANEX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diabetic neuropathic ulcers: Patient has a lower extremity diabetic neuropathic ulcer. Treatment will be given in combination with ulcer wound care (eg, debridement, infection control, and/or pressure relief)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
5 months

OTHER CRITERIA
N/A
**RELISTOR**

**MEDICATION(S)**
RELISTOR 12 MG/0.6 ML SYRINGE, RELISTOR 12 MG/0.6 ML VIAL, RELISTOR 8 MG/0.4 ML SYRINGE

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Opioid-induced constipation (OIC) (Initial): Diagnosis of OIC. Patient has used opioid medication for a minimum of 4 weeks. Patient is experiencing fewer than 3 bowel movements in a week or no bowel movement for longer than 2 days. One of the following: A) Patient is an adult with a diagnosis of chronic non-cancer pain AND patient had a trial and failure, contraindication, or intolerance to Amitiza (lubiprostone), OR B) Patient is receiving palliative care for an advanced illness.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
OIC (initial, reauth): 4 months

**OTHER CRITERIA**
OIC (Reauth): Diagnosis of OIC. One of the following: A) Patient is an adult with a diagnosis of chronic non-cancer pain, OR B) Both of the following: Patient is receiving palliative care for an advanced illness AND Patient has responded to therapy (e.g., increase in bowel movements).
MEDICATION(S)
REMICADE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Crohn's Disease (CD) and Fistulizing Crohn's Disease (FCD) (Initial): Diagnosis (Dx) of moderately to severely active CD or FCD. Failure, contraindication, or intolerance to one of the following conventional therapies: 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex/Trexall). Ulcerative colitis (UC) (Initial): Dx of moderately to severely active UC. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), aminosalicylate [eg, mesalamine (Asacol/Pentasa/Rowasa), Dipentum (olsalazine), Azulfidine (sulfasalazine)]. Rheumatoid arthritis (RA) (Initial): Dx of moderately to severely active RA. One of the following: Receiving concurrent therapy with methotrexate (Rheumatrex/Trexall), OR TF/C/I to methotrexate (Rheumatrex/Trexall). Ankylosing spondylitis (AS) (Initial): Dx of active AS. TF/C/I to two NSAIDs. Psoriatic arthritis (PsA) (Initial): Dx of active PsA. Plaque psoriasis (Initial): Dx of chronic severe (ie, extensive and/or disabling) plaque psoriasis. Sarcoidosis (initial): TF/C/I to one immunosuppressant [eg, methotrexate (Rheumatrex/Trexall), cyclophosphamide, or azathioprine (Imuran)] AND TF/C/I to one corticosteroid (eg, prednisone). All indications (Initial): Patient is not receiving Remicade in combination with a biologic DMARD [eg, Enbrel (etanercept), Rituxan (rituximab), Orencia (abatacept), Kineret (anakinra)]. Patient is not receiving Remicade in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

AGE RESTRICTION
N/A
PRESCRIBER RESTRICTION
CD, FCD, UC (Initial): Prescribed by or in consultation with a gastroenterologist. RA, AS (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with rheumatologist or dermatologist. Plaque Psoriasis (Initial): Prescribed by or in consultation with a dermatologist. Sarcoidosis (Initial): Prescribed by or in consultation with a pulmonologist, dermatologist, ophthalmologist.

COVERAGE DURATION
All indications (initial, reauth): 12 months

OTHER CRITERIA
Reauthorization for all indications: Documentation of positive clinical response to infliximab therapy. All indications (re-auth): Excluded if patient is receiving infliximab in combination with a Biologic Disease Modifying Antirheumatic Drug (DMARD) [eg, Enbrel (etanercept), Oncia (abatacept), Rituxan (rituximab), Kineret (anakinra), Cimzia (certolizumab)] or Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].
**MEDICATION(S)**
REMODULIN, TREPROSTINIL

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.

**COVERAGE DURATION**
PAH: Initial: 6 months. Reauth: 12 months.

**OTHER CRITERIA**
Subject to Part B vs. D Review. PAH (Reauth): Documentation of positive clinical response to therapy.
REPATHA

MEDICATION(S)
REPATHA PUSHTRONEX, REPATHA SURECLICK, REPATHA SYRINGE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
HeFH/ASCVD (initial): Submission of medical records (eg, chart notes, laboratory values) documenting one of the following diagnoses: Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following: (1) Documented assessment of patient using Dutch Lipid Clinic Network diagnostic criteria with a cumulative score greater than or equal to 9 points (ie, definite FH), or (2) Presence of tendinous xanthomas in patient, first degree relative, or second degree relative, AND Untreated/pre-treatment LDL-C greater than 190 mg/dL in an adult, or (3) Genetic confirmation of a mutation in the LDL receptor, ApoB, or PCSK9. OR Atherosclerotic cardiovascular disease (ASCVD) as confirmed by acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin. HoFH (initial): Submission of medical records (eg, chart notes, laboratory values) documenting diagnosis of homozygous familial hypercholesterolemia as confirmed by one of the following: (1) Genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (ie, LDLRAP1 or ARH), or (2) either untreated LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL, AND either xanthoma before 10 years of age or evidence of heterozygous familial hypercholesterolemia in both parents. HeFH/ASCVD/HoFH (initial): One of the following LDL-C values while on maximally tolerated lipid-lowering regimen within the last 30 days: (1) LDL-C greater than or equal to 100 mg/dL with ASCVD, or (2) LDL-C greater than or equal to 130 mg/dL without ASCVD.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
HeFH/ASCVD/HoFH (init, reauth): Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist
COVERAGE DURATION

OTHER CRITERIA
One of the following: (1) Patient has been receiving at least 12 consecutive weeks of one maximally-tolerated statin therapy and will continue to receive a statin at maximally tolerated dose, or (2) Patient is unable to tolerate statin as evidenced by intolerable and persistent (ie, more than 2 weeks) myalgia (muscle symptoms without CK elevations) or myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN]), or (3) Submission of medical records documenting patient has a labeled contraindication to all statins, or (4) Patient has experienced rhabdomyolysis on one statin therapy. HoFH (initial): One of the following: (1) Patient has been receiving at least 12 consecutive weeks of one maximally-tolerated statin therapy and will continue to receive a statin at maximally tolerated dose, or (2) both of the following: a) One of the following: 1. Patient is unable to tolerate statin as evidenced by intolerable and persistent (ie, more than 2 weeks) myalgia (muscle symptoms without CK elevations) or myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN]), or 2. Submission of medical records documenting patient has a labeled contraindication to all statins, or 3. Patient has experienced rhabdomyolysis on one statin therapy, AND b) patient has been receiving at least 12 consecutive weeks of other LDL-C lowering prescription therapy and will continue to receive an LDL-C lowering prescription therapy. HeFH/ASCVD (reauth): Patient continues to receive statin at the maximally tolerated dose (unless patient has documented inability to take statins). HoFH (reauth): Patient continues to receive statin at the maximally tolerated dose (or other LDL-C lowering prescription therapy if patient is unable to take a statin). HeFH/ASCVD/HoFH (reauth): Submission of medical records (eg, laboratory values) documenting a sustained LDL-C reduction from pre-treatment baseline (ie, prior to Repatha therapy) while on Repatha therapy. HeFH/ASCVD/HoFH (Initial, reauth): Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. HoFH (Initial, reauth): Not used in combination with Juxtapid (lomitapide) or Kynamro (mipomersen).
**REVATIO**

**MEDICATION(S)**
SILDENAFIL, SILDENAFIL 10 MG/ML ORAL SUSP, SILDENAFIL 20 MG TABLET

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. For Revatio injection only (Initial): Patient is temporarily unable to take oral medications. For Revatio oral suspension only (initial, reauth): One of the following: A) Intolerance to generic Revatio tablets, OR B) Patient is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to one of the following: age, oral-motor difficulties, or dysphagia.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.

**COVERAGE DURATION**
PAH: Initial: 6 months. Reauth: 12 months.

**OTHER CRITERIA**
PAH (Reauth): Documentation of positive clinical response to therapy
MEDICATION(S)
REVLMID

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Multiple myeloma (MM): Diagnosis of MM. Either used as 1) combination therapy with dexamethasone, or 2) maintenance therapy following autologous hematopoietic stem cell transplantation (auto-HSCT). Myelodysplastic syndromes (MDS): Patient has transfusion-dependent anemia due to low- or intermediate-1-risk MDS associated with a deletion. Mantle cell lymphoma (MCL): Diagnosis of MCL. Disease has relapsed, refractory, or progressed after at least one prior therapy (eg, bortezomib, bendamustine, cladribine, rituximab).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist/hematologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
RILUZOLE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Amyotrophic lateral sclerosis (ALS): Diagnosis of amyotrophic lateral sclerosis (ALS)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
ALS: 12 months

OTHER CRITERIA
N/A
MEDICATION(S)
RITUXAN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Rheumatoid Arthritis (RA) (init): Patient is not receiving Rituxan in combination with a biologic DMARD [eg, Enbrel (etanercept), Orencia (abatacept), Kineret (anakinra)]. Patient is not receiving Rituxan in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

REQUIRED MEDICAL INFORMATION
Non-Hodgkin's Lymphoma (NHL): As first-line treatment of diffuse large B-cell, CD20-positive, NHL in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens, or as first-line treatment of follicular, CD20-positive, B-cell NHL in combination with chemotherapy, or as a single-agent maintenance therapy for the treatment of follicular, CD20-positive, B-cell NHL in patients achieving a complete or partial response to Rituxan in combination with chemotherapy, or for the treatment of low-grade, CD20-positive, B-cell NHL in patients with stable disease following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/prednisone) chemotherapy or who achieve a partial or complete response following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/prednisone) chemotherapy, or diagnosis of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin's lymphoma. Rheumatoid Arthritis (RA) (init): Concurrently on or contraindication, or intolerance to methotrexate. Trial and failure, contraindication, or intolerance (TF/C/I) to a TNF antagonist (eg, adalimumab, etanercept, infliximab). Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA): Patient is concurrently on glucocorticoids (eg, prednisone) OR contraindication or intolerance to glucocorticoids (eg, prednisone). Immune or idiopathic thrombocytopenic purpura (ITP): TF/C/I to one of the following: corticosteroids, immunoglobulins, or splenectomy. Documented platelet count of less than 50x10^9/L.

AGE RESTRICTION
N/A
**PRESCRIBER RESTRICTION**

ITP: Prescribed by or in consultation with a hematologist or oncologist. RA: Prescribed by or in consultation with a rheumatologist. WG, MPA: Prescribed by or in consultation with a nephrologist, pulmonologist, or rheumatologist.

**COVERAGE DURATION**

All uses except RA, WG, MPA: 12 mos. RA: 3 months. WG, MPA: 3 months only.

**OTHER CRITERIA**

Approve for continuation of prior therapy.
MEDICATION(S)
RUBRACA 200 MG TABLET, RUBRACA 300 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of Ovarian cancer: advanced Treatment of deleterious germline and/or somatic BRCA mutation associated (as detected by an approved test) ovarian cancer in patients who have been treated with 2 or more prior lines of chemotherapy or Diagnosis of Ovarian cancer, recurrent (maintenance) Maintenance treatment of recurrent Ovarian cancer (epithelial, fallopian tube, or primary peritoneal) in patients who are in complete or partial response to platinum-based chemotherapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy
RUCONEST

MEDICATION(S)
RUCONEST

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks (eg, Berinert, Firazyr, or Kalbitor).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
HAE: Prescribed by an immunologist, allergist, or rheumatologist

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
**MEDICATION(S)**
RYDAPT

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Acute Myeloid Leukemia (AML): Newly diagnosed acute myeloid leukemia (AML), FMS-like tyrosine kinase 3 (FLT3) mutation-positive as detected by a U.S. Food and Drug Administration (FDA)-approved test, used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation. Aggressive Systemic Mastocytosis (ASM), Systemic Mastocytosis with Associated Hematological Neoplasm (SM-AHN), Mast Cell Leukemia (MCL): Diagnosis of one of the following: aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL).

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
All indications: Prescribed by or in consultation with a hematologist or oncologist.

**COVERAGE DURATION**
12 months

**OTHER CRITERIA**
Approve for continuation of prior therapy
MEDICATION(S)
SABRIL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Complex Partial Seizures (CPS): For use as adjunctive therapy. Failure, contraindication, or intolerance to two formulary anticonvulsants [eg, Lamictal (lamotrigine), Depakene (valproic acid), Dilantin (phenytoin)]. Infantile Spasms (IS): Diagnosis of infantile spasms.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
**MEDICATION(S)**
OCTREOTIDE 1,000 MCG/5 ML VIAL, OCTREOTIDE ACET 0.05 MG/ML VL, OCTREOTIDE ACET 100 MCG/ML AMP, OCTREOTIDE ACET 100 MCG/ML VL, OCTREOTIDE ACET 200 MCG/ML VL, OCTREOTIDE ACET 50 MCG/ML AMP, OCTREOTIDE ACET 50 MCG/ML VIAL, OCTREOTIDE ACET 500 MCG/ML AMP, OCTREOTIDE ACET 500 MCG/ML VL

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Acromegaly (initial): Diagnosis of acromegaly AND One of the following: A) History of failure to surgical resection and/or pituitary irradiation OR B) patient is not a candidate for surgical resection or pituitary irradiation AND Trial and failure or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses. Carcinoid tumor (initial): Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea and flushing episodes. Vasoactive intestinal peptide tumor (initial): Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
All Uses (Initial and reauth): 12 months

**OTHER CRITERIA**
Acromegaly (reauth): Patient has had a clinical response to therapy (e.g., reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size). Carcinoid tumor (reauth): patient has improvement in number of diarrhea and flushing episodes. Vasoactive intestinal peptide tumor (reauth): patient has improvement in number of diarrhea episodes.
MEDICATION(S)
SANDOSTATIN LAR DEPOT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Acromegaly (initial): Diagnosis of acromegaly AND One of the following: A) Failure to surgical resection and/or pituitary irradiation OR B) patient is not a candidate for surgical resection or pituitary irradiation AND Trial and failure or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses AND Patient had a trial of short-acting octreotide and responded to and tolerated therapy. Carcinoid tumor (initial): Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea and flushing episodes AND Patient had a trial of short-acting octreotide and responded to and tolerated therapy. Vasoactive peptide tumor (initial): Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea AND Patient had a trial of short-acting octreotide and responded to and tolerated therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
All Uses (Initial and reauth): 12 months

OTHER CRITERIA
Acromegaly (reauth): Patient has had a clinical response to therapy (e.g., reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size). Carcinoid tumor (reauth): patient has improvement in number of diarrhea and flushing episodes. Vasoactive intestinal peptide tumor (reauth): patient has improvement in number of diarrhea episodes.
SEROSTIM

**MEDICATION(S)**
SEROSTIM

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
HIV wasting (Initial): Diagnosis of HIV-associated wasting syndrome or cachexia, and one of the following: unintentional weight loss greater than 10% over the last 12 months, or unintentional weight loss greater than 7.5% over the last 6 months, or loss of 5% body cell mass (BCM) within 6 months, or body mass index (BMI) less than 20 kg/m2, or patient is male and has BCM less than 35% of total body weight (TBW) and BMI less than 27 kg/m2, or patient is female and has BCM less than 23% of TBW and BMI less than 27 kg/m2. Nutritional evaluation since onset of wasting first occurred. Anti-retroviral tx has been optimized to decrease the viral load. Patient has not had weight loss as a result of other underlying treatable conditions (eg, depression, mycobacterium avium complex, chronic infectious diarrhea, or malignancy with the exception of Kaposi’s sarcoma limited to skin or mucous membranes). Patient has tried and had an inadequate response or intolerance to dronabinol or megestrol acetate.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
Initial, Reauth: Prescribed by or in consultation with an infectious disease specialist.

**COVERAGE DURATION**
Initial: 3 months, Reauth: 6 months

**OTHER CRITERIA**
HIV wasting (reauth): Evidence of positive response to therapy. One of the following targets or goals has not been achieved: weight, BCM, BMI. Patient is currently receiving treatment with antiretrovirals.
MEDICATION(S)
SIGNIFOR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Cushing's disease (initial): Diagnosis of Cushing's disease AND failure to or patient is not a candidate for pituitary surgery.

AGE RESTRICTION
Initial: 18 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial: 3 months. Reauth: 12 months.

OTHER CRITERIA
Cushing's disease (reauth): a clinically meaningful reduction in 24-hour urinary free cortisol levels or improvement in signs or symptoms of the disease.
MEDICATION(S)
SIMPONI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: Receiving concurrent therapy with methotrexate (Rheumatrex/Trexall) OR trial and failure, contraindication, or intolerance (TF/C/I) to methotrexate (Rheumatrex/Trexall). One of the following: TF/C/I to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Simponi therapy. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: TF/C/I to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Simponi therapy. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. One of the following: TF/C/I to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Simponi therapy. Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. Patient is corticosteroid dependent (ie, an inability to successfully taper corticosteroids without a return of the symptoms of UC), OR TF/C/I to one of the following: oral aminosalicylate, oral corticosteroid, azathioprine, 6-mercaptopurine. One of the following: TF/C/I to Humira (adalimumab), OR for continuation of prior Simponi therapy. All indications (Initial, reauth): Patient is not receiving Simponi in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]. Patient is not receiving Simponi in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RA, AS (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with a rheumatologist or dermatologist. UC (Initial): Prescribed by or in consultation with a gastroenterologist.
COVERAGE DURATION
UC (Initial): 12 weeks. UC (Reauth): 12 months. RA, AS, PsA (Initial, reauth): 12 months

OTHER CRITERIA
All indications (Reauth): Documentation of positive clinical response to Simponi therapy.
**MEDICATION(S)**
SIMPONI ARIA

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Rheumatoid arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: Receiving concurrent therapy with methotrexate (Rheumatrex/Trexall), OR trial and failure, contraindication, or intolerance to methotrexate (Rheumatrex/Trexall). One of the following: trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Simponi Aria therapy. Patient is not receiving Simponi Aria in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Oncia (abatacept)]. Patient is not receiving Simponi Aria in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
RA (Initial): Prescribed by or in consultation with a rheumatologist.

**COVERAGE DURATION**
RA (Initial, reauth): 12 months

**OTHER CRITERIA**
RA (Reauth): Documentation of positive clinical response to Simponi Aria therapy. Patient is not receiving Simponi Aria in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Oncia (abatacept)]. Patient is not receiving Simponi Aria in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].
SIMVASTATIN

MEDICATION(S)
SIMVASTATIN 80 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Patient has been taking simvastatin 80 mg per day chronically (12 months or more) and no evidence of muscle toxicity/myopathy (eg, muscle pain, muscle tenderness, muscle weakness) on simvastatin 80 mg per day.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
SOMATULINE DEPOT

MEDICATION(S)
SOMATULINE DEPOT 60 MG/0.2 ML, SOMATULINE DEPOT 90 MG/0.3 ML

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Acromegaly (initial): Diagnosis of acromegaly AND One of the following: A) Failure to one of the following: surgery or radiotherapy, OR B) not a candidate for one of the following: surgery or radiotherapy. Gastroenteropancreatic neuroendocrine tumors (GEP-NETs) (initial): Diagnosis of unresectable, well- or moderately-differentiated, locally advanced or metastatic GEP-NETs

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
All Indications (Initial and reauth): 12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
**MEDICATION(S)**
SOMATULINE DEPOT 120 MG/0.5 ML

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Acromegaly (initial): Diagnosis of acromegaly AND One of the following: A) Failure to one of the following: surgery or radiotherapy, OR B) not a candidate for one of the following: surgery or radiotherapy. Gastroenteropancreatic neuroendocrine tumors (GEP-NETs) (initial): Diagnosis of unresectable, well- or moderately-differentiated, locally advanced or metastatic GEP-NETs

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
All Indications (Initial and reauth): 12 months

**OTHER CRITERIA**
Applies to New Starts only. Approve for continuation of prior therapy.
MEDICATION(S)
SOMAVERT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Acromegaly (initial): Diagnosis of acromegaly AND Failure to surgery and/or radiation therapy and/or other medical therapies (such as dopamine agonists [e.g., bromocriptine, cabergoline]) unless patient is not a candidate for these treatment options AND trial and failure or intolerance to generic octreotide (a somatostatin analogue)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial and reauth: 12 months

OTHER CRITERIA
Acromegaly (reauth): Patient has experienced an objective response to therapy (biochemical control, decrease or normalization of IGF-1 levels).
SOVALDI

MEDICATION(S)
SOVALDI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria will be applied consistent with current AASLD/IDSA guideline. For genotype (GT) 1 patients. All GT1 (except Sovaldi plus Daklinza therapy in post-liver transplant (tx) patients) and GT4: 1) trial and failure, intolerance or contraindication (TF/I/C) to both of the following: Harvoni and Zepatier therapy OR 2) For continuation of prior Sovaldi therapy. For GT2 (except in 1) post-liver tx patients, or 2) patients 12 to 17 years of age or 3) both of the following: a) patients weighing at least 35 kg and b) less than 18 years of age) or GT3 patients (except in 1) patients 12 to 17 years of age or 2) both of the following: a) patients weighing at least 35 kg and b) less than 18 years of age), using Sovaldi plus ribavirin: TF/I/C to Epclusa OR for continuation of prior Sovaldi therapy. All Sovaldi plus Daklinza therapy: One of the following: 1) Patient has not failed a prior HCV NS5A-containing regimen (eg, Daklinza) therapy, OR 2) patient has failed prior therapy with an NS5A-containing regimen AND submission of medical records (eg, chart notes) documenting that the patient does not have NS5A inhibitor resistance-associated variants detected using commercially available assays. For GT2 and GT3 (except post-liver tx patients) patients, using Sovaldi plus Daklinza: TF/I/C to Epclusa OR for continuation of prior Sovaldi therapy. For GT1 post-liver tx patients using Sovaldi plus Daklinza, TF/I/C to Harvoni OR for continuation of prior Sovaldi therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine

COVERAGE DURATION
12 to 48 wks. Criteria will be applied consistent with current AASLD/IDSA guideline
OTHER CRITERIA
N/A
MEDICATION(S)
ITRACONAZOLE 10 MG/ML SOLUTION, ITRACONAZOLE 100 MG CAPSULE, SPORANOX 10 MG/ML SOLUTION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
One of the following: 1) patient has a systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis), OR 2) patient is resistant to topical antifungal treatment and has one of the following diagnoses: a) tinea corporis (ringworm), OR b) tinea cruris (jock itch), OR c) tinea pedis (athlete's foot), OR d) tinea capitis (scalp ringworm), OR e) pityriasis versicolor, OR 3) all of the following: a) patient has a diagnosis of onychomycosis confirmed by one of the following (CAPSULE ONLY): i) positive potassium hydroxide (KOH) preparation, OR ii) culture, OR iii) histology, AND b) the patient's condition is causing debility or a disruption in their activities of daily living, AND c) patient has had a trial and inadequate response, intolerance or hypersensitivity to oral terbinafine, OR 4) patient has a diagnosis of candidiasis (esophageal or oropharyngeal) that is refractory to treatment with fluconazole (ORAL SOLUTION ONLY).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Systemic fungal fxn: 6mo, candidiasis: 1 mo., fingernail onycho: 5 weeks, toenail onycho, other: 3mo.

OTHER CRITERIA
N/A
**SPRAYATO**

**MEDICATION(S)**
SPRAYATO 56 MG DOSE PACK, SPRAYATO 84 MG DOSE PACK

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Treatment of treatment-resistant depression (TRD) in adults, in conjunction with an oral antidepressant.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
Prescribed by or in consultation with a psychiatrist.

**COVERAGE DURATION**
Initial: 1 months Reauth: 12 months

**OTHER CRITERIA**
Will only be available to be administered in certified treatment centers in accordance with the REMS.
SPRYCEL

MEDICATION(S)
SPRYCEL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML): Diagnosis of Ph+ CML. Ph+ acute lymphoblastic leukemia (ALL): Diagnosis of Ph+ ALL.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
All Uses: Prescribed by or in consultation with an oncologist or hematologist

COVERAGE DURATION
All Uses: 12 months

OTHER CRITERIA
All Uses: Approve for continuation of prior therapy.
MEDICATION(S)
STELARA 130 MG/26 ML VIAL, STELARA 45 MG/0.5 ML SYRINGE, STELARA 90 MG/ML SYRINGE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Plaque psoriasis (Initial - 45mg/0.5mL): Diagnosis of moderate to severe plaque psoriasis. Plaque psoriasis (Initial - 90mg/1mL): Diagnosis of moderate to severe plaque psoriasis. Patient's weight is greater than 100 kg (220 lbs). Psoriatic arthritis (PsA) (Initial - 45mg/0.5mL): Diagnosis of active PsA. PsA (Initial - 90mg/1mL): Diagnosis of active PsA. Patient's weight is greater than 100 kg (220 lbs). Diagnosis of co-existent moderate to severe psoriasis. Plaque psoriasis (Initial): One of the following: a) Trial and failure, contraindication, or intolerance (TF/C/I) to Enbrel (etanercept) OR Humira (adalimumab) OR b) for continuation of prior Stelara therapy. PsA (Initial): One of the following: a) TF/C/I to Enbrel (etanercept) and Humira (adalimumab) OR b) for continuation of prior Stelara therapy. Crohn's disease (CD) (Initial): Diagnosis of moderately to severely active Crohn's disease. One of the following: a) TF/C/I to Humira (adalimumab) OR b) TF/C/I to treatment with at least one immunomodulator or corticosteroid [e.g., Purinethol (6-mercaptopurine), Imuran (azathioprine), Sandimmune (cyclosporine A), Prograf (tacrolimus), MTX (methotrexate)], OR c) for continuation of prior Stelara therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Plaque psoriasis (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. CD (initial): Prescribed by or in consultation with a gastroenterologist.

COVERAGE DURATION
All uses (Initial, reauth): 12 months
OTHER CRITERIA
Reauthorization (all indications): Documentation of positive clinical response to Stelara therapy. All indications (initial, reauth): Patient is not receiving Stelara in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab).
STIVARGA

MEDICATION(S)
STIVARGA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Colorectal cancer, metastatic- Treatment of metastatic colorectal cancer in patients previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, antivascular endothelial growth factor (VEGF) therapy (e.g. Avastin [bevacizumab]) and antiepidermal growth factor receptor (EGFR) therapy [e.g. Vectibix (panitumumab), Erbitux (cetuximab)] (if RAS gene [HRAS, KRAS, NRAS] wild type) Gastrointestinal stromal tumors- Treatment of locally advanced, unresectable or metastatic gastrointestinal stromal tumors (GIST) in patients previously treated with imatinib and sunitinib. Liver Carcinoma- Treatment of Hepatocellular carcinoma in patients previously treated with sorafenib.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
STRENSIQ

MEDICATION(S)
STRENSIQ

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Hypophosphatasia: Diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia AND for patients requesting the 80 mg/0.8 mL vial only: Patient's weight is greater than or equal to 40 kg

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Hypophosphatasia: Prescribed by or in consultation with a specialist experienced in the treatment of inborn errors of metabolism or endocrinologist

COVERAGE DURATION
Hypophosphatasia: 12 months

OTHER CRITERIA
N/A
MEDICATION(S)
SUTENT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Renal cell carcinoma: Diagnosis of advanced or metastatic renal cell carcinoma. Gastrointestinal stromal tumor (GIST): Diagnosis of GIST after disease progression on or intolerance to Gleevec (imatinib). Pancreatic neuroendocrine tumors: Diagnosis of progressive, well-differentiated pancreatic neuroendocrine tumor that is unresectable locally advanced or metastatic disease.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
All Indications: Prescribed by or in consultation with an oncologist

COVERAGE DURATION
All Indications: 12 months

OTHER CRITERIA
All Indications: Approve for continuation of prior therapy
SYLATRON

MEDICATION(S)
SYLATRON, SYLATRON 4-PACK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Melanoma: Diagnosis of melanoma with microscopic or gross nodal involvement AND The prescribed medication will be used as adjuvant therapy within 84 days of definitive surgical resection, including complete lymphadenectomy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy
SYLVANT

**MEDICATION(S)**
SYLVANT 100 MG VIAL

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Multicentric Castleman's disease (MCD) (Initial): Diagnosis of MCD. Patient is human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
MCD (Initial): Prescribed by or in consultation with hematologist/oncologist or rheumatologist.

**COVERAGE DURATION**
MCD (initial, reauth): 6 months

**OTHER CRITERIA**
MCD (reauth): Documentation of positive clinical response to Sylvant therapy. Patient is HIV negative and HHV-8 negative.
**MEDICATION(S)**
SYMLINPEN 120, SYMLINPEN 60

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
Gastroparesis.

**REQUIRED MEDICAL INFORMATION**
One of the following diagnoses: A) Type 1 diabetes OR B) Type 2 diabetes.

**AGE RESTRICTION**
18 years of age or older

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
12 months

**OTHER CRITERIA**
N/A
SYNAGIS

MEDICATION(S)
SYNAGIS 50 MG/0.5 ML VIAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Patient will use palivizumab for immunoprophylaxis of respiratory syncytial virus (RSV) during the peak months of infection in the patients geographic region AND Patient meets one of the following criteria: 1) Infants born at 28 weeks, six days gestation or earlier and who are younger than 12 months of age at the start of the RSV season OR 2) Diagnosis of chronic lung disease of prematurity, born before 32 weeks, 0 days gestation, received greater than 21% oxygen for at least the first 28 days after birth, and one of the following: a) 12 months of age or younger at the start of the RSV season OR b) greater than 12 months of age to 24 months of age at the start of the RSV season and received medical support (i.e., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) within 6 months before the start of the second RSV season. OR 3) Patient is 12 months of age or younger at the start of the RSV season and has one of the following: a) acyanotic heart failure that will require a cardiac surgical procedure and the patient is receiving medication to control congestive heart failure, OR b) moderate to severe pulmonary hypertension OR c) cyanotic heart defect. OR 4) patient is younger than 24 months of age and will or has undergone a cardiac transplantation during the RSV season. OR 5) Patient is 12 months of age or younger at the start of the RSV season with a congenital abnormality or neuromuscular disorder and has an impaired ability to clear secretions from the upper airway due to an ineffective cough. OR 6) Patient is younger than 24 months of age with a lymphocyte count below the normal range for patients age and has received or will receive a solid organ transplant, hematopoietic stem cell transplant recipient, or chemotherapy during the RSV season.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a pediatric specialist (i.e., pulmonologist, neonatologist, neurologist, cardiologist, pediatric intensivist, or infectious disease specialist).
COVERAGE DURATION
12 months

OTHER CRITERIA
Approve 5 doses based on patient body weight for all other indications.
MEDICATION(S)
SYNRIBO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chronic myelogenous leukemia (CML): Diagnosis of CML in the chronic or accelerated phase AND Patient has tried and has had resistance, relapse, inadequate response, intolerance or is contraindicated to TWO tyrosine kinase inhibitors (i.e., Gleevec [imatinib], Sprycel, Tasigna, and Bosulif, Iclusig)

AGE RESTRICTION
CML: 18 years of age or older

PRESCRIBER RESTRICTION
CML: Prescribed by or in consultation with a hematologist/oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy
MEDICATION(S)
TACROLIMUS 0.03% OINTMENT, TACROLIMUS 0.1% OINTMENT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
For Protopic (tacrolimus) 0.03 percent, individual is 2 years of age and older. For Protopic (tacrolimus) 0.1 percent, individual is 16 years of age and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Individual had a trial of and inadequate response or intolerance to one topical prescription strength corticosteroid.
MEDICATION(S)
TAFINLAR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma. Cancer is BRAFV600 mutant type (MT) as detected by an FDA-approved test (THxID-BRAF Kit) or performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
TAGRISSO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Tumors are positive for epidermal growth factor receptor (EGFR) T790M mutation. The patient has experienced disease progression on or after one of the following EGFR Tyrosine Kinase Inhibitors (TKIs): Gilotrif (afatinib), Iressa (gefitinib), Tarceva (erlotinib).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
**TALTZ**

**MEDICATION(S)**
TALTZ AUTOINJECTOR, TALTZ AUTOINJECTOR (2 PACK), TALTZ AUTOINJECTOR (3 PACK), TALTZ SYRINGE, TALTZ SYRINGE (2 PACK)

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: Trial and failure, contraindication, or intolerance to both Cosentyx (secukinumab) and either Enbrel (etanercept) or Humira (adalimumab), OR for continuation of prior Taltz therapy. Patient is not receiving Taltz in combination with a biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].

**AGE RESTRICTION**
N/A

**PREScriBER RESTRICTION**
Plaque psoriasis (Initial): Prescribed by or in consultation with a dermatologist.

**COVERAGE DURATION**
Initial, reauth: 12 months

**OTHER CRITERIA**
Plaque psoriasis (Reauth): Documentation of positive clinical response to Taltz therapy. Patient is not receiving Taltz in combination with a biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].
MEDICATION(S)
TALZENNA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
CRITERIA: Breast cancer, locally advanced or metastatic (BRCA-mutated, HER2-negative) Treatment of deleterious or suspected deleterious germline BRCA-mutated, HER2-negative locally advanced or metastatic breast cancer in adults (as detected by an approved test)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A


**MEDICATION(S)**
ERLOTINIB HCL

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Non-small cell lung cancer (NSCLC): Diagnosis of locally advanced or metastatic (Stage III or IV) NSCLC AND Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutation as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility. Pancreatic Cancer: Diagnosis of locally advanced, unresectable, or metastatic pancreatic cancer AND TARCEVA will be used in combination with gemcitabine.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
All Indications: Prescribed by or in consultation with an oncologist

**COVERAGE DURATION**
All Indications: 12 months

**OTHER CRITERIA**
All Indications: Approve for continuation of prior therapy.
**MEDICATION(S)**
BEXAROTENE, TARGRETIN 1% GEL

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Cutaneous T-Cell Lymphoma (CTCL): Diagnosis of CTCL. Trial and failure, contraindication, or intolerance to at least one prior therapy (including skin-directed therapies [eg, corticosteroids {ie, clobetasol, diflorasone, halobetasol, augmented betamethasone dipropionate}] or systemic therapies [eg, interferons]).

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
Prescribed by or in consultation with an oncologist or dermatologist

**COVERAGE DURATION**
12 months

**OTHER CRITERIA**
Approve for continuation of prior therapy.
MEDICATION(S)
TASIGNA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chronic myelogenous leukemia (CML): Diagnosis of Ph+ CML

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist or hematologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
TAVALISSE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of covered use.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A
MEDICATION(S)
TAZAROTENE 0.1% CREAM, TAZORAC

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Acne vulgaris (initial): Diagnosis of acne vulgaris AND History of failure or intolerance to at least two topical acne products (e.g., tretinoin, adapalene, benzoyl peroxide, clindamycin, erythromycin, or azelaic acid). Plaque psoriasis (initial): Diagnosis of stable moderate to severe plaque psoriasis AND Patient has body surface area (BSA) involvement of less than 20 percent AND History of failure or intolerance to at least two topical psoriasis product (e.g., medium to high potency corticosteroids and/or vitamin D analogs).

AGE RESTRICTION
Acne (initial): 12 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
All uses (Initial and reauth): 12 months

OTHER CRITERIA
Acne, Plaque psoriasis (reauth): Documentation of positive clinical response to therapy.
TECFIDERA

MEDICATION(S)
TECFIDERA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
TECHNIVIE

MEDICATION(S)
TECHNIVIE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
All of the following: A) Criteria will be applied consistent with current AASLD/IDSA guideline, AND B) Patient is not receiving Technivie in combination with another HCV direct acting antiviral agent [eg, Harvoni (ledipasvir-sofosbuvir), Sovaldi (sofosbuvir), AND C) ONE of the following: Trial and failure, intolerance or contraindication to Harvoni and Zepatier therapy OR patient is currently on Technivie therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine

COVERAGE DURATION
12 wks. Criteria will be applied consistent with current AASLD/IDSA guideline

OTHER CRITERIA
N/A
TESTOSTERONE ENANTHATE

MEDICATION(S)
TESTOSTERONE ENAN 1,000 MG/5 ML, TESTOSTERONE ENAN 200 MG/ML

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than reference range for the lab OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter’s syndrome). Delayed puberty (DP): Dx of DP AND male patient at birth. Breast cancer (BC): Dx of inoperable BC AND used for palliative treatment AND female patient at birth. Gender Identity Disorder (GID) (off-label): Dx of GID. Patient is a female-to-male transsexual.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
OTHER CRITERIA
HG (Reauth): 1) Total serum T level within or below the normal limits of the reporting lab, or 2) Total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one of the following: Calculated free or bioavailable T level within or below the normal limits of the reporting lab, or calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted.
THALOMID

MEDICATION(S)
THALOMID

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Multiple myeloma (MM): Diagnosis of MM. Used in combination with dexamethasone, unless the patient has an intolerance to steroids. Erythema nodosum leprosum (ENL): Diagnosis of moderate to severe ENL with cutaneous manifestations. Thalomid is not used as monotherapy if moderate to severe neuritis is present.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
MM: Prescribed by or in consultation with an oncologist/hematologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
TIBSOVO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an approved test.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
TOPICAL RETINOIDS

MEDICATION(S)
TRETINOIN 0.01% GEL, TRETINOIN 0.025% CREAM, TRETINOIN 0.025% GEL, TRETINOIN 0.05% CREAM, TRETINOIN 0.05% GEL, TRETINOIN 0.1% CREAM, TRETINOIN MICROSPHERE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
One of the following: Acne: Diagnosis of acne.

AGE RESTRICTION
PA applies to members 26 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
BOSENTAN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Tracleer is contraindicated in pregnancy, use with cyclosporine A, use with glyburide, and hypersensitivity to bosentan or any of its components.

REQUIRED MEDICAL INFORMATION
Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.

COVERAGE DURATION
PAH: Initial: 6 months. Reauth: 12 months.

OTHER CRITERIA
PAH (Reauth): Documentation of positive clinical response to therapy.
TRANSMUCOSAL FENTANYL CITRATE

MEDICATION(S)
FENTANYL CITRATE OTFC 400 MCG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For the management of breakthrough cancer pain. Patient is currently taking a long-acting opioid around the clock for cancer pain. Patient must have at least a one week history of ONE of the following medications to demonstrate tolerance to opioids: Morphine sulfate at doses of greater than or equal to 60 mg/day, Fentanyl transdermal patch at doses greater than or equal to 25 g/hr, Oxycodone at a dose of greater than or equal to 30 mg/day, Oral hydromorphone at a dose of greater than or equal to 8 mg/day, Oral oxymorphone at a dose of greater than or equal to 25 mg/day, or an alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with one of the following: Pain specialist, Oncologist, Hematologist, Hospice care specialist, or Palliative care specialist.

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
TRELSTAR 22.5 MG VIAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Prostate Cancer: Diagnosis of advanced or metastatic prostate cancer. Trial and failure, contraindication, or intolerance to Lupron Depot (7.5 mg, 22.5 mg, 30 mg, and 45 mg).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
TRELSTAR 11.25 MG VIAL, TRELSTAR 3.75 MG VIAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Prostate cancer: Clinically localized disease with intermediate (T2b to T2c cancer, Gleason score of 7, or prostate specific antigen (PSA) value of 10-20 ng/mL) OR higher risk of recurrence as neoadjuvant therapy with radiation therapy or cryosurgery OR Following radical prostatectomy as adjuvant therapy when lymph node metastases are present OR Locally advanced disease OR Other advanced, recurrent, or metastatic disease.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
CLINDAMYCIN PHOS-TRETINOIN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Acne: Diagnosis of acne.

AGE RESTRICTION
PA applies to members 26 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
TYKERB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Breast Cancer: Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive metastatic or recurrent breast cancer. Used in combination with one of the following: Herceptin (trastuzumab), Xeloda (capecitabine), or aromatase inhibitors [eg, Aromasin (exemestane), Femara (letrozole), Arimidex (anastrozole)].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
TYSABRI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses). Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following: Aubagio (teriflunomide), Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone or Glatopa (glatiramer acetate), Extavia (interferon beta-1b), Gilenya (fingolimod), Rebif (interferon beta-1a), or Tecfidera (dimethyl fumarate). Patient is not taking Tysabri in combination with another MS agent [eg, Aubagio (teriflunomide), Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone (glatiramer acetate), Glatopa (glatiramer acetate), Extavia (interferon beta-1b), Gilenya (fingolimod), Lemtrada (alemtuzumab), Rebif (interferon beta-1a), or Tecfidera (dimethyl fumarate)].

Crohn's Disease (CD) (initial): Diagnosis of moderate to severe CD with evidence of inflammation (eg, elevated C-reactive protein [CRP], elevated erythrocyte sedimentation rate, presence of fecal leukocytes). Inadequate response or intolerance to one of the following conventional therapies: corticosteroids, 6-mercaptopurine (6MP [Purinethol], azathioprine (Imuran), methotrexate, aminosalicylates (eg, sulfasalazine, mesalamine, olsalazine).

Inadequate response or intolerance to a TNF-inhibitor (eg, Cimzia [certolizumab pegol], Humira [adalimumab], Remicade [infliximab]).

CD (initial and reauth): Patient is not taking Tysabri in combination with an immunosuppressant (eg, 6-MP, azathioprine, cyclosporine, or methotrexate) or a TNF-inhibitor (eg, Enbrel [etanercept], Humira [adalimumab], or Remicade [infliximab]).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A
**COVERAGE DURATION**
MS: 12mo. CD (Init): 3 mo. CD (Reauth): 6 mo if not on steroids. Otherwise, 3 mo.

**OTHER CRITERIA**
CD (reauth): Diagnostic and/or clinical documentation (eg, improved disease activity index) that indicates patient has experienced clinical benefit from receiving (induction) Tysabri therapy by week 12.
**MEDICATION(S)**
UPTRAVI

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Pulmonary arterial hypertension (PAH) (initial): Diagnosis of PAH AND Patient is symptomatic AND One of the following: a) Diagnosis of PAH was confirmed by right heart catheterization OR b) patient is currently on any therapy for the diagnosis of PAH. One of the following: a) History of trial and failure, contraindication, or intolerance to a PDE5 inhibitor (ie, Adcirca, Revatio) or Adempas (riociguat), and History of trial and failure, contraindication, or intolerance to an endothelin receptor antagonist [e.g. Letairis (ambrisentan), Opsumit (macitentan), or Tracleer (bosentan)] OR b) For continuation of prior Uptravi therapy. Not taken in combination with a prostanoid/prostacyclin analogue (eg, epoprostenol, iloprost, treprostinil).

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist

**COVERAGE DURATION**
Initial: 6 months Reauth: 12 months

**OTHER CRITERIA**
PAH (Reauth): Documentation of positive clinical response to Uptravi therapy. Not taken in combination with a prostanoid/prostacyclin analogue (eg, epoprostenol, iloprost, treprostinil)
MEDICATION(S)
VALCHLOR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL) (initial): All of the following: 1) diagnosis of Stage IA MF-CTCL, OR diagnosis of Stage IB MF-CTCL, AND 2) patient has received at least one prior skin-directed therapy [e.g., topical corticosteroids, bexarotene topical gel (Targretin topical gel), topical nitrogen mustard, etc.].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist or dermatologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
VANCOMYCIN CAPSULE

MEDICATION(S)
VANCOMYCIN HCL 125 MG CAPSULE, VANCOMYCIN HCL 250 MG CAPSULE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual is being treated for enterocolitis caused by Staphylococcal aureus including methicillin-resistant strains. Individual is being treated for clostridium difficile AND individual has had a trial and inadequate response or intolerance to oral metronidazole for mild to moderate Clostridium difficile infection. OR individual is being treated for a severe or severe, complicated Clostridium difficile infection.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
14 days

OTHER CRITERIA
N/A
MEDICATION(S)
VELCADE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Multiple myeloma (MM): Diagnosis of MM. Mantle cell lymphoma (MCL): Diagnosis of MCL.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
MM, MCL: Prescribed by or in consultation with an oncologist/hematologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
VENCLEXTA, VENCLEXTA STARTING PACK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL): Diagnosis of CLL or SLL with 17p deletion or TP53 mutation. Patient has received at least one prior therapy for CLL/SLL [e.g., Cytoxan (cyclophosphamide), Fludara (fludarabine), Rituxan (rituximab)].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hematologist or oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
VENTAVIS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.

COVERAGE DURATION
PAH (Initial): 6 months. (Reauth): 12 months

OTHER CRITERIA
Subject to Part B vs D review. PAH (Reauth): Documentation of positive clinical response to therapy.
MEDICATION(S)
VITRAKVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of Solid tumors. Treatment of solid tumors (in adult and pediatric patients) that have a neurotrophic receptor tyrosine 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 no satisfactory alternative treatments or that have progressed following treatment.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
VIVITROL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Alcohol dependence, opioid dependence (init, reauth): 24 weeks

OTHER CRITERIA
Alcohol dependence, opioid dependence (reauth): Confirmation of clinical benefit to the patient.
MEDICATION(S)
VIZIMPRO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
First-line treatment of metastatic non-small cell lung cancer (NSCLC) in patients with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an approved test.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
VOSEVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIREMED MEDICAL INFORMATION
Criteria will be applied consistent with current AASLD/IDSA guideline. Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of Hepatitis C, genotype 1, 2,3,4, 5, or 6. Must provide genotype and lab documentation. Patient is without decompensated liver disease (defined as Child-Pugh Class B or C). Patient must have detectable baseline HCV RNA with labs done within the last 24 weeks, Patient is not receiving Vosevi in combination with another HCV direct acting antiviral agent [e.g., Harvoni].

AGE RESTRICTION
Must be greater than 18 years of age

PRESCRIBER RESTRICTION
Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine or transplant specialist.

COVERAGE DURATION
12 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.

OTHER CRITERIA
N/A
MEDICATION(S)
VOTRIENT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Renal cell carcinoma (RCC): Diagnosis of advanced/metastatic RCC. Soft tissue sarcoma: Diagnosis of advanced soft tissue sarcoma and patient received at least one prior chemotherapy (e.g., ifosfamide, doxorubicin, cisplatin, dacarbazine, docetaxel, oxaliplatin, etc.)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
All Uses: Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
**MEDICATION(S)**
VPRIV

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Gaucher disease: Diagnosis of type 1 Gaucher disease. Patient has evidence of symptomatic disease (e.g., moderate to severe anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly).

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Gaucher disease: 12 months

**OTHER CRITERIA**
N/A
MEDICATION(S)
VYNDAQEL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chart notes indication diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization.

AGE RESTRICTION
Patient must be 18 years of age or older

PRESCRIBER RESTRICTION
Must be prescribed by a cardiologist or in consultation with a cardiologist.

COVERAGE DURATION
Initial Auth: 12 months

OTHER CRITERIA
Reauth: Documentation of positive clinical response to therapy. 12 months.
MEDICATION(S)
XALKORI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Non-small cell lung cancer (NSCLC): Diagnosis of locally advanced or metastatic (stage IIIB or IV) NSCLC AND One of the following: A) Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility or B) Patient has MET amplification- or ROS1 rearrangements-positive tumor as detected with an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
NSCLC: Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy
MEDICATION(S)
XELJANZ, XELJANZ XR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Rheumatoid arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: Failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), OR patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-IV-TR 300.29 for specific phobia diagnostic criteria), OR for continuation of prior tofacitinib therapy. Patient is not receiving tofacitinib in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]. Patient is not receiving tofacitinib in combination with a potent immunosuppressant (eg, azathioprine, cyclosporine).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RA (Initial): Prescribed by or in consultation with a rheumatologist

COVERAGE DURATION
RA, PsA, UC (initial, reauth): 12 months

OTHER CRITERIA
RA (Reauth): Documentation of positive clinical response to tofacitinib therapy. Patient is not receiving tofacitinib in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]. Patient is not receiving tofacitinib in combination with a potent immunosuppressant (eg, azathioprine, cyclosporine).
MEDICATION(S)
TETRABENAZINE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION

AGE RESTRICTION
Tardive dyskinesia (Initial): Age greater than or equal to 18 years.

PRESCRIBER RESTRICTION
HD (Initial): Prescribed by or in consultation with a neurologist. Tardive dyskinesia, Tourette's syndrome (Initial): Prescribed by or in consultation with neurologist or psychiatrist.

COVERAGE DURATION
All indications: (Initial) 3 months, (Reauth) 12 months.

OTHER CRITERIA
All indications (Reauth): Documentation of clinical response and benefit from therapy.
MEDICATION(S)
XEOMIN 50 UNIT VIAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
All indications (init, reauth): 3 months (for 1 dose)

OTHER CRITERIA
All indications (reauth): Confirmed improvement in symptoms with initial Xeomin treatment. At least 3 months have elapsed since the last treatment with Xeomin.
MEDICATION(S)
XGEVA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Bone metastasis from solid tumors (BMST): Both of the following: 1) diagnosis of solid tumors (eg, breast cancer, kidney cancer, lung cancer, prostate cancer, thyroid cancer), AND 2) documented evidence of one or more metastatic bone lesions. Giant cell tumor of bone (GCTB): Both of the following: 1) diagnosis of giant cell tumor of bone AND 2) One of the following: a) tumor is unresectable, OR b) surgical resection is likely to result in severe morbidity. Hypercalcemia of malignancy (HCM): Both of the following: 1) diagnosis of hypercalcemia of malignancy, AND 2) Trial and failure, contraindication, or intolerance to one intravenous bisphosphonate (eg, Aredia (pamidronate), Zometa (zoledronic acid)).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
GCTB, HCM: Prescribed by or in consultation with an oncologist

COVERAGE DURATION
BMST, GCTB: 12 mo. HCM: 2 mo.

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
XIFAXAN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Travelers' diarrhea (TD) (200 mg strength only): Diagnosis of travelers' diarrhea, AND one of the following: a) Trial and failure, contraindication, or intolerance to one of the following: Cipro (ciprofloxacin), Levaquin (levofloxacin), ofloxacin, Zithromax (azithromycin) OR b) resistance to all of the following: Cipro (ciprofloxacin), Levaquin (levofloxacin), ofloxacin, Zithromax (azithromycin).
Prophylaxis of hepatic encephalopathy (HE) recurrence (550mg strength only): Used for the prophylaxis of hepatic encephalopathy recurrence, AND trial and failure, contraindication or intolerance to lactulose. Irritable bowel syndrome with diarrhea (IBS-D) (550mg strength only) (initial): Diagnosis of IBS-D, AND trial and failure, contraindication or intolerance to an antidiarrheal agent [eg, loperamide].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
TD: One time only. HE: 6 months. IBS-D (initial, reauth): 2 weeks.

OTHER CRITERIA
IBS-D (reauth): Patient experiences IBS-D symptom recurrence AND patient has not already received 3 treatment courses of Xifaxan for IBS-D in their lifetime.
MEDICATION(S)
XIIDRA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of dry eye disease. Patient has suppressed tear production due to ocular inflammation as determined by at least one of the following diagnostic tests: Schirmer test (aqueous tear production and clearance), tear break-up time, ocular surface dye staining, tear film osmolarity, or fluorescein clearance test/tear function test. Failure, contraindication, or intolerance to Restasis at an optimal dose and frequency for at least 2 weeks

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial, reauth: 12 months

OTHER CRITERIA
Reauth: Documentation of positive clinical response to Xiidra therapy (e.g., increased tear production or improvement in dry eye symptoms).
MEDICATION(S)
XOLAIR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Patient has Moderate Persistent to Severe Persistent Asthma AND has a positive skin test or in vitro reactivity to a perennial aeroallergen, AND Mbr has an FEV1 less than 80% predicted AND Mbr IgE level is equal to or greater than 30 IU/ml. Severe asthma as defined by the National Heart, Lung, and Blood Institute: Severe Persistent Asthma: symptoms throughout the day, extremely limited normal activity. Nocturnal symptoms are frequent, FEV1 or PEF is less than or equal to 60% predicted. Moderate Persistent Asthma as defined by the National Heart, Lung, and Blood Institute: Daily symptoms, daily use of inhaled short-acting beta2-agonist, somewhat limited activity, Nocturnal symptoms occur greater than 1 time per week, FEV1 or PEF is greater than 60% and less then 80% predicted, FEV1 FVC is reduced 5 percent or exacerbations requiring oral systemic corticosteroids use for more than or equal to 2 times per year. Treatment of chronic idiopathic urticaria in adults and adolescents 12 years and older who remain symptomatic despite H1 antihistamine treatment.

AGE RESTRICTION
Patient is 12 years of age or older for urticaria and 6 years of age or older for moderate to severe persistent asthma

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months
OTHER CRITERIA
For moderate to severe persistent asthma, Mbr symptoms are inadequately controlled after a minimum of 3 months with combination controller therapy (medium to high doses of inhaled corticosteroids plus long acting beta-2 agonists or Leukotriene modifiers), or cannot tolerate these medications. Continued treatment beyond 12 months is allowed when treatment has resulted in clinical improvement as documented by one or more of the following: Decreased utilization of rescue medications OR Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids) OR Increase in percent predicted FEV1 from pretreatment baseline OR Reduction in reported asthma-related symptoms, such as, but not limited to, wheezing, shortness of breath, coughing, fatigue, sleep disturbance, or asthmatic symptoms upon awakening. For chronic idiopathic urticaria, individual is refractory to prior treatment of ONE potent antihistamine at maximal FDA approved dosage.
MEDICATION(S)
XOSPATA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of Acute myeloid leukemia, relapsed or refractory. Treatment of relapsed or refractory acute myeloid leukemia (AML) in adult patients with an FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an approved test.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
FMS-like tyrosine kinase 3 (FLT3) mutation
MEDICATION(S)
XTANDI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Metastatic castration-resistant prostate cancer (mCRPC): Diagnosis of mCRPC.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed or in consultation with an oncologist or urologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
XYREM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Narcolepsy with cataplexy (Narcolepsy Type 1)(initial): Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), AND symptoms of cataplexy are present, AND symptoms of excessive daytime sleepiness (eg, irrepressible need to sleep or daytime lapses into sleep) are present. Narcolepsy without cataplexy (Narcolepsy Type 2)(initial): Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), AND symptoms of cataplexy are absent, AND symptoms of excessive daytime sleepiness (eg, irrepressible need to sleep or daytime lapses into sleep) are present, AND trial and failure, contraindication, or intolerance to one of the following: 1) amphetamine-based stimulant (eg, amphetamine, dextroamphetamine), OR 2) methylphenidate-based stimulant.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
All uses (initial, reauth): 12 months
OTHER CRITERIA
Narcolepsy Type 1 (reauth): Documentation demonstrating a reduction in the frequency of cataplexy attacks associated with Xyrem therapy, OR documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with Xyrem therapy. Narcolepsy Type 2 (reauth): Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with Xyrem therapy.
MEDICATION(S)
YERVOY 50 MG/10 ML VIAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Unrestable or metastatic melanoma: Diagnosis of unresectable, metastatic melanoma. Cutaneous melanoma: Diagnosis of cutaneous melanoma with pathologic involvement of regional lymph nodes of more than 1 mm. Patient has undergone resection, including total lymphadenectomy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
YONSA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Females who are or may become pregnant

REQUIRED MEDICAL INFORMATION
Diagnosis of covered use

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A
MEDICATION(S)
ZALTRAP 100 MG/4 ML VIAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Colon and/or rectal cancer: Diagnosis of metastatic colon and/or rectal cancer. Ziv-aflibercept is being used in combination with 5-fluorouracil, leucovorin, and irinotecan (FOLFIRI) regimen. Patient has disease that is resistant to or has progressed following an oxaliplatin-containing regimen [e.g., 5-fluorouracil, leucovorin, and oxaliplatin (FOLFOX)].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
ZARXIO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm^3), AND 2) patients with a history of FN during a previous course of chemotherapy. Neutropenia associated with dose-dense chemotherapy (NDDC): One of the following: 1) Patient is receiving National Cancer Institute’s Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, OR 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown. Treatment of FN (off-label): Both of the following: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm^3), AND 2) patients with FN at high risk for infection-associated complications.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by hematologist/oncologist except HIVN: Prescribed by hematologist/oncologist or infectious disease specialist

COVERAGE DURATION
BMSCT, AML, CFN, secondary prophy of FN, NDDC:3mo or duration of tx. HIVN:6mo. Tx of FN, ARS:1 mo.

OTHER CRITERIA
N/A
MEDICATION(S)
MIGLUSTAT, ZAVESCA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Gaucher disease: Diagnosis of mild to moderate type 1 Gaucher disease. Patient is unable to receive enzyme replacement therapy due to one of the following conditions: allergy or hypersensitivity to enzyme replacement therapy, poor venous access, unavailability of enzyme replacement therapy (e.g., Cerezyme, VPRIV).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Gaucher disease: 12 months

OTHER CRITERIA
N/A
ZEJULA

MEDICATION(S)
ZEJULA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of recurrent epithelial ovarian cancer, recurrent fallopian tube cancer, or recurrent primary peritoneal cancer. Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy
MEDICATION(S)
ZELBORAF

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma. Cancer is BRAFV600 mutant type (MT) as detected by an FDA-approved test (eg, cobas 4600 BRAFV600 Mutation Test) or performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
ZOLEDRONIC ACID 5 MG/100 ML

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Paget's disease of bone in men and women, treatment is indicated with elevations in serum alkaline phosphatase of two times or higher than the upper limit of the age-specific normal reference range, or those who are symptomatic, or those at risk for complications from their disease.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
ZOLINZA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Cutaneous T-cell lymphoma (CTCL): Diagnosis of CTCL. Progressive, persistent or recurrent disease on or contraindication or intolerance to two systemic therapies (e.g., bexarotene, romidepsin, etc.).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hematologist/oncologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
ZORBTIVE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Short Bowel Syndrome (SBS): Diagnosis of SBS. Patient is currently receiving specialized nutritional support (eg, intravenous parenteral nutrition, fluid, and micronutrient supplements). Patient has not previously received 4 weeks of treatment with Zorbtive.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a gastroenterologist.

COVERAGE DURATION
SBS: 4 weeks.

OTHER CRITERIA
N/A
MEDICATION(S)
ZORTRESS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Prevention of kidney transplant organ rejection: The medication is being used for prevention of kidney transplant organ rejection. Patient is at low-to-moderate immunologic risk. Patient is prescribed concurrent therapy with reduced doses of cyclosporine AND corticosteroids. Prevention of liver transplant organ rejection: The medication is being used for prevention of liver transplant organ rejection. Thirty (30) or more days have passed since the transplant procedure. Patient is prescribed concurrent therapy with reduced doses of tacrolimus and corticosteroids.

AGE RESTRICTION
All indications: 18 years of age or older

PRESCRIBER RESTRICTION
All indications: Prescriber is experienced in immunosuppressive therapy and management of transplant patients.

COVERAGE DURATION
12 months

OTHER CRITERIA
Subject to Part B vs. Part D review. Approve for continuation of prior therapy.
MEDICATION(S)
ZYDELIG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chronic lymphocytic leukemia (CLL): Diagnosis of CLL. Used in combination with Rituxan (rituximab). The patient has relapsed on at least one prior therapy (eg, purine analogues [fludarabine, pentostatin, cladribine], alkylating agents [chlorambucil, cyclophosphamide], or monoclonal antibodies [rituximab]). Patient is a candidate for Rituxan (rituximab) monotherapy due to presence of other comorbidities (eg, coronary artery disease, peripheral vascular disease, diabetes mellitus, pulmonary disease [COPD]). Follicular Lymphoma (FL): Diagnosis of FL. The patient has relapsed on at least two prior systemic therapies (eg, rituximab, alkylating agents [cyclophosphamide, chlorambucil], anthracyclines [doxorubicin, daunorubicine], purine analogs [fludarabine]). Small lymphocytic lymphoma (SLL): Diagnosis of SLL. The patient has relapsed on at least two prior systemic therapies (eg, rituximab, alkylating agents [cyclophosphamide, chlorambucil], anthracyclines [doxorubicin, daunorubicine], purine analogs [fludarabine]).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
All uses: Prescribed by or in consultation with an oncologist/hematologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
ZYKADIA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC that is metastatic or recurrent. Tumor is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility. Trial and failure or intolerance to Xalkori (crizotinib).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
**ZYTIGA**

**MEDICATION(S)**
ABIRATERONE ACETATE, ZYTIGA 250 MG TABLET

**PA INDICATION INDICATOR**
3 - All Medically-Accepted Indications

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Prostate Cancer: Diagnosis of metastatic, castration-resistant (chemical or surgical) prostate cancer AND used in combination with prednisone. Diagnosis of metastatic, high-risk castration-sensitive prostate cancer AND used in combination with prednisone.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
Prostate Cancer: Prescribed by or in consultation with an oncologist or urologist

**COVERAGE DURATION**
Prostate Cancer: 12 months

**OTHER CRITERIA**
Approve for continuation of prior therapy
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