ACTEMRA SC (S)

MEDICATION(S)
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: a) Either a trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib) or attestation demonstrating a trial may be inappropriate, OR b) For continuation of prior therapy. Giant Cell Arteritis (GCA) (Initial): Diagnosis of GCA. Trial and failure, contraindication, or intolerance to a glucocorticoid. Systemic Juvenile Idiopathic Arthritis (SJIA) (Initial): Diagnosis of active SJIA. Trial and failure, contraindication, or intolerance to one of the following: NSAID, methotrexate, or systemic glucocorticoid. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of active PJIA. One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior therapy. Systemic sclerosis-associated interstitial lung disease (SSc-ILD) (Initial): Diagnosis of SSc-ILD as documented by the following: a) Exclusion of other known causes of ILD (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity) AND b) One of the following: i) In patients not subjected to surgical lung biopsy, the presence of idiopathic interstitial pneumonia (eg, fibrotic nonspecific interstitial pneumonia [NSIP], usual interstitial pneumonia [UIP] and centrilobular fibrosis) pattern on high-resolution computed tomography (HRCT) revealing SSc-ILD or probable SSc-ILD, OR ii) In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

RA, GC, SJIA, PJIA (initial): Prescribed by or in consultation with a rheumatologist. SSc-ILD (initial): Prescribed by or in consultation with a pulmonologist or rheumatologist.

COVERAGE DURATION

RA, GC, SJIA, PJIA, SSc-ILD (initial, reauth): 12 months

OTHER CRITERIA

RA, GC, SJIA, PJIA, SSc-ILD (Reauth): Documentation of positive clinical response to therapy.

ACTIMMUNE (S)

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.

ADAKVEO (S)

MEDICATION(S)
ADAKVEO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of Sickle Cell Disease. Documentation of 2 vaso-occlusive events that required medical facility visits and treatments in the past 12 months (e.g., sickle cell crisis, acute pain episodes, acute chest syndrome, hepatic sequestration, splenic sequestration, priapism). Trial and failure or inadequate response, contraindication, or intolerance to one of the following: 1) Hydroxyurea or 2) L-glutamine (i.e., Endari).

AGE RESTRICTION
Initial: Patient is 16 years of age or greater.

PRESCRIBER RESTRICTION
Initial: Prescribed by or in consultation with one of the following: 1) Hematologist/Oncologist or 2) Specialist w/ expertise in the diagnosis and management of sickle cell disease.

COVERAGE DURATION
Initial, Reauth: 12 months.

OTHER CRITERIA
Reauth: Documentation of positive clinical response to therapy (e.g., reduction in annual rate of vaso-occlusive events, increased time between each vaso-occlusive event).

ADCIRCA (S)

MEDICATION(S)
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.

ADEMPAS (S)

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 (S)

MEDICATION(S)

AFINITOR 10 MG TABLET, EVEROLIMUS 2.5 MG TABLET, EVEROLIMUS 5 MG TABLET, EVEROLIMUS 7.5 MG TABLET

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 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 uses: Prescribed by or in consultation with an oncologist

COVERAGE DURATION

All uses: 12 months

OTHER CRITERIA

All Indications: Approve for continuation of prior therapy.

AFINITOR DISPERZ (S)

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. TSC-associated partial-onset seizures: Diagnosis of TSC-associated partial-onset seizures. Used as adjunctive therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
SEGA: Prescribed by or in consultation with an oncologist. TSC-associated partial-onset seizures: Prescribed by or in consultation with a neurologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

AIMOVIG (S)

MEDICATION(S)
AIMOVIG AUTOINJECTOR, AIMOVIG AUTOINJECTOR (2 PACK)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Episodic Migraines (EM) (initial): Diagnosis of EM. Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month. Chronic Migraines (CM) (initial): Diagnosis of CM. Medication overuse headache has been considered and potentially offending medication(s) have been discontinued. Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months. All Indications (initial): Two of the following: a) History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine), OR patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine), b) History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate), OR patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate), or c) History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol, OR patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol. Medication will not be used in combination with another injectable CGRP inhibitor.

AGE RESTRICTION
EM, CM (initial): 18 years of age or older.

PRESCRIBER RESTRICTION
EM, CM (initial, reauth): Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.

COVERAGE DURATION

EM, CM (initial): 6 months. EM, CM (reauth): 12 months.

OTHER CRITERIA

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

ALDURAZYME (S)

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

ALECENSA (S)

MEDICATION(S)
ALECENSA

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): A) Diagnosis of metastatic NSCLC AND B) Patient has anaplastic lymphoma kinase (ALK)-positive disease as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).

AGE 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.

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

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 antitrypsin (AAT) deficiency: Diagnosis of congenital AAT deficiency. Diagnosis of emphysema. Continued optimal conventional treatment for emphysema (e.g., bronchodilators). One of the following: 1) PiZZ, PiZ(null), or Pi(null)(null) protein phenotypes (homozygous) OR 2) other rare AAT disease-causing alleles associated with serum AAT level less than 11 M/L [e.g., Pi(Malton, Malton)]. One of the following: Circulating serum concentration of AAT level less than 11 M/L (which corresponds to less than 80 mg/dL if measured by radial immunodiffusion or less than 57 mg/dL if measured by nephelometry) OR the patient has a concomitant diagnosis of necrotizing panniculitis. 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 OR the patient has a concomitant diagnosis of necrotizing panniculitis. Trial and failure, or intolerance to Prolastin.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

ALPHA-1 PROTEINASE INHIBITOR, PROLASTIN (S)

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 antitrypsin (AAT) deficiency: Diagnosis of congenital AAT deficiency. Diagnosis of emphysema. Continued optimal conventional treatment for emphysema (e.g., bronchodilators). One of the following: 1) PiZZ, PiZ(null), or Pi(null)(null) protein phenotypes (homozygous) OR 2) other rare AAT disease-causing alleles associated with serum AAT level less than 11 ¿M/L [e.g., Pi(Malton, Malton)]. Circulating serum concentration of AAT level less than 11 ¿M/L (which corresponds to less than 80 mg/dL if measured by radial immunodiffusion or less than 57 mg/dL if measured by nephelometry), unless the patient has a concomitant diagnosis of necrotizing panniculitis. 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 OR the patient has a concomitant diagnosis of necrotizing panniculitis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

ALUNBRIG (S)

MEDICATION(S)
ALUNBRIG

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 a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).

AGE 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.

AMPYRA (S)

MEDICATION(S)
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 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 (S)

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 two standard therapies for anemia (i.e., erythropoiesis-stimulating agents, immunosuppressants) AND Treatment will not replace other supportive measures (e.g., transfusion, correction of iron, folic acid, vitamin B12 or pyridoxine deficiency, antibacterial therapy, corticosteroids).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial, reauth: 12 months

OTHER CRITERIA
Anemia (reauth): Documentation of a positive clinical response to therapy as evidenced by an improvement in anemia (e.g., increased hemoglobin, increased reticulocyte count, reduction/elimination for need of blood transfusions).

APOKYN (S)

MEDICATION(S)
APOKYN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
PD (Initial): Used with any 5-HT3 antagonist (eg, ondansetron, granisetron, dolasetron, palonosetron, alosetron)

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
PD (Initial, reauth): 12 months

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

ARANESP (S)

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 receiving chemo. CKD (init, reauth), Chemo (init), MDS (init): Verify iron evaluation for adequate iron stores. 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

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. One of the following: 1) Most recent or average (avg) Hct over 3 mo is 33% or less (Hgb 11 g/dL or less) for patients on dialysis, without ESRD, 2) Most recent or avg Hct over 3 mo is 30% or less (Hgb 10 g/dL or less) for patients not on dialysis, OR 3) Most recent or avg Hct over 3 mo is 36% or less (Hgb 12 g/dL or less) for pediatric patients. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Chemo (Reauth): Anemia by lab values (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 weeks of request. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Patient is receiving chemo. MDS (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Off-label uses (except MDS, HCV): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%.

ARCALYST (S)

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. Deficiency of Interleukin-1 Receptor Antagonist (DIRA): Diagnosis of DIRA. Patient weighs at least 10 kg. Patient is currently in remission (e.g., no fever, skin rash, and bone pain/no radiological evidence of active bone lesions/C-reactive protein [CRP] less than 5 mg/L). Recurrent Pericarditis (Initial): Diagnosis of recurrent pericarditis as evidenced by at least 2 episodes that occur a minimum of 4 to 6 weeks apart. Trial and failure, contraindication, or intolerance (TF/C/I) to at least one of the following: nonsteroidal anti-inflammatory drugs (e.g., ibuprofen, naproxen), colchicine, or corticosteroids (e.g., prednisone).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
CAPS (initial): Prescribed by or in consultation with an immunologist, allergist, dermatologist, rheumatologist, neurologist or other medical specialist. Recurrent Pericarditis (initial): Prescribed by or in consultation with a cardiologist.

COVERAGE DURATION
CAPS, Recurrent Pericarditis (initial, reauth): 12 months. DIRA: 12 months.

OTHER CRITERIA
CAPS (Reauth): Patient has experienced disease stability or improvement in clinical symptoms while

on therapy as evidence by one of the following: A) improvement in rash, fever, joint pain, headache, conjunctivitis, B) decreased number of disease flare days, C) normalization of inflammatory markers (CRP, ESR, SAA), D) corticosteroid dose reduction, OR E) improvement in MD global score or active joint count. Recurrent Pericarditis (Reauth): Documentation of positive clinical response to therapy.

AURYXIA (S)

MEDICATION(S)
AURYXIA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Exclude if used for iron deficiency anemia in chronic kidney disease (CKD) not on dialysis.

REQUIRED MEDICAL INFORMATION
Hyperphosphatemia in chronic kidney disease: Diagnosis of hyperphosphatemia. Patient has chronic kidney disease (CKD). Patient is on dialysis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

AUSTEDO (S)

MEDICATION(S)
AUSTEDO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chorea associated with Huntington's disease (initial): Diagnosis of Chorea associated with Huntington's disease. Tardive dyskinesia (initial): Diagnosis of moderate to severe tardive dyskinesia. One of the following: 1) Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication or 2) Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Huntington's disease chorea (initial): Prescribed by a neurologist. Tardive dyskinesia (initial): Prescribed by or in consultation with a neurologist or psychiatrist.

COVERAGE DURATION
Initial: 3 months. Reauth: 12 months

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

AVASTIN (S)

MEDICATION(S)
AVASTIN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Non-Small Cell Lung Cancer: Excluded if squamous cell histology.

REQUIRED MEDICAL INFORMATION
Colorectal Cancer: Diagnosis of metastatic colorectal cancer. One of the following: 1) Both of the following: a) used as first- or second-line treatment and b) used in combination with an intravenous 5-fluorouracil-based chemotherapy, OR 2) All of the following: a) used as second-line treatment, b) used in combination with fluoropyrimidine-irinotecan-based chemotherapy or fluoropyrimidine-oxaliplatin-based chemotherapy, and c) patient has progressed on a first-line bevacizumab-containing regimen. Non-Small Cell Lung Cancer (NSCLC): Diagnosis of NSCLC. Disease is unresectable, locally advanced, recurrent, or metastatic. Used as first-line treatment. Used in combination with paclitaxel and carboplatin. Renal Cell Cancer: Diagnosis of metastatic renal cell cancer. Used in combination with interferon-alpha. Cervical Cancer: Diagnosis of carcinoma of the cervix. Disease is persistent, recurrent, or metastatic. Used in combination with one of the following: a) paclitaxel and cisplatin or b) paclitaxel and topotecan. Glioblastoma: Diagnosis of recurrent glioblastoma. Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer: Diagnosis of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. One of the following: 1) All of the following: a) disease is stage 3 or 4, b) patient has been treated with bevacizumab as a single agent, c) treatment is following surgical resection, and d) used in combination with carboplatin and paclitaxel, OR 2) All of the following: a) disease is platinum-resistant recurrent, b) patient has received no more than 2 prior chemotherapy regimens, and c) used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, OR 3) All of the following: a) disease is platinum-sensitive recurrent, b) patient has been treated with bevacizumab as a single agent, and c) used in combination with one of the following: i) carboplatin and paclitaxel or ii) carboplatin and gemcitabine.

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.

AYVAKIT (S)

MEDICATION(S)
AYVAKIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Gastrointestinal stromal tumor (GIST): Diagnosis of GIST. Disease is one of the following: unresectable or metastatic. Presence of platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations. Advanced Systemic Mastocytosis (AdvSM): Diagnosis of AdvSM. Patient has one of the following: a) aggressive systemic mastocytosis (ASM), b) systemic mastocytosis with an associated hematological neoplasm (SM-AHN), or c) mast cell leukemia (MCL).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
GIST: Prescribed by or in consultation with an oncologist. AdvSM: Prescribed by or in consultation with an oncologist/hematologist, allergist, or immunologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

BAFIERTAM (S)

MEDICATION(S)
BAFIERTAM

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 (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: a) Failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS: 1) Aubagio (teriflunomide), 2) Gilenya (fingolimod), or 3) Brand Tecfidera/generic dimethyl fumarate, OR b) for continuation of prior therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

BALVERSA (S)

MEDICATION(S)
BALVERSA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Urothelial Carcinoma: Diagnosis of urothelial carcinoma (UC). One of the following: Locally advanced or Metastatic AND Patient has fibroblast growth factor receptor (FGFR) 3 or FGFR2 genetic alterations as detected by an U.S. Food and Drug Administration (FDA)-approved test (therascreen FGFR RGQ RT-PCR Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). One of the following: 1) Patient has progressed during or following at least one line of prior chemotherapy or immunotherapy OR 2) Patient has progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

AGE 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.

BENLYSTA (S)

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, Plaquenil (hydroxychloroquine)], corticosteroids [eg, prednisone], or immunosuppressants [eg, methotrexate, Imuran (azathioprine)]). Lupus Nephritis (init): Diagnosis of active lupus nephritis. Currently receiving standard of care treatment for active lupus nephritis (e.g., corticosteroids [e.g., prednisone] with mycophenolate or cyclophosphamide).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
SLE (init): Prescribed by or in consultation with a rheumatologist. Lupus Nephritis (init): Prescribed by or in consultation with a nephrologist or rheumatologist.

COVERAGE DURATION
SLE, Lupus Nephritis (init, reauth): 6 months

OTHER CRITERIA
SLE, Lupus Nephritis (reauth): Documentation of positive clinical response to therapy.

BENZODIAZEPINES (S)

MEDICATION(S)

LORAZEPAM 2 MG/ML CARPUJECT, LORAZEPAM 2 MG/ML SYRINGE, LORAZEPAM 2 MG/ML VIAL, LORAZEPAM 20 MG/10 ML VIAL, LORAZEPAM 4 MG/ML CARPUJECT, LORAZEPAM 4 MG/ML VIAL, LORAZEPAM 40 MG/10 ML VIAL

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.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

12 months

OTHER CRITERIA

N/A

BERINERT (S)

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.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

BOSULIF (S)

MEDICATION(S)
BOSULIF

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chronic myelogenous/myeloid leukemia (CML): Diagnosis of Philadelphia chromosome-positive (Ph+) CML.

AGE 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.

BRAFTOVI (S)

MEDICATION(S)
BRAFTOVI

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 BRAF V600E or V600K mutant type (MT) as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with Mektovi (binimetinib). Colorectal Cancer: One of the following diagnoses: Colon Cancer or Rectal Cancer. One of the following: 1) Unresectable or advanced disease or 2) Metastatic disease. Patient has received prior therapy. Cancer is BRAF V600E mutant type as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with Erbitux (cetuximab).

AGE 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

BRIVIACT (S)

MEDICATION(S)

BRIVIACT 10 MG TABLET, BRIVIACT 10 MG/ML ORAL SOLN, BRIVIACT 100 MG TABLET, BRIVIACT 25 MG TABLET, BRIVIACT 50 MG TABLET, BRIVIACT 75 MG TABLET

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Partial-onset seizures: Diagnosis of partial-onset seizures.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

12 months

OTHER CRITERIA

Approve for continuation of prior therapy.

BRONCHITOL (S)

MEDICATION(S)
BRONCHITOL

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 has passed the Bronchitol Tolerance Test (BTT). One of the following: 1) Patient is currently receiving Pulmozyme (dornase alfa), OR 2) Patient has a contraindication, intolerance, or is not a candidate for continued Pulmozyme therapy. Trial and failure, contraindication, or intolerance to inhaled hypertonic saline.

AGE RESTRICTION
CF (initial): Patient is 18 years of age or older.

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

COVERAGE DURATION
CF (initial): 6 months. CF (reauth): 12 months.

OTHER CRITERIA
CF (reauth): Documentation of positive clinical response to therapy (e.g., improvement in lung function [forced expiratory volume in one second {FEV1}]).

BRUKINSA (S)

MEDICATION(S)
BRUKINSA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of relapsed or refractory mantle cell lymphoma (MCL). Trial and failure, contraindication, or intolerance to at least ONE combination treatment of rituximab and chemotherapy (e.g., BR, R-CHOP, R-CVP, R-FCM).

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.

BYNFEZIA (S)

MEDICATION(S)
BYNFEZIA

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. One of the following: A) Inadequate response to surgical resection and/or pituitary irradiation OR B) Patient is not a candidate for surgical resection or pituitary irradiation. Trial and failure, contraindication or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses. Carcinoid tumor (initial): Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea or flushing episodes. Vasoactive intestinal peptide tumor (initial): Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea. All indications (initial): Trial and failure, or intolerance to generic octreotide.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

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

CABLIVI (S)

MEDICATION(S)
CABLIVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Acquired thrombotic thrombocytopenic purpura (aTTP): Diagnosis of aTTP. First dose was/will be administered by a healthcare provider as a bolus intravenous injection. Used in combination with immunosuppressive therapy (e.g. rituximab, glucocorticoids). One of the following: 1) Used in combination with plasma exchange or 2) both of the following: patient has completed plasma exchange and less than 59 days have or will have elapsed beyond the last plasma exchange.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
3 months

OTHER CRITERIA
N/A

CABOMETYX (S)

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. Hepatocellular Carcinoma (HCC): Diagnosis of HCC. One of the following: a) Trial and failure or intolerance to Nexavar (sorafenib tosylate), or b) Patient has metastatic disease, or c) Patient has extensive liver tumor burden, or d) Patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only), or e) Disease is unresectable.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RCC: Prescribed by or in consultation with one of the following: an oncologist or nephrologist. HCC: Prescribed by or in consultation with one of the following: oncologist, hepatologist, or gastroenterologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

CALQUENCE (S)

MEDICATION(S)
CALQUENCE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Mantle Cell Lymphoma: Diagnosis of mantle cell lymphoma (MCL) AND patient has received at least one prior therapy for MCL. Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL): Diagnosis of CLL or SLL.

AGE 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.

CAPRELSA (S)

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 (S)

MEDICATION(S)
CARISOPRODOL

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 (S)

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).

CERDELGA (S)

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.

CEREZYME (S)

MEDICATION(S)
CEREZYME

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

CHENODAL (S)

MEDICATION(S)
CHENODAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Radiolucent stones (RS) (intial): Diagnosis of radiolucent stones. Patient has a well-opacifying gallbladder visualized by oral cholecystography. Trial and failure, contraindication or intolerance to ursodiol. Patient is not a candidate for surgery. Stones are not calcified (radiopaque) or radiolucent bile pigment stones.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
RS (initial, reauth): 12 months.

OTHER CRITERIA
RS (reauth): Patient¿s disease status has been re-evaluated since the last authorization to confirm the patient¿s condition warrants continued treatment as evidenced by oral cholecystograms or ultrasonograms.

CHOLBAM (S)

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) 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 therapy.

CICLOPIROX (S)

MEDICATION(S)
CICLODAN 8% SOLUTION, CICLOPIROX 8% SOLUTION

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) Patient does not have lunula (matrix) involvement, 2) one of the following: a) Diagnosis of onychomycosis of the toenails, OR b) Diagnosis of onychomycosis of the fingernails, 3) Diagnosis of onychomycosis has been confirmed by one of the following: a) positive potassium hydroxide (KOH) preparation, OR b) culture, OR c) histology, 4) If toenail onychomycosis, patient has mild to moderate disease involving at least 1 great toenail, AND 5) Trial and failure, contraindication, or intolerance to oral terbinafine.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
48 weeks.

OTHER CRITERIA
N/A

CIMZIA (S)

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. One of the following: a) Either a trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib) or attestation demonstrating a trial may be inappropriate, OR b) For continuation of prior therapy. Crohn's Disease (CD, initial): Dx of moderately to severely active CD. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine (Purinethol), Azathioprine (Imuran), Corticosteroid (eg, prednisone, methylprednisolone), Methotrexate (Rheumatrex, Trexall). TF/C/I to Humira OR for continuation of prior therapy. Psoriatic Arthritis (PsA, initial): Dx of active PsA. One of the following: a) Either a TF/C/I to Enbrel and Humira, or attestation demonstrating a trial may be inappropriate, OR b) for continuation of prior therapy. Ankylosing Spondylitis (AS, initial): Dx of active AS. TF/C/I to both Enbrel and Humira, or attestation demonstrating a trial may be inappropriate, OR for continuation of prior therapy. Plaque Psoriasis (initial): Dx of moderate to severe plaque psoriasis. TF/C/I to Cosentyx AND one of the following: Humira, Enbrel, or Skyrizi (risankizumab) OR for continuation of prior therapy. Non-radiographic axial spondyloarthritis (nr-axSpA, initial): Dx of nr-axSpA with objective signs of inflammation (eg, C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) TF/C/I to two non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., diclofenac, ibuprofen, meloxicam, naproxen).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

CD (init): Prescribed by or in consultation with a gastroenterologist. RA, AS, nr-axSpA (init): Prescribed by or in consultation with a rheumatologist. PsA (init): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque psoriasis (init): Prescribed by or in consultation with a dermatologist.

COVERAGE DURATION

RA, PsA, AS, Plaque psoriasis, nr-axSpA (init, reauth): 12 mos. CD (init): 16 wks. (reauth): 12 mos.

OTHER CRITERIA

Reauth (RA, CD, PsA, AS, nr-axSpA): Documentation of positive clinical response to therapy. Reauth (Plaque psoriasis): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline.

CINRYZE (S)

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.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
HAE (prophylaxis): Prescribed by or in consultation with an immunologist, allergist, or rheumatologist

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

COMETRIQ (S)

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.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
All uses: 12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

COPIKTRA (S)

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 (CLL)/Small Lymphocytic Lymphoma (SLL): Diagnosis of CLL or SLL. Disease is relapsed or refractory. Trial and failure, contraindication, or intolerance to at least two prior therapies for CLL/SLL (e.g., Leukeran [chlorambucil], Gazyva [obinutuzumab], Arzerra [ofatumumab], Bendeka [bendamustine], Imbruvica [ibrutinib], Rituxan [rituximab], etc.). Follicular Lymphoma: Diagnosis of follicular lymphoma. Disease is relapsed or refractory. Trial and failure, contraindication, or intolerance to at least two prior systemic therapies for follicular lymphoma (e.g., Leukeran [chlorambucil], Gazyva [obinutuzumab], Arzerra [ofatumumab], Bendeka [bendamustine], Imbruvica [ibrutinib], Rituxan [rituximab], etc.).

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.

CORLANOR (S)

MEDICATION(S)
CORLANOR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chronic heart failure (CHF) (initial): Diagnosis of CHF. Patient has NYHA Class II, III, or IV symptoms. Patient has a left ventricular ejection fraction less than or equal to 35%. Patient is in sinus rhythm. Patient has a resting heart rate of greater than or equal to 70 beats per minute. One of the following: patient is on a beta-blocker (e.g., bisoprolol, carvedilol, metoprolol succinate extended release) at a maximally tolerated dose, or patient has a contraindication or intolerance to beta-blocker therapy. Patient has been hospitalized for worsening HF in the previous 12 months. Trial and failure, contraindication, or intolerance to maximally tolerated doses of an ACE inhibitor (e.g., captopril, enalapril, lisinopril) or ARB (e.g., candesartan, losartan, valsartan). Dilated Cardiomyopathy (DCM) (initial): Diagnosis of heart failure due to DCM. Patient has NYHA Class II, III, or, IV symptoms. Patient is in sinus rhythm. Patient has an elevated heart rate. Trial and failure, contraindication or intolerance to one of the following: 1) Beta blocker (e.g., bisoprolol, metoprolol succinate extended release), 2) Angiotensin-converting enzyme (ACE) inhibitor (e.g., captopril, enalapril), or 3) Diuretic Agent (e.g., spironolactone, furosemide).

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA

CHF, DCM (reauth): Documentation of positive clinical response to therapy.

COSENTYX (S)

MEDICATION(S)

COSENTYX (2 SYRINGES), COSENTYX PEN, COSENTYX PEN (2 PENS), COSENTYX SYRINGE

PENDING CMS APPROVAL

COTELLIC (S)

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 a U.S. Food and Drug Administration (FDA)-approved test (e.g., cobas 4800 BRAF V600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with vemurafenib.

AGE 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.

CYSTADROPS (S)

MEDICATION(S)
CYSTADROPS

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.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

CYSTARAN (S)

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.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

D.H.E. 45 (S)

MEDICATION(S)
DIHYDROERGOTAMINE 1 MG/ML AMP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Migraines (initial): Diagnosis of migraine headaches with or without aura. Will be used for the acute treatment of migraine. One of the following: Trial and failure or intolerance to one triptan (e.g., eletriptan, rizatriptan, sumatriptan) or contraindication to all triptans. If patient has 4 or more headache days per month, patient must meet one of the following: a) currently being treated with Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications, OR b) currently being treated with Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications, OR c) currently being treated with a beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications. Cluster Headaches (CH) (initial): Diagnosis of cluster headache. Trial and failure, contraindication, or intolerance to sumatriptan injection.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Migraines, CH (initial, reauth): Prescribed by or in consultation with a neurologist or pain specialist.

COVERAGE DURATION
Migraines, CH (initial): 3 months. Migraines, CH (reauth): 12 months.

OTHER CRITERIA
Migraines (reauth): Patient has experienced a positive response to therapy (e.g., reduction in pain,

photophobia, phonophobia, nausea). CH (reauth): Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity.

DALIRESP (S)

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 COPD. History of COPD exacerbations which required the use of systemic corticosteroids, antibiotics, or hospital admission. Trial and failure, intolerance, or contraindication to two prior therapies for COPD (e.g., Combivent, Spiriva).

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 therapy.

DARAPRIM (S)

MEDICATION(S)
PYRIMETHAMINE 25 MG TABLET

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

AGE 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.

DARZALEX FASPRO (S)

MEDICATION(S)
DARZALEX FASPRO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Relapsed/Refractory Multiple Myeloma (MM): Diagnosis of MM. One of the following: A) Both of the following: Used as monotherapy and One of the following: i) Patient has received at least three prior treatment regimens which included both a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis]) and an immunomodulatory agent (e.g., lenalidomide [Revlimid], thalidomide [Thalomid]) or ii) patient is double-refractory to a proteasome inhibitor and an immunomodulatory agent. OR B) Both of the following: used in combination with one of the following treatment regimens: lenalidomide and dexamethasone, or bortezomib and dexamethasone, AND patient has received at least one prior therapy (e.g., bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro], lenalidomide [Revlimid], thalidomide [Thalomid). Newly Diagnosed MM: Newly diagnosed MM. Patient is ineligible for autologous stem cell transplant. One of the following: 1) used in combination with all of the following: bortezomib, melphalan, and prednisone or 2) used in combination with both of the following: lenalidomide and dexamethasone.

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

DAURISMO (S)

MEDICATION(S)
DAURISMO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Acute myeloid leukemia (AML): Diagnosis of newly-diagnosed acute myeloid leukemia (AML) AND Used in combination with low-dose cytarabine AND One of the following: 1) Patient is greater than or equal to 75 years old, or 2) Patient has comorbidities that preclude the use of intensive induction chemotherapy.

AGE 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.

DEFERASIROX (S)

MEDICATION(S)
DEFERASIROX, JADENU SPRINKLE

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): 6mo.

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

DIACOMIT (S)

MEDICATION(S)
DIACOMIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of seizures associated with Dravet syndrome (DS). Used in combination with clobazam.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

DOJOLVI (S)

MEDICATION(S)
DOJOLVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Not used with any other medium-chain triglyceride (MCT) product.

REQUIRED MEDICAL INFORMATION
Long-Chain Fatty Acid Oxidation Disorder (LC-FAOD) (initial): Diagnosis of a LC-FAOD. Disease has been molecularly confirmed (i.e., genetic testing).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a clinical specialist knowledgeable in appropriate disease-related dietary management (e.g., geneticist, cardiologist, gastroenterologist, etc.).

COVERAGE DURATION
LC-FAOD (initial, reauth): 12 months

OTHER CRITERIA
LC-FAOD (reauth): Prescriber attests to continued need of therapy.

DUOBRII (S)

MEDICATION(S)
DUOBRII

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Plaque Psoriasis: Diagnosis of plaque psoriasis. Both of the following: 1) Trial and failure, intolerance or contraindication to one high potency corticosteroid topical treatment (e.g., halobetasol propionate, clobetasol propionate, fluocinonide) AND 2) Trial and failure or intolerance to tazarotene.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Plaque Psoriasis: Prescribed by or in consultation with a dermatologist.

COVERAGE DURATION
Plaque Psoriasis: 12 months

OTHER CRITERIA
N/A

DUPIXENT (S)

MEDICATION(S)

DUPIXENT PEN, DUPIXENT 200 MG/1.14 ML SYRING, DUPIXENT 300 MG/2 ML SYRINGE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

Asthma (initial): Age greater than or equal to 12 years. Atopic dermatitis/CRSwNP: no age restriction.

PRESCRIBER RESTRICTION

Atopic dermatitis (Initial): Prescribed by or in consultation with one of the following: dermatologist, allergist/immunologist. Asthma (initial, reauth): Prescribed by or in consultation with a pulmonologist or allergist/immunologist.CRSwNP (initial, reauth): Prescribed by or in consultation with an otolaryngologist, allergist/immunologist, or pulmonologist.

COVERAGE DURATION

Atopic Dermatitis, CRSwNP (Init/Reauth): 12 months. Asthma (Init): 6 mo. Asthma (reauth): 12 mo.

OTHER CRITERIA

Chronic rhinosinusitis with nasal polyposis (CRSwNP) (initial): Diagnosis of CRSwNP. Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (eg, fluticasone, mometasone). Used in combination with another agent for CRSwNP (eg, intranasal corticosteroid). Atopic dermatitis (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in body surface area involvement, reduction in pruritus severity). EA (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications). CDA (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in exacerbations, improvement in FEV1, reduction in oral corticosteroid dose). EA, CDA (reauth): Patient is currently being treated with ONE of the following unless there is a contraindication or intolerance to these medications: 1) Inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) and additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), tiotropium] OR 2) A combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Dulera [mometasone/formoterol], Symbicort [budesonide/formoterol], Breo Ellipta [fluticasone/vilanterol]). CRSwNP (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS, 0-8 scale], improvement in nasal congestion/obstruction score [NC, 0-3 scale]). Used in combination with another agent for CRSwNP (eg, intranasal corticosteroid).

EGRIFTA (S)

MEDICATION(S)
EGRIFTA SV

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/m^2, 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 therapy.

ELAPRASE (S)

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

EMFLAZA (S)

MEDICATION(S)
EMFLAZA

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). Patient has received genetic testing for a mutation of the dystrophin gene. One of the following: A) Documentation of a confirmed mutation of the dystrophin gene or B) Muscle biopsy confirmed an absence of dystrophin protein. Patient has had a trial and failure or intolerance to prednisone or prednisolone. Dose will not exceed 0.9 milligrams per kilogram of body weight once daily.

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

PRESCRIBER RESTRICTION
Initial: Prescribed by or in consultation with a neurologist who has experience treating children

COVERAGE DURATION
Initial, Reauth: 12 months

OTHER CRITERIA
Reauth: Patient has experienced a benefit from therapy (e.g., improvement or preservation of muscle strength). Dose will not exceed 0.9 milligrams per kilogram of body weight once daily.

EMGALITY (S)

MEDICATION(S)
EMGALITY PEN, EMGALITY SYRINGE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Episodic Migraines (EM) (120 mg/mL strength only) (initial): Diagnosis of EM. Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month. Chronic Migraines (CM) (120 mg strength/mL only) (initial): Diagnosis of CM. Medication overuse headache has been considered and potentially offending medication(s) have been discontinued. Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months. Episodic Cluster Headache (ECH) (100 mg/mL strength only) (initial): Diagnosis of episodic cluster headache. Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months. EM, CM (120 mg/mL strength only) (initial): Two of the following: a) History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine), OR patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine), b) History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate), OR patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate), or c) History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol, OR patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol. All Indications (initial): Medication will not be used in combination with another injectable CGRP inhibitor.

AGE RESTRICTION
EM, CM, ECH (initial): 18 years of age or older.

PRESCRIBER RESTRICTION
EM, CM, ECH (initial, reauth): Prescribed by or in consultation with a neurologist, headache specialist,

or pain specialist.

COVERAGE DURATION

EM, CM (initial): 6 months. ECH (initial): 3 months. EM, CM, ECH (reauth): 12 months.

OTHER CRITERIA

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

ENBREL (S)

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. Trial and failure, contraindication, or intolerance to one disease-modifying antirheumatic drug (DMARD) [eg, methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)]. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Trial and failure, contraindication, or intolerance to one of the following DMARDs: Arava (leflunomide) or methotrexate (Rheumatrex/Trexall). Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Trial and failure, contraindication, or intolerance to two NSAIDs (e.g., diclofenac, ibuprofen, meloxicam, naproxen).

AGE 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 uses (initial, reauth): 12 months

OTHER CRITERIA
RA, PJIA, PsA, AS (Reauth): Documentation of positive clinical response to therapy. Plaque psoriasis

(Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline.

ENDARI (S)

MEDICATION(S)
ENDARI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Sickle cell disease (initial): Diagnosis of sickle cell disease. Used to reduce acute complications of sickle cell disease. Patient has had 2 or more painful sickle cell crises within the past 12 months.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Sickle cell disease (initial): Prescribed by or in consultation with a hematologist/oncologist

COVERAGE DURATION
Sickle cell disease (initial, reauth): 12 months

OTHER CRITERIA
Sickle cell disease (reauth): Documentation of positive clinical response to therapy.

ENSPRYNG (S)

MEDICATION(S)
ENSPRYNG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Neuromyelitis Optica Spectrum Disorder (NMOSD) (initial): Diagnosis of NMOSD. Patient is anti-aquaporin-4 (AQP4) antibody positive.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
NMOSD (initial): Prescribed by or in consultation with a neurologist or ophthalmologist.

COVERAGE DURATION
NMOSD (initial, reauth): 12 months

OTHER CRITERIA
NMOSD (reauth): Documentation of positive clinical response to therapy.

ENTYVIO (S)

MEDICATION(S)
ENTYVIO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Ulcerative Colitis (UC) (init): Diagnosis (Dx) of moderately to severely active UC. Trial and failure, contraindication, or intolerance (F/C/I) to one of the following conventional therapies: 6-mercaptopurine (Purinethol), aminosalicylates [eg, mesalamine (Asacol, Pentasa, Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine, Sulfazine)], azathioprine (Imuran), corticosteroids (eg, prednisone, methylprednisolone). F/C/I to one tumor necrosis factor (TNF) inhibitor [eg, Humira (adalimumab), infliximab]. Crohn's Disease (CD) (init): Dx of moderately to severely active CD. F/C/I to one of the following medications: 6-mercaptopurine (Purinethol), azathioprine (Imuran), corticosteroids (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex, Trexall). F/C/I to one TNF inhibitor [eg, Humira (adalimumab), infliximab].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
UC, CD (init): Prescribed by or in consultation with a gastroenterologist

COVERAGE DURATION
UC, CD (init): 14 weeks. UC, CD (reauth): 12 months.

OTHER CRITERIA
UC, CD (reauth): Documentation of positive clinical response to therapy.

EPCLUSA PREFERRED (S)

MEDICATION(S)
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. Diagnosis of chronic hepatitis C. Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)].

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

EPIDIOLEX (S)

MEDICATION(S)
EPIDIOLEX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Lennox-Gastaut syndrome (LGS): Diagnosis of seizures associated with LGS. Trial of, contraindication, or intolerance to two formulary anticonvulsants (e.g., topiramate, lamotrigine, valproate). Dravet syndrome (DS): Diagnosis of seizures associated with DS. Tuberous sclerosis complex (TSC): Diagnosis of seizures associated with TSC.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
LGS, DS, TSC: Prescribed by or in consultation with a neurologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

ERIVEDGE (S)

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
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.

ERLEADA (S)

MEDICATION(S)
ERLEADA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Non-metastatic castration-resistant or castration-recurrent prostate cancer (NM-CRPC): Diagnosis of non-metastatic, castration-resistant (chemical or surgical) or recurrent prostate cancer. Metastatic castration-sensitive prostate cancer (M-CSPC): Diagnosis of metastatic, castration-sensitive prostate cancer.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
NM-CRPC, M-CSPC: Prescribed by or in consultation with an oncologist or urologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

ESBRIET (S)

MEDICATION(S)
ESBRIET

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): 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.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
IPF (initial): Prescribed by or in consultation with a pulmonologist

COVERAGE DURATION
initial, reauth: 12 months

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

EUCRISA (S)

MEDICATION(S)
EUCRISA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Atopic dermatitis (initial): Diagnosis of mild to moderate atopic dermatitis. Trial and failure, contraindication, or intolerance to one prescription strength topical corticosteroid, unless the affected area is sensitive (i.e., face, axillae, groin).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Reauth: Documentation of a positive clinical response to therapy (e.g., reduction in body surface area involvement, reduction in pruritus severity).

EVENITY (S)

MEDICATION(S)
EVENITY, EVENITY (2 SYRINGES)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of postmenopausal osteoporosis. One of the following: Set I) Both of the following: A) Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) One of the following: 1) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) trial and failure, contraindication, or intolerance (TF/C/I) to one anti-resorptive treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]), or Set II) Both of the following: A) BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) One of the following: 1) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) both of the following: i) TF/C/I to one anti-resorptive treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]) and ii) one of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities: a) major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions, or b) hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions. Trial of, contraindication, or intolerance to one of the following: Forteo (teriparatide) or Tymlos (abaloparatide). Treatment duration of Evenity (romosozumab-aqqg) has not exceeded a total of 12 months during the patient's lifetime.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

12 months (max 12 months of therapy per lifetime)

OTHER CRITERIA

N/A

EVRYSDI (S)

MEDICATION(S)
EVRYSDI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Spinal muscular atrophy (SMA) (initial): Diagnosis of spinal muscular atrophy (SMA) type I, II, or III. Both of the following: a) The mutation or deletion of genes in chromosome 5q resulting in one of the following: 1) Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13) or 2) Compound heterozygous mutation (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2]) AND b) Patient has at least 2 copies of SMN2. Patient is not dependent on both of the following: 1) Invasive ventilation or tracheostomy and 2) Use of non-invasive ventilation beyond use for naps and nighttime sleep. At least one of the following exams (based on patient age and motor ability) has been conducted to establish baseline motor ability: Hammersmith Infant Neurological Exam (HINE) (infant to early childhood), Hammersmith Functional Motor Scale Expanded (HFMSE), Upper Limb Module (ULM) Test (Non ambulatory), or Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND), or Motor Function Measure 32 (MFM-32) Scale. Patient is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Spinraza). One of the following: a) patient has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma) or b) patient has previously received gene therapy for the treatment of SMA (e.g., Zolgensma) AND provider attests that there has been an inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months).

AGE RESTRICTION
Initial: Patient is at least 2 months of age or older

PRESCRIBER RESTRICTION
SMA (Initial, Reauth): Prescribed by or in consultation with a neurologist with expertise in the diagnosis

and treatment of SMA

COVERAGE DURATION

Initial, Reauth: 12 months

OTHER CRITERIA

SMA (Reauth): Documentation of positive clinical response to therapy from pretreatment baseline status as demonstrated by the most recent results from one of the following exams: A) One of the following HINE-2 milestones: 1) Improvement or maintenance of previous improvement of at least a 2 point (or maximal score) increase in ability to kick OR 2) Improvement or maintenance of a previous improvement of at least a 1 point increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp OR 3) Patient exhibited improvement, or maintenance of previous improvement in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement) OR 4) Patient has achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk) OR B) One of the following HFMSE milestones: 1) Improvement or maintenance of a previous improvement of at least a 3 point increase in score from pretreatment baseline OR 2) Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk) OR C) One of the following ULM test milestones: 1) Improvement or maintenance of a previous improvement of at least a 2 point increase in score from pretreatment baseline OR 2) Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk) OR D) One of the following CHOP INTEND milestones: 1) Improvement or maintenance of a previous improvement of at least a 4 point increase in score from pretreatment baseline OR 2) Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk) OR E) One of the following MFM-32 milestones: 1) Improvement or maintenance of a previous improvement of at least a 3 point increase in score from pretreatment baseline OR 2) Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk). Patient continues to not be dependent on both of the following: 1) Invasive ventilation or tracheostomy AND 2) use of non-invasive ventilation beyond use for naps and nighttime sleep. Patient is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Spinraza). One of the following: a) patient has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma) or b) patient has previously received gene therapy for the treatment of SMA (e.g., Zolgensma) AND provider attests that there has been an inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months).

EXSERVAN (S)

MEDICATION(S)
EXSERVAN

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 ALS. Trial and failure or intolerance to generic riluzole tablets.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

FABRAZYME (S)

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. Fabrazyme will not be used in combination with Galafold (migalastat).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Fabry Disease: 12 months

OTHER CRITERIA
N/A

FARYDAK (S)

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.

FASENRA (S)

MEDICATION(S)
FASENRA, FASENRA PEN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Asthma (initial): Diagnosis of severe asthma. Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter. One of the following: 1) Patient has had at least one or more asthma exacerbations requiring systemic corticosteroids within the past 12 months, OR 2) Any prior intubation for an asthma exacerbation, OR 3) Prior asthma-related hospitalization within the past 12 months. Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) High-dose inhaled corticosteroid (ICS) [e.g., greater than 500 mcg fluticasone propionate equivalent/day] and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), tiotropium], OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone/vilanterol)].

AGE RESTRICTION
Asthma (Initial): Patient is 12 years of age or older

PRESCRIBER RESTRICTION
Asthma (Initial/Reauth): Prescribed by or in consultation with a pulmonologist or allergist/immunologist

COVERAGE DURATION
Asthma (init): 6 months. Asthma (reauth): 12 months

OTHER CRITERIA
Asthma (Reauth): Documentation of positive clinical response to therapy (e.g., reduction in

exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications). Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), tiotropium], OR b) A combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone/vilanterol)].

FENTANYL (S)

MEDICATION(S)

FENTANYL CIT OTFC 1,200 MCG, FENTANYL CIT OTFC 1,600 MCG, FENTANYL CITRATE OTFC 200 MCG, FENTANYL CITRATE OTFC 400 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

FERRIPROX (S)

MEDICATION(S)

DEFERIPRONE, FERRIPROX, FERRIPROX (2 TIMES A DAY), FERRIPROX (3 TIMES A DAY)

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Transfusional iron overload (Initial): Diagnosis of transfusional iron overload due to one of the following: thalassemia syndromes, sickle cell disease, or other transfusion-dependent anemias. Patient has Absolute Neutrophil Count (ANC) greater than 1.5 x 10^9/L. One of the following: A) Trial and failure, defined as serum ferritin greater than 2,500 mcg/L, to one chelation therapy (i.e., deferoxamine, deferasirox) OR B) History of contraindication or intolerance to one chelation therapy (i.e., deferoxamine, deferasirox).

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

12 months

OTHER CRITERIA

All uses (reauth): Documentation of positive clinical response to therapy.

FINTEPLA (S)

MEDICATION(S)
FINTEPLA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of seizures associated with Dravet syndrome

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

FIRAZYR (S)

MEDICATION(S)
ICATIBANT

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.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

FIRDAPSE (S)

MEDICATION(S)
FIRDAPSE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Lambert-Eaton Myasthenic Syndrome (LEMS) (initial): Diagnosis of LEMS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
LEMS (initial): Prescribed by or in consultation with a neurologist.

COVERAGE DURATION
LEMS (initial): 3 months. LEMS (reauth): 12 months.

OTHER CRITERIA
LEMS (reauth): Documentation of positive clinical response to therapy (e.g., improvement in dynamometry, Timed 25-Foot Walk Test, Timed Up and Go Test).

FIRMAGON (S)

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.

FOTIVDA (S)

MEDICATION(S)
FOTIVDA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of renal cell carcinoma. Disease is one of the following: relapsed or refractory. Patient has received two or more prior systemic therapies (e.g., cabozantinib + nivolumab, lenvatinib + pembrolizumab, etc.).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist, nephrologist, or urologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

FULPHILA (S)

MEDICATION(S)
FULPHILA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Febrile neutropenia (FN) prophylaxis: Patient will be receiving prophylaxis for FN due to one of the following: 1) Patient is receiving National Cancer Institute¿s Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown, 3) patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN, 4) both of the following: a) patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN, AND b) patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia, OR 5) both of the following: a) patient is receiving myelosuppressive anticancer drugs associated with neutropenia, AND b) patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis). Treatment of FN (off-label): Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia. Diagnosis of FN. Patient is at high risk for infection-associated complications. Acute radiation syndrome (ARS) (off-label): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS).

AGE RESTRICTION
N/A

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

COVERAGE DURATION
ARS: 1 mo. FN (prophylaxis, treatment): 3 mo or duration of tx.

OTHER CRITERIA

All Indications: Trial and failure or intolerance to both of the following: Neulasta/Neulasta Onpro AND Udenyca.

GALAFOLD (S)

MEDICATION(S)
GALAFOLD

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Fabry Disease (FD) (initial): Diagnosis of FD. Patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data. FD (initial, reauthorization): Will not be used in combination with Fabrazyme (agalsidase beta).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
FD (initial, reauth): 12 months.

OTHER CRITERIA
FD (reauthorization): Documentation of positive clinical response to therapy.

GAMASTAN S/D (S)

MEDICATION(S)
GAMASTAN, 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.

GATTEX (S)

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. Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient is dependent on parenteral nutrition/intravenous (PN/IV) support for at least 12 months.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
SBS (Init, reauth): Prescribed by or in consultation with a gastroenterologist.

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

OTHER CRITERIA
SBS (Reauth): Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has had a reduction in weekly parenteral nutrition/intravenous (PN/IV) support from baseline while on therapy.

GAVRETO (S)

MEDICATION(S)
GAVRETO

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. Presence of rearranged during transfection (RET) gene fusion-positive tumor(s). Medullary Thyroid Cancer (MTC): Diagnosis of medullary thyroid cancer (MTC). Disease is one of the following: advanced or metastatic. Disease has presence of rearranged during transfection (RET) gene mutation tumor(s). Disease requires treatment with systemic therapy. Thyroid Cancer: Diagnosis of thyroid cancer. Disease is one of the following: advanced or metastatic. Disease has presence of rearranged during transfection (RET) gene fusion-positive tumor(s). Disease requires treatment with systemic therapy. One of the following: patient is radioactive iodine-refractory or radioactive iodine therapy is not appropriate.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
NSCLC, MTC: Prescribed by or in consultation with an oncologist. Thyroid Cancer: Prescribed by or in consultation with an endocrinologist or an oncologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy

GILENYA (S)

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, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

GILOTRIF (S)

MEDICATION(S)
GILOTRIF

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): A) Diagnosis of advanced or metastatic (stage IIIB or IV) NSCLC AND B) One of the following: 1) Both of the following: a) Tumors have non-resistant epidermal growth factor (EGFR) mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) AND b) GILOTRIF will be used as first-line treatment, OR 2) All of the following: a) disease progressed after platinum-based chemotherapy and b) squamous NSCLC.

AGE 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.

GIVLAARI (S)

MEDICATION(S)
GIVLAARI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of acute hepatic porphyria (i.e., acute intermittent porphyria, hereditary coproporphyria, variegate porphyria, ALA dehydrase deficient porphyria). Patient has active disease with at least two documented porphyria attacks within the past 6 months. Provider attestation documenting elevated urinary or plasma levels of one of the following within the past 12 months: 1) porphobilinogen (PBG) or 2) delta-aminolevulinic acid (ALA). Patient has not had a liver transplant.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Initial, Reauth: Prescribed by or in consultation with a gastroenterologist or a specialist with expertise in the diagnosis and management of acute hepatic porphyria.

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

OTHER CRITERIA
Reauth: Documentation of positive clinical response while on therapy as demonstrated by both of the following: 1) Reduction in hemin administration requirements and 2) Reduction in the rate or number of porphyria attacks. Patient has not had a liver transplant.

GLATIRAMER ACETATE (S)

MEDICATION(S)
GLATIRAMER ACETATE, GLATOPA

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, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

GLEEVEC (S)

MEDICATION(S)
IMATINIB MESYLATE

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 Philadelphia chromosome positive (Ph+)/BCR ABL-positive chronic myelogenous leukemia (CML) OR B) Ph+/BCR ABL+ acute lymphoblastic leukemia (ALL) OR C) Gastrointestinal stromal tumor (GIST) AND one of the following: 1) Patient has documented c-KIT (CD117) positive unresectable or metastatic malignant GIST, OR 2) Patient had resection of c-KIT (CD117) positive GIST and imatinib will be used as adjuvant therapy OR D) Dermatofibrosarcoma protuberans that is unresectable, recurrent, or metastatic OR E) Hypereosinophilic syndrome or chronic eosinophilic leukemia OR F) Myelodysplastic syndrome (MDS) or myeloproliferative disease associated with platelet-derived growth factor receptor gene re-arrangements OR G) Aggressive systemic mastocytosis without the D816V c-KIT mutation or with c-KIT mutational status unknown.

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.

GOCOVRI (S)

MEDICATION(S)
GOCOVRI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Dyskinesia in Parkinson's disease (PD) (initial): Diagnosis of Parkinson's disease, patient is experiencing dyskinesia, patient is receiving levodopa-based therapy. Trial and failure or intolerance to amantadine immediate release. "Off" Episodes in Parkinson's disease (initial): Diagnosis of Parkinson's disease. Patient is experiencing "off" episodes. Used in combination with levodopa/carbidopa therapy. Both of the following: 1) Trial and failure, or intolerance to amantadine immediate release and 2) Trial and failure, contraindication, or intolerance to one of following: MAO-B inhibitor (eg, rasagiline, selegiline), dopamine agonist (eg, pramipexole, ropinirole), or COMT inhibitor (eg, entacapone).

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
All Indications (reauthorization): Documentation of positive clinical response to therapy (e.g., decreased "off" periods or decreased "on" time with troublesome dyskinesia).

GROWTH HORMONE, PREFERRED (S)

MEDICATION(S)
GENOTROPIN

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

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 uses (initial, reauth): 12 months

OTHER CRITERIA
AGHD(initial):dx of AGHD with clin records supporting dx of childhood-onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg,damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1GH stim test (insulin tolerance test [ITT], arginine/GHRH,glucagon,arginine,macimorelin) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L],[GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2],[glucagon at or below 3mcg/L],[Arg at or below 0.4mcg/L],[macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 mins after administration]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IFG-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab. AGHD,IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level. TransitionPhaseAdolescent Pts(TPAP)(initial): attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones: ACTH,TSH,prolactin,FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,GHRH+ARG,ARG,glucagon,macimorelin) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], [macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 mins after administration], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon, macimorelin) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], [macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 mins after administration]. 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 after 2 GH stim tests(ITT,L-ARG,glucagon,macimorelin), w/ 2 corresponding peak GH values [ITT at or below 5mcg/L],[Arg at or below 5mcg/L],[glucagon at or below 3mcg/L],[macimorelin less than 2.8 ng/mL 30,45,60, and 90 mins after administration].

H.P. ACTHAR GEL (S)

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). Dosing for infantile spasms (West Syndrome) is in accordance with the United States Food and Drug Administration (FDA) approved labeling: not to exceed 150U/m^2 daily. Multiple Sclerosis (MS): Acute exacerbations of MS. Dosing for multiple sclerosis is in accordance with the United States FDA approved labeling: not to exceed 120 units once daily. 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 erythematous, 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. All indications (except infantile spasms, multiple sclerosis): Dosing is in accordance with the United States FDA approved labeling: not to exceed 80 units per day.

AGE RESTRICTION
Infantile spasms: less than 2 years old

PRESCRIBER RESTRICTION

Infantile Spasm, MS: neurologist. Rheumatic disorder, collagen disease: rheumatologist. Dermatologic: dermatologist. Allergic state: allergist, immunologist. Ophthalmic disease: optometrist, ophthalmologist. Respiratory diseases: pulmonologist. Edematous state: nephrologist, rheumatologist.

COVERAGE DURATION

Infantile Spasms: 4 weeks. MS: 3 weeks. All other FDA-approved uses: 3 months.

OTHER CRITERIA

N/A

HAEGARDA (S)

MEDICATION(S)
HAEGARDA

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.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

HERCEPTIN (S)

MEDICATION(S)
HERCEPTIN 150 MG VIAL

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) Platinol (cisplatin) and 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.

HERCEPTIN HYLECTA (S)

MEDICATION(S)
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 HER2-overexpressing breast cancer. One of the following: 1) Used as adjuvant breast cancer treatment with one of the following regimens: a) administered as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel, b) administered as part of a treatment regimen with docetaxel and carboplatin, or c) administered as a single agent following multi-modality anthracycline based therapy, OR 2) Both of the following: a) disease is metastatic and b) one of the following regimens: i) administered in combination with paclitaxel for first-line treatment, or ii) administered as a single agent for treatment in patients who have received one or more chemotherapy regimens for metastatic 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.

HETLIOZ (S)

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). Smith-Magenis Syndrome (SMS) (initial): Diagnosis of Smith-Magenis Syndrome (SMS). Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking).

AGE RESTRICTION
SMS (initial): 16 years of age or older

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

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

OTHER CRITERIA
Non-24 (reauth): Documentation of positive clinical response to therapy. SMS (reauth): Documentation of positive clinical response to therapy (i.e., improvement in nighttime total sleep time, improvement in nighttime sleep quality)

HETLIOZ LQ (S)

MEDICATION(S)
HETLIOZ LQ

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Smith-Magenis Syndrome (SMS) (initial): Diagnosis of Smith-Magenis Syndrome (SMS). Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking).

AGE RESTRICTION
SMS (initial): Patient is 3 through 15 years of age

PRESCRIBER RESTRICTION
SMS (initial): Prescribed by or in consultation with a specialist in sleep disorders or neurologist.

COVERAGE DURATION
SMS (initial): 6 mo. (reauth): 12 mo

OTHER CRITERIA
SMS (reauth): Documentation of positive clinical response to therapy (i.e., improvement in nighttime total sleep time, improvement in nighttime sleep quality).

HRM - ANTIHISTAMINES

MEDICATION(S)
PHENADOZ, PROMETHEGAN 12.5 MG SUPPOS

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

HRM - ANTIPSYCHOTICS

MEDICATION(S)
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 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. Trial and failure, contraindication or intolerance to one of the following: haloperidol, fluphenazine, or an atypical antipsychotic.

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.

HRM - BUTALBITAL

MEDICATION(S)

BUTALBITAL-ACETAMINOPHN 50-325, BUTALB-ACETAMIN-CAFF 50-325-40, BUTALBITAL-ASA-CAFFEINE CAP, TENCON

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.

HRM - PHENOBARBITAL, PENTOBARBITAL

MEDICATION(S)
PHENOBARBITAL, PHENOBARBITAL SODIUM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
The drug 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
Applies to New Starts only.

HRM - SKELETAL MUSCLE RELAXANTS

MEDICATION(S)

CHLORZOXAZONE 500 MG TABLET, CYCLOBENZAPRINE 10 MG TABLET, CYCLOBENZAPRINE 5 MG TABLET, METHOCARBAMOL 500 MG TABLET, METHOCARBAMOL 750 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

N/A

HRM - TCA

MEDICATION(S)

AMITRIPTYLINE HCL, CHLORDIAZEPOXIDE-AMITRIPTYLINE, 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, PERPHENAZINE-AMITRIPTYLINE

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.

HUMIRA (S)

MEDICATION(S)

HUMIRA, HUMIRA PEDIATRIC CROHN'S, HUMIRA PEN, HUMIRA PEN CROHN'S-UC-HS, HUMIRA PEN PSOR-UVEITS-ADOL HS, HUMIRA(CF), HUMIRA(CF) PEDIATRIC CROHN'S, HUMIRA(CF) PEN, HUMIRA(CF) PEN CROHN'S-UC-HS, HUMIRA(CF) PEN PEDIATRIC UC, HUMIRA(CF) PEN PSOR-UV-ADOL HS

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

RA, AS, JIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque Psoriasis, HS (initial): Prescribed by or in consultation with a dermatologist. CD, UC (initial): Prescribed by or in consultation with a gastroenterologist. Uveitis (initial): Prescribed by or in consultation with an ophthalmologist or rheumatologist.

COVERAGE DURATION

UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial, reauth): 12 mo.

OTHER CRITERIA

RA, JIA, PsA, AS, CD, Hidradenitis suppurativa (HS), Uveitis (Reauth): Documentation of positive clinical response to therapy. Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. UC (Reauth): For patients who initiated therapy within the past 12 weeks: Documentation of clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy OR For patients who have been maintained on therapy for longer than 12 weeks: Documentation of positive clinical response to therapy.

IBRANCE (S)

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 advanced or metastatic breast cancer. Disease is a) hormone receptor (HR)-positive, and b) human epidermal growth factor receptor 2 (HER2)-negative. One of the following: 1) used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) and one of the following: a) patient is a male, or b) patient is a postmenopausal woman, OR 2) both of the following: used in combination with Faslodex (fulvestrant) and disease has progressed following endocrine therapy.

AGE 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.

ICLUSIG (S)

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

AGE 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.

IDHIFA (S)

MEDICATION(S)
IDHIFA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Acute Myeloid Leukemia (AML): Diagnosis of AML. Disease is relapsed or refractory. Patient has an isocitrate dehydrogenase-2 (IDH2) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., Abbott RealTime IDH2 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).

AGE 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.

ILARIS (S)

MEDICATION(S)
ILARIS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Periodic Fever Syndromes (Cryopyrin-Associated Periodic Syndromes (CAPS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), Familial Mediterranean Fever (FMF)). (Initial) Diagnosis of one of the autoinflammatory Periodic Fever Syndromes: CAPS (including Familial Cold Auto-inflammatory Syndrome (FCAS) and/or Muckle-Wells Syndrome (MWS)), TRAPS, HIDS/MKD, or FMF, AND The medication will not be used in combination with another biologic agent. Systemic juvenile idiopathic arthritis (sJIA) (Initial): Diagnosis of active sJIA AND The medication will not be used in combination with another biologic.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Periodic Fever Syndromes (CAPS, TRAPS, HIDS/MKD, FMF) (initial): Prescribed by or in consultation with an immunologist, allergist, dermatologist, rheumatologist, neurologist or other medical specialist

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

OTHER CRITERIA
SJIA (initial): Trial and failure, contraindication, or intolerance to non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), methotrexate, or corticosteroids. Periodic Fever Syndrome (CAPS, TRAPS, HIDS/MKD, FMF) and SJIA (Reauth): Documentation of positive clinical response to

therapy.

ILUMYA (S)

MEDICATION(S)
ILUMYA

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: set A) Both of the following: 1) Trial and failure, contraindication, or intolerance to one of the following: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab), AND 2) Trial and failure, contraindication, or intolerance to Cosentyx (secukinumab), or set B) For continuation of prior therapy.

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 therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline.

IMBRUVICA (S)

MEDICATION(S)
IMBRUVICA

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. Waldenstrom's macroglobulinemia: Diagnosis of Waldenstrom¿s macroglobulinemia/lymphoplasmacytic lymphoma. Small lymphocytic lymphoma (SLL): Diagnosis of SLL. Marginal zone lymphoma (MZL): Diagnosis of MZL AND patient has received at least one prior anti-CD20-based therapy for MZL [e.g., Rituxan (rituximab), Zevalin (ibritumomab), Gazyva (obinutuzumab, etc.)]. Chronic graft versus host disease (cGVHD): Diagnosis of cGVHD AND trial and failure of one or more lines of systemic therapy (e.g., corticosteroids, mycophenolate).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
All uses (except chronic graft versus host disease): Prescribed by or in consultation with an oncologist or hematologist. Chronic graft versus host disease: Prescribed by or in consultation with a hematologist, oncologist, or physician experienced in the management of transplant patients.

COVERAGE DURATION
All Uses: 12 months

OTHER CRITERIA
All Uses: Approve for continuation of prior therapy.

INBRIJA (S)

MEDICATION(S)
INBRIJA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Parkinson's disease (PD) (initial): Diagnosis of PD. Patient is experiencing intermittent OFF episodes. Used in combination with carbidopa/levodopa. Trial and failure, contraindication or intolerance to two of the following: MAO-B inhibitor (e.g., rasagiline, selegiline), dopamine agonist (e.g., pramipexole, ropinirole), or COMT Inhibitor (e.g., entacapone).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PD (initial): Prescribed by or in consultation with a neurologist

COVERAGE DURATION
PD (initial, reauth): 12 months

OTHER CRITERIA
PD (reauth): Documentation of positive clinical response to therapy. Used in combination with carbidopa/levodopa.

INCRELEX (S)

MEDICATION(S)
INCRELEX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Insulin-like Growth Factor-1 (IGF-1) deficiency (initial): Diagnosis of severe primary IGF-1 deficiency. Height standard deviation score of -3.0 or less. Basal IGF-1 standard deviation score of -3.0 or less. Normal or elevated growth hormone (GH). GH gene deletion (initial): Diagnosis of GH gene deletion in patients who have developed neutralizing antibodies to GH.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Initial: Prescribed by or in consultation with a pediatric endocrinologist

COVERAGE DURATION
Initial, reauth: 12 months

OTHER CRITERIA
(Reauth): Evidence of positive response to therapy.

INFLECTRA (S)

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 (e.g., diclofenac, ibuprofen, meloxicam, naproxen). All indications (initial): One of the following: 1) Trial and failure or intolerance to Remicade or 2) For continuation of prior Inflectra therapy.

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 uses (initial, reauth): 12 months

OTHER CRITERIA

Reauth (CD, UC, AS, PsA, RA): Documentation of positive clinical response to therapy. Reauth (plaque psoriasis): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline.

INGREZZA (S)

MEDICATION(S)
INGREZZA, INGREZZA INITIATION PACK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Tardive Dyskinesia (initial): Diagnosis of moderate to severe tardive dyskinesia. One of the following: a) patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication OR b) patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Initial: Prescribed by or in consultation with a neurologist or psychiatrist.

COVERAGE DURATION
Initial: 3 months. Reauth: 12 months

OTHER CRITERIA
Tardive Dyskinesia (reauth): Documentation of positive clinical response to therapy.

INLYTA (S)

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 carcinoma (RCC): Diagnosis of RCC. One of the following: (1) disease has relapsed or (2) 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.

INQOVI (S)

MEDICATION(S)
INQOVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Myelodysplastic syndrome (MDS): Diagnosis of myelodysplastic syndrome. Patient has ONE of the following French- American-British subtypes: a) refractory anemia, b) refractory anemia with ringed sideroblasts, c) refractory anemia with excess blasts, or d) chronic myelomonocytic leukemia (CMML).

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.

INREBIC (S)

MEDICATION(S)
INREBIC

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Myelofibrosis: Diagnosis of one of the following: primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis.

AGE 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.

INTRON A (S)

MEDICATION(S)
INTRON A

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.

IRESSA (S)

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 a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).

AGE 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.

ISOTRETINOIN (S)

MEDICATION(S)

ACCUTANE 20 MG CAPSULE, ACCUTANE 30 MG CAPSULE, ACCUTANE 40 MG CAPSULE, AMNESTEEM, CLARAVIS, ISOTRETINOIN 10 MG CAPSULE, ISOTRETINOIN 20 MG CAPSULE, ISOTRETINOIN 30 MG CAPSULE, ISOTRETINOIN 40 MG CAPSULE, 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. One of the following: A) Prescribed by a dermatologist or, B) Trial and failure, contraindication or intolerance to an adequate trial (at least 6 weeks) on two of the following conventional therapy regimens: a) topical retinoid or retinoid-like agent [eg, Retin-A/Retin-A Micro (tretinoin)], b) oral antibiotic [eg, Ery-Tab (erythromycin), Minocin (minocycline)], c) topical antibiotic with or without benzoyl peroxide [eg, Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl peroxide/erythromycin)].

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Acne (initial): 5 months. Acne (reauth): Retreatment - 5 months, Dose Titration - 1 month

OTHER CRITERIA

Acne, Retreatment (reauth): After more than 2 months off therapy, persistent or recurring acne is still present. Acne, Dose Titration (reauth): Confirmation that the total cumulative dose is less than 150 mg/kg.

ISTODAX (S)

MEDICATION(S)
ROMIDEPSIN 27.5 MG/5.5 ML VIAL

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 systemic therapy for the treatment of CTCL [e.g., Trexall (methotrexate), Targretin (bexarotene), cyclophosphamide] Peripheral T-cell lymphoma (PTCL): Diagnosis of PTCL. Trial and failure, contraindication, or intolerance to at least one therapy for the treatment of PTCL (e.g., conventional chemotherapy such as CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone), CHOEP (cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone), Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin), HyperCVAD (cyclophosphamide, vincristine, doxorubicin, dexamethasone) alternating with high-dose methotrexate and cytarabine).

AGE 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.

ISTURISA (S)

MEDICATION(S)
ISTURISA

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. One of the following: a) Patient is not a candidate for pituitary surgery, OR b) Pituitary surgery has not been curative for the patient.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Cushing's disease (initial): Prescribed by or in consultation with an endocrinologist.

COVERAGE DURATION
Cushing's disease (initial, reauth): 12 months

OTHER CRITERIA
Cushing's disease (reauth): Documentation of positive clinical response to therapy (e.g., a clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs or symptoms of the disease).

IVERMECTIN (S)

MEDICATION(S)
IVERMECTIN 3 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Strongyloidiasis: Diagnosis of intestinal (i.e., nondisseminated) strongyloidiasis due to the nematode parasite Strongyloides stercoralis OR both of the following: member received the drug within the past 120 days and member requires continuation of therapy. Onchocerciasis: Diagnosis of onchocerciasis due to the nematode parasite Onchocerca volvulus OR both of the following: member received the drug within the past 120 days and member requires continuation of therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Strongyloidiasis: 3 weeks. Onchocerciasis: 6 months.

OTHER CRITERIA
N/A

IVIG (S)

MEDICATION(S)

ASCENIV, BIVIGAM, FLEBOGAMMA DIF, 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, 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.

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).

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-Barr¿ syndrome. 3) Inflammatory myopathies (dermatomyositis or polymyositis) AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, methotrexate, cyclosporine A, cyclophosphamide, or tacrolimus). 4) Lambert-Eaton myasthenic syndrome AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (e.g., azathioprine). 5) Multifocal motor neuropathy. 6) Myasthenia gravis with severe exacerbations or myasthenic crises AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, cyclosporine, cyclophosphamide, or mycophenolate mofetil). 7) Stiff person syndrome AND Patient had a TF/C/I to at least 2 standard therapies (i.e., benzodiazepines, muscle relaxants, or anti-convulsants). [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.

JAKAFI (S)

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. Acute graft versus host disease (aGVHD): Diagnosis of aGVHD. Disease is steroid-refractory.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Myelofibrosis, Polycythemia vera: Prescribed by or in consultation with a hematologist/oncologist. Acute graft versus host disease: Prescribed by or in consultation with one of the following: hematologist, oncologist, physician experienced in the management of transplant patients.

COVERAGE DURATION
12 months.

OTHER CRITERIA
Approve for continuation of prior therapy.

JUXTAPID (S)

MEDICATION(S)
JUXTAPID

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 is receiving other lipid-lowering therapy. Trial and failure, contraindication, or intolerance to Repatha therapy. Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor.

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 other lipid-lowering therapy. Submission of medical records (eg, chart notes, laboratory values) documenting LDL-C reduction while on therapy. Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor.

KALBITOR (S)

MEDICATION(S)
KALBITOR

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.

AGE RESTRICTION
12 years of age or older

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

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

KALYDECO (S)

MEDICATION(S)
KALYDECO

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 cystic fibrosis. Patient has one of the following mutations on at least one allele in the cystic fibrosis transmembrane conductance regulator gene as detected by a U.S. Food and Drug Administration (FDA)-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA): A455E, A1067T, D110E, D110H, D579G, D1152H, D1270N, E56K, E193K, E831X, F1052V, F1074L, G178R, G551D, G551S, G1069R, G1244E, G1349D, K1060T, L206W, P67L, R74W, R117C, R117H, R347H, R352Q, R1070Q, R1070W, S549N, S549R, S945L, S977F, S1251N, S1255P, 711+3A-G, 2789+5G-A, 3272-26A-G, or 3849+10kbC-T.

AGE RESTRICTION
CF (Initial): 4 months of age or older

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

COVERAGE DURATION
CF (initial, reauth): 12 months

OTHER CRITERIA
CF (Reauth): Documentation of positive clinical response (i.e. improvement in lung function [percent predicted forced expiratory volume in one second (PPFEV1)], decreased number of pulmonary exacerbations) while on therapy.

KANUMA (S)

MEDICATION(S)
KANUMA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE 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

KESIMPTA (S)

MEDICATION(S)
KESIMPTA PEN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Relapsing forms of multiple sclerosis (RRMS) (initial): Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: a) Failure after a trial of at least 4 weeks, contraindication, or intolerance to one of the following: Aubagio (teriflunomide), Avonex (interferon beta-1a), Bafiertam (monomethyl fumarate), Betaseron (interferon beta-1b), Copaxone/Glatopa (glatiramer acetate), Extavia (interferon beta-1b), Gilenya (fingolimod), Mavenclad (cladribine), Mayzent (siponimod), Plegridy (peginterferon beta-1a), Rebif (interferon beta-1a), Brand Tecfidera/generic dimethyl fumarate, Vumerity (diroximel fumarate), Zeposia (ozanimod), OR b) Patient is not a candidate for any of the drugs listed as prerequisites due to the severity of their multiple sclerosis, OR c) For continuation of prior therapy. Not used in combination with another disease-modifying therapy for MS. Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ocrelizumab [Ocrevus]).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RRMS (Initial, Reauth): Prescribed by or in consultation with a neurologist

COVERAGE DURATION
Initial, Reauth: 12 months

OTHER CRITERIA

RRMS (Reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapse, or disease progression). Not used in combination with another disease-modifying therapy for MS. Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ocrelizumab [Ocrevus]).

KEVEYIS (S)

MEDICATION(S)
KEVEYIS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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 therapy.

KEVZARA (S)

MEDICATION(S)
KEVZARA

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: a) Either a trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib), or attestation demonstrating a trial may be inappropriate, OR b) For continuation of prior therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Initial: Prescribed by or in consultation with a rheumatologist

COVERAGE DURATION
Initial, Reauth: 12 months

OTHER CRITERIA
RA (reauth): Documentation of positive clinical response to therapy.

KINERET (S)

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: a) Either a trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib), or attestation demonstrating a trial may be inappropriate, OR b) For continuation of prior therapy. Neonatal-Onset Multisystem Inflammatory Disease (NOMID) (initial): Diagnosis of NOMID AND dx of NOMID has been confirmed by one of the following: 1) 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 2) Both of the following: a) two of the following clinical symptoms: urticaria-like rash, cold/stress triggered episodes, sensorineural hearing loss, musculoskeletal symptoms (e.g., arthralgia, arthritis, myalgia), chronic aseptic meningitis, or skeletal abnormalities (e.g., epiphyseal overgrowth, frontal bossing) AND b) elevated acute phase reactants (eg, erythrocyte sedimentation rate [ESR], C-reactive protein [CRP], serum amyloid A [SAA]). Deficiency of Interleukin-1 Receptor Antagonist (DIRA): Diagnosis of DIRA.

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
RA, NOMID (initial, reauth): 12 months. DIRA: 12 months.

OTHER CRITERIA

RA, NOMID (Reauth): Documentation of positive clinical response to therapy.

KISQALI (S)

MEDICATION(S)
KISQALI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Breast cancer: Diagnosis of advanced or metastatic breast cancer. Disease is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative. One of the following: A) Used in combination with an aromatase inhibitor [e.g., Femara (letrozole)] OR B) Used in combination with Faslodex (fulvestrant).

AGE 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 (S)

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
Breast cancer: Diagnosis of advanced or metastatic breast cancer. Disease is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative. One of the following: A) Patient is postmenopausal OR B) Both of the following: a) Patient is pre/perimenopausal AND b) Treated with a Luteinizing Hormone-Releasing Hormone (LHRH) agonist (e.g. leuprolide).

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.

KORLYM (S)

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
Reauth: Documentation of one of the following: patient has improved glucose tolerance while on therapy or patient has stable glucose tolerance while on therapy.

KOSELUGO (S)

MEDICATION(S)
KOSELUGO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Neurofibromatosis Type 1 (NF1): Diagnosis of NF1. Patient has plexiform neurofibromas that are both of the following: inoperable and causing significant morbidity (e.g., disfigurement, motor dysfunction, pain, airway dysfunction, visual impairment). Patient is able to swallow a capsule whole.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with one of the following: oncologist or neurologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

KUVAN (S)

MEDICATION(S)
KUVAN, SAPROPTERIN DIHYDROCHLORIDE

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 will have blood Phe levels measured after 1 week of therapy (new starts to therapy only) and periodically for up to 2 months of therapy to determine response.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
PKU (reauth): 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.

KYNMOBI (S)

MEDICATION(S)

KYNMOBI 10 MG SL FILM, KYNMOBI 15 MG SL FILM, KYNMOBI 20 MG SL FILM, KYNMOBI 25 MG SL FILM, KYNMOBI 30 MG SL FILM

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Parkinson's disease (PD) (Initial): Not used with any 5-HT3 antagonist (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron)

REQUIRED MEDICAL INFORMATION

Parkinson's disease (PD) (Initial): Diagnosis of PD. Patient is experiencing acute intermittent hypomobility (defined as off episodes characterized by muscle stiffness, slow movements, or difficulty starting movements). Used in combination with other medications for the treatment of PD (e.g., carbidopa/levodopa, pramipexole, ropinirole, etc.).

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

PD (Initial): Prescribed by or in consultation with a neurologist.

COVERAGE DURATION

PD (Initial, reauth): 12 months

OTHER CRITERIA

PD (Reauth): Documentation of positive clinical response to therapy.

LEMTRADA (S)

MEDICATION(S)
LEMTRADA

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). One of the following: 1) Patient has not been previously treated with alemtuzumab, and failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS: Aubagio (teriflunomide), Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone/Glatopa (glatiramer acetate), Extavia (interferon beta-1b), Gilenya (fingolimod), Mavenclad (cladribine), Mayzent (siponimod), Ocrevus (ocrelizumab), Plegridy (peginterferon beta-1a), Rebif (interferon beta-1a), Tecfidera (dimethyl fumarate), Tysabri (natalizumab), or 2) Patient has previously received treatment with alemtuzumab, and at least 12 months have or will have elapsed since the most recent treatment course with alemtuzumab. Not used in combination with another disease-modifying therapy for MS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
MS: 12 months.

OTHER CRITERIA
N/A

LENVIMA (S)

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. Treatment follows one prior anti-angiogenic therapy. Used in combination with everolimus. Hepatocellular Carcinoma (HCC): Diagnosis of HCC. One of the following: patient has metastatic disease, or patient has extensive liver tumor burden, or patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only), or disease is unresectable. Endometrial Carcinoma (EC): Diagnosis of advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR). Patient has disease progression following systemic therapy. Used in combination with Keytruda (pembrolizumab) therapy. Patient is not a candidate for curative surgery or radiation.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
DTC/RCC/EC: Prescribed by or in consultation with an oncologist. HCC: Prescribed by or in consultation with one of the following: oncologist, hepatologist, or gastroenterologist.

COVERAGE DURATION
12 months

OTHER CRITERIA

Approve for continuation of prior therapy.

LETAIRIS (S)

MEDICATION(S)
AMBRISENTAN

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 (S)

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) patient has non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic BMT, OR 2) used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis, OR 3) patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy. Acute myeloid leukemia (AML): Diagnosis of AML. Patient has completed induction or consolidation chemotherapy. Age greater than or equal to 55 years. Febrile Neutropenia (FN) Prophylaxis: Patient will be receiving prophylaxis for FN due to one of the following: 1) Patient is receiving National Cancer Institute¿s Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown, 3) patient is receiving chemotherapy regimen(s) associated with a greater than 20% incidence of FN, 4) both of the following: a) patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN, AND b) patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia, OR 5)Both of the following: a) patient is receiving myelosuppressive anticancer drugs associated with neutropenia, AND b) patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis). Acute radiation syndrome (ARS): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS). Treatment of High-Risk FN: Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia. Diagnosis of FN. Patient is at high risk for infection-associated complications. HIV-related neutropenia (HIVN): Patient is infected with HIV, and ANC less than or equal to 1000 (cells/mm^3).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

HIVN: Prescribed by or in consultation with a hematologist/oncologist or infectious disease specialist. All other uses:Prescribed by or in consultation with a hematologist/oncologist.

COVERAGE DURATION

BMSCT, AML, FN (prophylaxis, treatment):3mo or duration of tx. HIVN:6mo. ARS:1 mo.

OTHER CRITERIA

N/A

LIDOCAINE TOPICAL (S)

MEDICATION(S)

APRIZIO PAK, DERMACINRX EMPRICAINE, DERMACINRX PRIZOPAK, GLYDO, LIDOCAINE 5% OINTMENT, LIDOCAINE HCL 2% JEL UROJET AC, LIDOCAINE HCL 2% JELLY, LIDOCAINE HCL 2% JELLY URO-JET, LIDOCAINE HCL 4% SOLUTION, LIDOCAINE-PRILOCAINE

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

3 months

OTHER CRITERIA

N/A

LIDODERM (S)

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
Post-herpetic neuralgia: Diagnosis of post-herpetic neuralgia.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

LONSURF (S)

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. Gastric/Gastroesophageal Junction Adenocarcinoma: Diagnosis of metastatic gastric cancer or diagnosis of metastatic gastroesophageal junction adenocarcinoma. Trial and failure, contraindication or intolerance to at least two of the following: fluropyrimidine-based chemotherapy (e.g. fluorouracil), Platinum-based chemotherapy (e.g., carboplatin, cisplatin, oxaliplatin), Taxane (e.g., docetaxel, paclitaxel) or irinotecan-based chemotherapy, HER2/neu-targeted therapy (e.g., trastuzumab) (if HER2 overexpression).

AGE 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 (S)

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 (NSCLC): Diagnosis of metastatic NSCLC. Patient has an anaplastic lymphoma kinase (ALK)-positive tumor.

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.

LOTRONEX (S)

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 therapy.

LOVAZA (S)

MEDICATION(S)
OMEGA-3 ACID ETHYL ESTERS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Severe Hypertriglyceridemia (initial): Diagnosis of hypertriglyceridemia and patient has a pre-treatment triglyceride (TG) level greater than or equal to 500 mg/dL.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial/Reauth: 12 months

OTHER CRITERIA
Severe Hypertriglyceridemia (reauth):Documentation of positive clinical response to therapy.

LUMAKRAS (S)

MEDICATION(S)
LUMAKRAS

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. Disease is one of the following: a) locally advanced or b) metastatic. Tumor is KRAS G12C-mutated as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has received at least one prior systemic therapy (e.g., cisplatin/pemetrexed, atezolizumab, nivolumab, capmatinib).

AGE 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.

LUMIZYME (S)

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

LUPANETA PACK (S)

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.

LUPKYNIS (S)

MEDICATION(S)
LUPKYNIS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Lupus Nephritis (initial): Diagnosis of active lupus nephritis. Used in combination with immunosuppressive therapy (e.g., mycophenolate mofetil, methylprednisolone).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Lupus Nephritis (initial): Prescribed by or in consultation with a nephrologist or rheumatologist

COVERAGE DURATION
Lupus Nephritis (initial, reauth): 12 months

OTHER CRITERIA
Lupus Nephritis (reauth): Documentation of positive clinical response to therapy.

LUPRON (S)

MEDICATION(S)

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.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Prostate CA: 12 months

OTHER CRITERIA

Approve for continuation of prior therapy.

LUPRON DEPOT (S)

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.

LUPRON DEPOT PED (S)

MEDICATION(S)

LUPRON DEPOT-PED 11.25 MG KIT, LUPRON DEPOT-PED 15 MG KIT, LUPRON DEPOT-PED 30 MG 3MO 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.

LYNPARZA TABLET (S)

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, advanced disease with known or suspected BRCA mutation with 3 or more prior lines of chemotherapy: Diagnosis of advanced ovarian cancer. Presence of deleterious or suspected deleterious germline BRCA-mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Trial and failure, contraindication, or intolerance to three or more prior lines of chemotherapy (e.g., paclitaxel with cisplatin). Maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: recurrent epithelial ovarian cancer, recurrent fallopian tube cancer, or recurrent primary peritoneal cancer. Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin). Breast cancer: Diagnosis of metastatic breast cancer. Presence of a deleterious or suspected deleterious germline BRCA-mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Disease is human epidermal growth factor receptor 2 (HER2)-negative. Patient has been previously treated with chemotherapy (e.g., anthracycline, taxane) in the neoadjuvant, adjuvant, or metastatic setting. One of the following: a) Disease is hormone receptor (HR) negative, or b) Disease is hormone receptor (HR)-positive and one of the following: i) patient has been treated with prior endocrine therapy or ii) patient is considered an inappropriate candidate for endocrine therapy. See Other Criteria

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

All uses (except prostate cancer): Prescribed by or in consultation with an oncologist. Prostate cancer: Prescribed by or in consultation with an oncologist or urologist.

COVERAGE DURATION

12 months

OTHER CRITERIA

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

MAKENA (S)

MEDICATION(S)
HYDROXYPROGEST 1,250 MG/5 ML, HYDROXYPROGEST 250 MG/ML VIAL, MAKENA 275 MG/1.1 ML AUTOINJCT

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 or in consultation with a specialist in obstetrics and gynecology

COVERAGE DURATION
Preterm birth prophylaxis: 21 weeks

OTHER CRITERIA
N/A

MARINOL (S)

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.

MAVENCLAD (S)

MEDICATION(S)
MAVENCLAD

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 (e.g., relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: 1) Patient has not been previously treated with cladribine AND Failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS: Aubagio (teriflunomide), Avonex (interferon beta-1a), Bafiertam (monomethyl fumarate), Betaseron (interferon beta-1b), Copaxone/Glatopa (glatiramer acetate), Extavia (interferon beta-1b), Gilenya (fingolimod), Kesimpta (ofatumumab), Lemtrada (alemtuzumab), Mayzent (siponimod), Ocrevus (ocrelizumab), Plegridy (peginterferon beta-1a), Rebif (interferon beta-1a), Brand Tecfidera/generic dimethyl fumarate, Tysabri (natalizumab), Vumerity (diroximel fumarate), Zeposia (ozanimod), OR 2) Patient has previously received treatment with cladribine AND Patient has not already received the FDA-recommended lifetime limit of 2 treatment courses (or 4 treatment cycles total) of cladribine. Not used in combination with another disease-modifying therapy for MS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
MS: 1 month

OTHER CRITERIA

N/A

MAVYRET (S)

MEDICATION(S)
MAVYRET 100-40 MG TABLET

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 patients: Diagnosis of chronic hepatitis C, patient is without decompensated liver disease (defined as Child-Pugh Class B or C), and not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni, Zepatier].

AGE 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
8 to 16 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.

OTHER CRITERIA
N/A

MAYZENT (S)

MEDICATION(S)
MAYZENT

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, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

MEKINIST (S)

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 or metastatic melanoma AND cancer is BRAF V600E or V600K mutant type as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Adjuvant Treatment for Melanoma: Diagnosis of melanoma. Cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Involvement of lymph nodes following complete resection. Used as adjunctive therapy. Medication is used in combination with Tafinlar (dabrafenib).Non-small Cell Lung Cancer (NSCLC): All of the following: diagnosis of metastatic non-small cell lung cancer AND cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) AND medication is used in combination with Tafinlar (dabrafenib). Anaplastic Thyroid Cancer (ATC): Diagnosis of locally advanced or metastatic ATC. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Cancer may not be treated with standard locoregional treatment options. Medication is used in combination with Tafinlar (dabrafenib).

AGE 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.

MEKTOVI (S)

MEDICATION(S)
MEKTOVI

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 BRAF V600E or V600K mutant type (MT) as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with Braftovi (encorafenib).

AGE 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

METHOTREXATE INJECTION (S)

MEDICATION(S)
RASUVO

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 severe, active RA. Polyarticular juvenile idiopathic arthritis (PJIA) (initial): Diagnosis of active PJIA. Psoriasis (initial): Diagnosis of severe psoriasis. All Indications (initial): Trial and failure or intolerance to oral methotrexate.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RA, PJIA (initial): Prescribed by or in consultation with a rheuamtologist. 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 therapy.

MIGRANAL (S)

MEDICATION(S)
DIHYDROERGOTAMINE 4 MG/ML SPRY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of migraine headaches with or without aura. Will be used for the acute treatment of migraine. One of the following: Trial and failure or intolerance to one triptan (e.g., eletriptan, rizatriptan, sumatriptan) or contraindication to all triptans. If patient has 4 or more headache days per month, patient must meet one of the following: a) currently being treated with Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications, OR b) currently being treated with Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications, OR c) currently being treated with a beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Initial, Reauth: Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.

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

OTHER CRITERIA
Reauth: Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea).

MIRVASO (S)

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 therapy.

MOZOBIL (S)

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) [e.g., Neupogen (filgrastim), Zarxio (filgrastim)].

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

MS INTERFERONS (NON-PREFERRED) (S)

MEDICATION(S)
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, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following: Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Extavia (interferon beta-1b), Plegridy (peginterferon beta-1a), or 2) for continuation of prior therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

MS INTERFERONS (PREFERRED) (S)

MEDICATION(S)

AVONEX PREFILLED SYR 30 MCG KT, AVONEX PEN, BETASERON, EXTAVIA, PLEGRIDY, PLEGRIDY PEN

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, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions).

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

12 months

OTHER CRITERIA

N/A

MULPLETA (S)

MEDICATION(S)
MULPLETA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Thrombocytopenia Prior to Planned Procedure (TPPP): Diagnosis (dx) of thrombocytopenia. Baseline platelet count is less than 50,000/mcL. Patient has chronic liver disease and is scheduled to undergo a procedure.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 month

OTHER CRITERIA
N/A

MVASI (S)

MEDICATION(S)
MVASI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Non-Small Cell Lung Cancer: Excluded if squamous cell histology.

REQUIRED MEDICAL INFORMATION
Colorectal Cancer: Diagnosis of metastatic colorectal cancer. One of the following: 1) Both of the following: a) used as first- or second-line treatment and b) used in combination with an intravenous 5-fluorouracil-based chemotherapy, OR 2) All of the following: a) used as second-line treatment, b) used in combination with fluoropyrimidine-irinotecan-based chemotherapy or fluoropyrimidine-oxaliplatin-based chemotherapy, and c) patient has progressed on a first-line bevacizumab-containing regimen. Non-Small Cell Lung Cancer (NSCLC): Diagnosis of NSCLC. Disease is unresectable, locally advanced, recurrent, or metastatic. Used as first-line treatment. Used in combination with paclitaxel and carboplatin. Renal Cell Cancer: Diagnosis of metastatic renal cell cancer. Used in combination with interferon-alpha. Cervical Cancer: Diagnosis of carcinoma of the cervix. Disease is persistent, recurrent, or metastatic. Used in combination with one of the following: a) paclitaxel and cisplatin or b) paclitaxel and topotecan. Glioblastoma: Diagnosis of recurrent glioblastoma. Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer: Diagnosis of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. One of the following: 1) All of the following: a) disease is stage 3 or 4, b) patient has been treated with bevacizumab as a single agent, c) treatment is following surgical resection, and d) used in combination with carboplatin and paclitaxel, OR 2) All of the following: a) disease is platinum-resistant recurrent, b) patient has received no more than 2 prior chemotherapy regimens, and c) used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, OR 3) All of the following: a) disease is platinum-sensitive recurrent, b) patient has been treated with bevacizumab as a single agent, and c) used in combination with one of the following: i) carboplatin and paclitaxel or ii) carboplatin and gemcitabine.

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.

MYALEPT (S)

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 one of the following: 1) Diabetes mellitus or insulin resistance despite optimized insulin therapy at maximum tolerated doses OR 2) Hypertriglyceridemia despite optimized therapy with at least two triglyceride-lowering agents from different classes (e.g., fibrates, statins).

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial, reauth: 12 months

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

MYCAPSSA (S)

MEDICATION(S)
MYCAPSSA

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. One of the following: 1) Inadequate response to surgical resection and/or pituitary irradiation, or 2) Patient is not a candidate for surgical resection or pituitary irradiation. Patient has responded to and tolerated treatment with octreotide or lanreotide.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Acromegaly (initial, reauth): 12 months

OTHER CRITERIA
Acromegaly (reauth): Documentation of positive clinical response to therapy (e.g., reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size)

MYFEMBREE (S)

MEDICATION(S)
MYFEMBREE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids). Patient is premenopausal. One of the following: 1) History of inadequate control of bleeding following a trial of at least 3 months, or history of intolerance or contraindication to one of the following: combination (estrogen/progestin) contraceptive, progestins, or tranexamic acid or 2) Patient has had a previous interventional therapy to reduce bleeding. Treatment duration of therapy has not exceeded a total of 24 months.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Reauth: Patient has improvement in bleeding associated with uterine leiomyomas (fibroids) (e.g., significant/sustained reduction in menstrual blood loss per cycle, improved quality of life, etc.). Treatment duration of therapy has not exceeded a total of 24 months.

NAGLAZYME (S)

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

NATPARA (S)

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. Not used in the setting of acute post-surgical hypoparathyroidism. Patient does not have a known calcium-sensing receptor mutation. Patient has a documented parathyroid hormone concentration that is inappropriately low for the level of calcium, recorded on at least two occasions within the previous 12 months. Patient has normal thyroid-stimulating hormone concentrations if not on thyroid hormone replacement therapy (or if on therapy, the dose had to have been stable for greater than or equal to 3 months). Patient has normal magnesium and serum 25-hydroxyvitamin D concentrations. Will be used as an adjunct treatment.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial: 6 months. Reauth: 12 months

OTHER CRITERIA
Hypocalcemia (Reauth): One of the following: A) Patient has achieved and maintained serum calcium levels in the ideal range (7.5 - 10.6 mg/dL), OR B) Patient has experienced a 50% or greater reduction in oral calcium intake, OR C) Patient has experienced a 50% or greater reduction in oral vitamin D intake.

NERLYNX (S)

MEDICATION(S)
NERLYNX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Early Stage Breast cancer: Diagnosis (dx) of early stage breast cancer. Disease is human epidermal growth factor receptor 2 (HER2)-positive. Patient has received adjuvant trastuzumab-based therapy. Advanced or Metastatic Breast Cancer: Dx of advanced or metastatic breast cancer. Disease is human epidermal growth factor receptor 2 (HER2)-positive. Patient has received two or more prior anti-HER2 based regimens (e.g., trastuzumab + pertuzumab + docetaxel, ado-trastuzumab emtansine, etc.). Used in combination with capecitabine.

AGE 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.

NEULASTA (S)

MEDICATION(S)
NEULASTA, NEULASTA ONPRO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Febrile neutropenia (FN) prophylaxis: Patient will be receiving prophylaxis for FN due to one of the following: 1) Patient is receiving National Cancer Institute¿s Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown, 3) patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN, 4) both of the following: a) patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN, AND b) patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia, OR 5) Both of the following: a) patient is receiving myelosuppressive anticancer drugs associated with neutropenia, AND b) patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis). Acute radiation syndrome (ARS): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS). Treatment of FN: Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia. Diagnosis of FN. Patient is at high risk for infection-associated complications.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
ARS: 1 mo. FN (prophylaxis, treatment): 3 mo or duration of tx.

OTHER CRITERIA

N/A

NEXAVAR (S)

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. Hepatocellular carcinoma (HCC): Diagnosis of HCC. One of the following: patient has metastatic disease, or patient has extensive liver tumor burden, or patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only), or disease is unresectable. Differentiated thyroid carcinoma (DTC): Diagnosis of DTC (ie, follicular carcinoma, Hurthle cell carcinoma, or papillary carcinoma). One of the following: locally recurrent disease, metastatic disease, or unresectable disease. One of the following: patient has symptomatic disease or patient has progressive disease. Disease is refractory to radioactive iodine (RAI) treatment. Medullary thyroid carcinoma (MTC): Diagnosis of MTC. One of the following: 1) Disease is progressive or 2) Disease is symptomatic with distant metastases. Trial and failure, contraindication, or intolerance to Caprelsa (vandetanib) or Cometriq (cabozantinib).

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA

Approve for continuation of prior therapy.

NEXLETOL (S)

MEDICATION(S)
NEXLETOL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: One of the following diagnoses: A) Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following: (1) Both of the following: a) Untreated/pre-treatment LDL-C greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age), AND b) One of the following: i) Family history (hx) of myocardial infarction in 1st-degree relative less than 60 years of age, ii) Family hx of myocardial infarction in 2nd-degree relative less than 50 years of age, iii) Family hx of LDL-C greater than 190 mg/dL in 1st- or 2nd-degree relative, iv) Family hx of FH in 1st- or 2nd-degree relative, or v) Family hx of tendinous xanthomas and/or arcus cornealis in 1st- or 2nd-degree relative, or (2) Both of the following: a) Untreated/pre-treatment LDL-C greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age), AND b) One of the following: i) Functional mutation in the LDL receptor, ApoB, or PCSK9 gene, ii) Tendinous xanthomata, or iii) Arcus cornealis before age 45 OR B) Atherosclerotic cardiovascular disease (ASCVD) as confirmed by acute coronary syndromes, hx of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization (eg, percutaneous coronary intervention [PCI] or coronary artery bypass graft [CABG] surgery), stroke, transient ischemic attack, peripheral arterial disease presumed to be of atherosclerotic origin, or clinically significant coronary heart disease diagnosed by invasive or noninvasive testing (e.g., coronary angiography, stress test using treadmill, stress echocardiography or nuclear imaging). One of the following LDL-C values while on max tolerated statin tx within the last 120 days: (1) LDL-C greater than or equal to 70 mg/dL with ASCVD or (2) LDL-C greater than or equal to 100 mg/dL without ASCVD.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 6 months. Reauth: 12 months

OTHER CRITERIA

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

NINLARO (S)

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.

NON-PREFERRED TIRF (S)

MEDICATION(S)

ABSTRAL 400 MCG TAB SUBLINGUAL, ABSTRAL 600 MCG TAB SUBLINGUAL, ABSTRAL 800 MCG TAB SUBLINGUAL, FENTANYL CIT 100 MCG BUCCAL TB, FENTANYL CIT 200 MCG BUCCAL TB, FENTANYL CIT 400 MCG BUCCAL TB, FENTANYL CIT 600 MCG BUCCAL TB, FENTANYL CIT 800 MCG BUCCAL TB, LAZANDA 100 MCG NASAL SPRAY, LAZANDA 400 MCG NASAL SPRAY

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

NORTHERA (S)

MEDICATION(S)
DROXIDOPA, 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 (eg, Parkinson's disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, non-diabetic autonomic neuropathy. Trial and failure, contraindication, or intolerance to one of the following agents: fludrocortisone acetate, midodrine.

AGE 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 (S)

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): 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. Trial and failure, contraindication, or intolerance to one of the following disease-modifying therapies for MS: Avonex (interferon beta-1a), Aubagio (teriflunomide), Betaseron (interferon beta-1b), Copaxone/Glatopa (glatiramer acetate), Extavia (interferon beta-1b), Gilenya (fingolimod), Lemtrada (alemtuzumab), Mavenclad (cladribine), Mayzent (siponimod), Ocrevus (ocrelizumab), Plegridy (peginterferon beta-1a), Rebif (interferon beta-1a), Tecfidera (dimethyl fumarate), Tysabri (natalizumab). 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): 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): 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
PC: Prescribed by or in consultation with an oncologist. ANLL: Prescribed by or in consultation with a hematologist/oncologist.

COVERAGE DURATION

All Uses: 6 months

OTHER CRITERIA

Approve for continuation of prior therapy.

NPLATE (S)

MEDICATION(S)
NPLATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Immune thrombocytopenia (ITP): Diagnosis of one of the following: a) ITP or b) relapsed/refractory ITP. Baseline platelet count is less than 30,000/mcL. Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding. Trial and failure, contraindication, or intolerance to one of the following: corticosteroids (e.g., dexamethasone, prednisone), immune globulins (e.g., Gammaplex, Gammagard S/D), or splenectomy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
ITP (initial): Prescribed by or in consultation with a hematologist/oncologist.

COVERAGE DURATION
ITP (initial, reauth): 12 months

OTHER CRITERIA
ITP (reauth): Documentation of positive clinical response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding.

NUBEQA (S)

MEDICATION(S)
NUBEQA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Non-metastatic castration-resistant or castration-recurrent prostate cancer (nmCRPC): Diagnosis of non-metastatic castration-resistant (chemical or surgical) or castration-recurrent prostate cancer.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

NUCALA (S)

MEDICATION(S)
NUCALA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Asthma (init): Diagnosis of severe asthma. Asthma is an eosinophilic phenotype as defined by one of the following: baseline (pre-treatment) peripheral blood eosinophil level is greater than or equal to 150 cells/microliter or peripheral blood eosinophil levels were greater than or equal to 300 cells/microliter within the past 12 months. Patient has had at least one or more asthma exacerbations requiring systemic corticosteroids within the past 12 months or Patient has had any prior intubation for an asthma exacerbation or Patient has had a prior asthma-related hospitalization within the past 12 months. Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) High-dose inhaled corticosteroid (ICS) [e.g., greater than 500 mcg fluticasone propionate equivalent/day] and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), tiotropium], OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone/vilanterol)]. Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) (init): Diagnosis of CRSwNP. Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone). Used in combination with another agent for CRSwNP. Eosinophilic Granulomatosis with Polyangiitis (EGPA) (init): Diagnosis of EGPA. Patient's disease has relapsed or is refractory to standard of care therapy (i.e., corticosteroid treatment with or without immunosuppressive therapy). Patient is currently receiving corticosteroid therapy (e.g., prednisolone, prednisone).

AGE RESTRICTION
Asthma (init): Age greater than or equal to 6 years

PRESCRIBER RESTRICTION

Asthma (init, reauth): Prescribed by or in consultation with a pulmonologist or allergist/immunologist. CRSwNP (init, reauth): Prescribed by or in consultation with an allergist/immunologist, otolaryngologist, or pulmonologist. EGPA (init): Prescribed by or in consultation with a pulmonologist, rheumatologist or allergist/immunologist. HES (init): Prescribed by or in consultation with an allergist/immunologist or hematologist.

COVERAGE DURATION

Asthma (init): 6 mo, Asthma (reauth): 12 months. CRSwNP, EGPA, HES (init, reauth): 12 months

OTHER CRITERIA

Hypereosinophilic Syndrome (HES) (init): Diagnosis of HES. Patient has been diagnosed for at least 6 months. Verification that other non-hematologic secondary causes have been ruled out (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy). Patient is FIP1L1-PDGFRA-negative. Patient has uncontrolled HES defined as both of the following: a) History of 2 or more flares within the past 12 months AND b) Pre-treatment blood eosinophil count greater than or equal to 1000 cells/microliter. Trial and failure, contraindication, or intolerance to corticosteroid therapy (e.g., prednisone) or cytotoxic/immunosuppressive therapy (e.g., hydroxyurea, cyclosporine, imatinib). Asthma (reauth): Documentation of positive clinical response to therapy (eg, reduction in exacerbations, improvement in forced expiratory volume in 1 second (FEV1), decreased use of rescue medications). Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), tiotropium], OR b) A combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone/vilanterol)]. CRSwNP (reauth): Documentation of positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS, 0-8 scale], improvement in nasal obstruction symptoms via visual analog scale [VAS, 0-10 scale]). Used in combination with another agent for CRSwNP. EGPA (reauth): Documentation of positive clinical response to therapy (e.g., increase in remission time). HES (reauth): Documentation of positive clinical response to therapy (e.g., reduction in flares, decreased blood eosinophil count, reduction in corticosteroid dose).

NUEDEXTA (S)

MEDICATION(S)
NUEDEXTA

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. Patient does not have any of the following contraindications: a) Concomitant use with other drugs containing quinidine, quinine, or mefloquine, b) History of Nuedexta, quinine, mefloquine or quinidine-induced thrombocytopenia, hepatitis, bone marrow depression, or lupus-like syndrome, c) Known hypersensitivity to dextromethorphan (e.g., rash, hives), d) Taking monoamine oxidase inhibitors (MAOIs) (e.g., phenelzine, selegiline, tranylcypromine) or have taken MAOIs within the preceding 14 days, e) Has prolonged QT interval, congenital long QT syndrome or a history suggestive of torsades de pointes, or has heart failure, f) Receiving drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine, pimozide), g) Has complete atrioventricular (AV) block without implanted pacemakers, or at high risk of complete AV block. PBA (reauth): Documentation of clinical benefit from ongoing therapy as demonstrated by a decrease in inappropriate laughing or crying episodes.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PBA (initial): Prescribed by or in consultation with one of the following specialists: neurologist, psychiatrist.

COVERAGE DURATION
PBA (initial/reauth): 12 months

OTHER CRITERIA

N/A

NULOJIX (S)

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
Approve for continuation of prior therapy.

NUPLAZID (S)

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.

NURTEC (S)

MEDICATION(S)
NURTEC ODT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Acute Treatment of Migraine (initial): Diagnosis of migraine with or without aura. Will be used for the acute treatment of migraine. Patient has fewer than 15 headache days per month. Trial and failure or intolerance to one triptan (e.g., eletriptan, rizatriptan, sumatriptan) or a contraindication to all triptans. If patient has 4 or more headache days per month, patient must meet one of the following: a) currently being treated with Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications, OR b) currently being treated with Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications, OR c) currently being treated with a beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications. Medication will not be used in combination with another oral CGRP inhibitor.

AGE RESTRICTION
All Indications (initial): 18 years of age or older.

PRESCRIBER RESTRICTION
All Indications (initial, reauth): Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.

COVERAGE DURATION
Acute Treatment (init): 3mo. Preventive Treatment (init): 6mo. All Indications (reauth): 12mo.

OTHER CRITERIA
Preventive Treatment of Episodic Migraine (EM) (initial): Both of the following: 1) Diagnosis of EM and

2) Patient has 4 to 18 migraine days per month, but no more than 18 headache days per month. Two of the following: a) History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine), OR patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine), b) History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate), OR patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate), or c) History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol, OR patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol. Medication will not be used in combination with an injectable CGRP inhibitor. Acute Treatment of Migraine (reauth): Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea). Medication will not be used in combination with another oral CGRP inhibitor. Preventive Treatment of EM (reauth): Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity. Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy. Medication will not be used in combination with an injectable CGRP inhibitor.

NUVIGIL (S)

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 (OSA) (Initial): Diagnosis (dx) of OSA defined by one of the following: a) 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), or b) both of the following: 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), AND 1 of the following symptoms: unintentional sleep episodes during wakefulness, daytime sleepiness, unrefreshing sleep, fatigue, insomnia, waking up breath holding/gasping/choking, loud snoring, or breathing interruptions during sleep. Shift-work disorder (SWD) (Initial):Dx of SWD confirmed by one of the following: 1) symptoms of excessive sleepiness or insomnia for at least 3 months, which is associated with a work period (usually night work) that occurs during the normal sleep period, OR 2) A sleep study demonstrating loss of a normal sleep-wake pattern (ie, disturbed chronobiologic rhythmicity). Confirmation that no other medical conditions or medications are causing the symptoms of excessive sleepiness or insomnia. Narcolepsy (initial): Dx of narcolepsy as confirmed by sleep study (unless prescriber provides justification confirming that a sleep study is not feasible).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
OSA, SWD: Initial, Reauth: 6 mo. Narcolepsy: Initial, Reauth: 12 mo

OTHER CRITERIA

OSA, Narcolepsy (Reauth): Documentation of positive clinical response to armodafinil therapy. SWD (Reauth): Documentation of positive clinical response to armodafinil therapy.

NYVEPRIA (S)

MEDICATION(S)
NYVEPRIA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Febrile neutropenia (FN) prophylaxis: Patient will be receiving prophylaxis for FN due to one of the following: 1) Patient is receiving National Cancer Institutes Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown, 3) patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN, 4) both of the following: a) patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN, AND b) patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia, OR 5) both of the following: a) patient is receiving myelosuppressive anticancer drugs associated with neutropenia, AND b) patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis). Treatment of FN (off-label): Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia. Diagnosis of FN. Patient is at high risk for infection-associated complications. Acute radiation syndrome (ARS) (off-label): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS).

AGE RESTRICTION
N/A

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

COVERAGE DURATION
ARS: 1 mo. FN (prophylaxis, treatment): 3 mo or duration of tx.

OTHER CRITERIA

All Indications: Trial and failure or intolerance to both of the following: Neulasta/Neulasta Onpro AND Udenyca.

OCALIVA (S)

MEDICATION(S)
OCALIVA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED 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 treatment with ursodeoxycholic acid (UDCA) (e.g., Urso, Urso Forte, ursodiol) AND used in combination with UDCA, OR b) contraindication or intolerance to UDCA. Patient does not have evidence of advanced cirrhosis (i.e., cirrhosis with current or prior evidence of hepatic decompensation including encephalopathy or coagulopathy). Patient does not have evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia).

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 obeticholic acid therapy) while on therapy. Patient does not have evidence of advanced cirrhosis (i.e., cirrhosis with current or prior evidence of hepatic decompensation including encephalopathy or coagulopathy). Patient does not have evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia).

OCREVUS (S)

MEDICATION(S)
OCREVUS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Relapsing forms of multiple sclerosis (initial): Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., relapsing-remitting MS, secondary-progressive MS with relapses). One of the following: a) Failure after a trial of at least 4 weeks, contraindication, or intolerance to one of the following disease-modifying therapies for MS: Aubagio (teriflunomide), Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone/Glatopa (glatiramer acetate), Extavia (interferon beta-1b), Gilenya (fingolimod), Lemtrada (alemtuzumab), Mavenclad (cladribine), Mayzent (siponimod), Plegridy (peginterferon beta-1a), Rebif (interferon beta-1a), Tecfidera (dimethyl fumarate), Tysabri (natalizumab), OR b) Patient is not a candidate for any of the drugs listed as prerequisites due to the severity of their multiple sclerosis, OR c) For continuation of prior Ocrevus therapy. Primary progressive MS (initial): Diagnosis of primary progressive multiple sclerosis (PPMS). All indications (initial, reauth): Not used in combination with another disease-modifying therapy for MS. Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra]). Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA

All indications (reauth): Documentation of positive clinical response to therapy.

ODOMZO (S)

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 (S)

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

IPF, SSc-ILD, Chronic Fibrosing ILDs with a Progressive Phenotype (initial): Prescribed by or in consultation with a pulmonologist

COVERAGE DURATION

Initial, reauth: 12 months

OTHER CRITERIA

IPF, SSc-ILD, Chronic Fibrosing ILDs with a Progressive Phenotype (reauth): Documentation of positive clinical response to therapy.

OLUMIANT (S)

MEDICATION(S)
OLUMIANT

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: a) Either a trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib), or attestation demonstrating a trial may be inappropriate, OR b) For continuation of prior therapy. Not used in combination with a potent immunosuppressant (e.g., azathioprine, cyclosporine).

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial, reauth: 12 months

OTHER CRITERIA
Reauth: Documentation of positive clinical response to therapy. Not used in combination with a potent immunosuppressant (e.g., azathioprine, cyclosporine).

ONPATTRO (S)

MEDICATION(S)
ONPATTRO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) (initial): Diagnosis of hATTR amyloidosis with polyneuropathy. Patient has a transthyretin (TTR) mutation (e.g., V30M). Patient has a baseline polyneuropathy disability (PND) score less than or equal to IIIb, a baseline familial amyloidotic polyneuropathy (FAP) stage of 1 or 2, or a baseline neuropathy impairment score (NIS) between 10 and 130. Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
hATTR amyloidosis (initial): Prescribed by or in consultation with a neurologist

COVERAGE DURATION
hATTR amyloidosis (initial, reauth): 12 months

OTHER CRITERIA
Subject to Part B vs D review. hATTR amyloidosis (reauth): Patient has demonstrated a benefit from therapy (e.g., improved neurologic impairment, slowing of disease progression, quality of life assessment). Patient continues to have a PND score less than or equal to IIIb, a FAP stage of 1 or 2, or a NIS between 10 and 130.

ONTRUZANT (S)

MEDICATION(S)
ONTRUZANT

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) Platinol (cisplatin) and 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.

ONUREG (S)

MEDICATION(S)
ONUREG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Acute Myeloid Leukemia (AML): Diagnosis of acute myeloid leukemia (AML). Patient has received previous treatment with an intensive induction chemotherapy regimen (e.g., cytarabine + daunorubicin, cytarabine + idarubicin, etc.). Patient has achieved one of the following: a) first complete remission (CR) or b) complete remission with incomplete blood count recovery (CRi). Patient is not able to complete intensive curative therapy.

AGE 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.

OPSUMIT (S)

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.

ORENCIA IV (S)

MEDICATION(S)
ORENCIA 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. One of the following: a) Trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), or Xeljanz/Xeljanz XR (tofacitinib), or b) attestation demonstrating a trial may be inappropriate, OR c) For continuation of prior Orencia therapy. Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. JIA, PsA (Initial): One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior Orencia therapy.

AGE RESTRICTION
N/A

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

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

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

ORENCIA SC (S)

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: a) Either a trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib), or attestation demonstrating a trial may be inappropriate, OR b) For continuation of prior therapy. Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. One of the following: a) Either a trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR b) for continuation of prior therapy. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: a) Either a trial and failure, contraindication, or intolerance to Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR b) for continuation of prior therapy.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

RA, JIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist.

COVERAGE DURATION

All uses (initial, reauth): 12 months

OTHER CRITERIA

All indications (Reauth): Documentation of positive clinical response to therapy.

ORENITRAM (S)

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.

ORGOVYX (S)

MEDICATION(S)
ORGOVYX

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 prostate cancer. Disease is one of the following: 1) Evidence of biochemical or clinical relapse following local primary intervention with curative intent or 2) Newly diagnosed androgen-sensitive metastatic disease or 3) Advanced localized disease unlikely to be cured by local primary intervention with curative intent.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

ORIAHNN (S)

MEDICATION(S)
ORIAHNN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids). Patient is premenopausal. One of the following: 1) History of inadequate control of bleeding following a trial of at least 3 months, or history of intolerance or contraindication to one of the following: combination (estrogen/progestin) contraceptive, progestins, or tranexamic acid or 2) Patient has had a previous interventional therapy to reduce bleeding. Treatment duration of therapy has not exceeded a total of 24 months.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Reauth: Patient has improvement in bleeding associated with uterine leiomyomas (fibroids) (e.g., significant/sustained reduction in menstrual blood loss per cycle, improved quality of life, etc.). Treatment duration of therapy has not exceeded a total of 24 months.

ORILISSA (S)

MEDICATION(S)
ORILISSA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Endometriosis (EM) (initial - 150 mg): Diagnosis of moderate to severe pain associated with EM. One of the following: 1) History of inadequate pain control response following a trial of at least 3 months, or history of intolerance or contraindication to one of the following: danazol, combination (estrogen/progesterone) oral contraceptive, or progestins, or 2) Patient has had surgical ablation to prevent recurrence. EM (200 mg): Diagnosis of moderate to severe pain associated with EM. One of the following: 1) History of inadequate pain control response following a trial of at least 3 months, or history of intolerance or contraindication to one of the following: danazol, combination (estrogen/progesterone) oral contraceptive, or progestins, or 2) Patient has had surgical ablation to prevent recurrence.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
EM (init, reauth-150mg): 6 mo. EM (200mg): 6 mo.

OTHER CRITERIA
EM (reauthorization - 150 mg): Patient has improvement in pain associated with endometriosis (e.g., improvement in dysmenorrhea and nonmenstrual pelvic pain). Treatment duration has not exceeded a total of 24 months.

ORKAMBI (S)

MEDICATION(S)
ORKAMBI 100 MG-125 MG TABLET, ORKAMBI 200 MG-125 MG TABLET

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 as detected by a U.S. Food and Drug Administration (FDA)-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).

AGE RESTRICTION
CF (Initial): Patient is 6 years of age or older

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

COVERAGE DURATION
CF (initial, reauth): 12 months

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

ORKAMBI GRANULES (S)

MEDICATION(S)
ORKAMBI 100-125 MG GRANULE PKT, ORKAMBI 150-188 MG GRANULE PKT

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 as detected by a U.S. Food and Drug Administration (FDA)-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). One of the following: A) Patient is 2 through 5 years of age, OR B) Both of the following: Patient is 6 years of age or greater AND Patient is unable to swallow oral tablets.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
CF (initial, reauth): 12 months

OTHER CRITERIA
CF (Reauth): Patient is benefiting from treatment (i.e., improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations). One of the following: A) Patient is 2 through 5 years of age, OR B) Both of the following: Patient is 6 years of age or greater AND Patient is unable to swallow oral tablets.

ORLADEYO (S)

MEDICATION(S)
ORLADEYO

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.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
HAE (prophylaxis): Prescribed by or in consultation with an immunologist or allergist

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

OSPHENA (S)

MEDICATION(S)
OSPHENA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Dyspareunia (initial): Diagnosis of moderate to severe dyspareunia due to vulvar and vaginal atrophy associated with menopause. Vaginal dryness (initial): Diagnosis of moderate to severe vaginal dryness due to vulvar and vaginal atrophy associated with menopause.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
Dyspareunia, Vaginal dryness (reauth): Documentation of positive clinical response to therapy.

OTEZLA (S)

MEDICATION(S)
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. One of the following: a) Either a trial and failure, contraindication, or intolerance to Humira (adalimumab) and Enbrel (etanercept), or attestation demonstrating a trial may be inappropriate, OR b) for continuation of prior therapy. Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: set A) Both of the following: 1) Trial and failure, contraindication, or intolerance to one of the following: Enbrel (etanercept), Humira (adalimumab), or Skyrizi (risankizumab), AND 2) Trial and failure, contraindication, or intolerance to Cosentyx (secukinumab), or set B) for continuation of prior therapy. Oral ulcers associated with Behcet's Disease (Initial): Diagnosis of Behcet's Disease. Patient has active oral ulcers.

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
Reauth (PsA): Documentation of positive clinical response to therapy. Reauth (plaque psoriasis): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction

in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. Reauth (oral ulcers associated with Behcet¿s Disease): Documentation of positive clinical response to therapy (eg, reduction in pain from oral ulcers or reduction in number of oral ulcers).

OXANDRIN (S)

MEDICATION(S)
OXANDROLONE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Promote weight gain (initial): Used as adjunctive therapy to promote weight gain AND Diagnosis of one of the following: Extensive surgery, Chronic infections, Severe trauma, Failure to gain or maintain at least 90% of ideal body weight without definite pathophysiologic reasons AND a nutritional consult was performed. Counterbalance protein catabolism (initial): Used to counterbalance protein catabolism associated with chronic corticosteroid administration. Bone pain: Diagnosis of bone pain associated with osteoporosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
All diagnoses except bone pain (reauth): Documentation of a positive clinical response to therapy as evidenced by an improvement in weight gain or increase in lean body mass.

OXBRYTA (S)

MEDICATION(S)
OXBRYTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of Sickle Cell Disease. Documentation of hemoglobin level that does not exceed 10.5 g/dL prior to therapy initiation. Trial and failure or inadequate response, contraindication, or intolerance to hydroxyurea.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Initial: Prescribed by or in consultation with one of the following: 1) Hematologist/Oncologist or 2) Specialist w/ expertise in the diagnosis and management of sickle cell disease.

COVERAGE DURATION
Initial, Reauth: 12 months.

OTHER CRITERIA
Reauth: Documentation of positive clinical response to therapy (e.g., an increase in hemoglobin level of 1 g/dL or greater from baseline, decreased annualized incidence rate of vaso-occlusive crises [VOCs]). Documentation of hemoglobin level that does not exceed 10.5 g/dL.

OXERVATE (S)

MEDICATION(S)
OXERVATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Neurotrophic keratitis (NK): Diagnosis of NK.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an ophthalmologist or optometrist.

COVERAGE DURATION
8 weeks.

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, ADRUCIL, AKYNZEO 300-0.5 MG CAPSULE, ALBUTEROL 100 MG/20 ML SOLN, 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 15% IV SOLUTION, AMINOSYN-PF 10% IV SOLUTION, AMPHOTERICIN B, APREPITANT, AZASAN, AZATHIOPRINE 50 MG TABLET, BLEOMYCIN SULFATE, BUDESONIDE 0.25 MG/2 ML SUSP, BUDESONIDE 0.5 MG/2 ML SUSP, BUDESONIDE 1 MG/2 ML INH SUSP, CLINISOL, 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, CYTARABINE, EMEND 125 MG POWDER PACKET, ENGERIX-B ADULT, ENGERIX-B PEDIATRIC-ADOLESCENT, EVEROLIMUS 0.25 MG TABLET, EVEROLIMUS 0.5 MG TABLET, EVEROLIMUS 0.75 MG TABLET, FENTANYL 1,000 MCG/20 ML VIAL, FENTANYL 100 MCG/2 ML AMPUL, FENTANYL 100 MCG/2 ML CARPUJCT, FENTANYL 100 MCG/2 ML SYRINGE, FENTANYL 100 MCG/2 ML VIAL, FENTANYL 2,500 MCG/50 ML VIAL, FENTANYL 250 MCG/5 ML AMPUL, FENTANYL 250 MCG/5 ML VIAL, FENTANYL 50 MCG/ML VIAL, FENTANYL 500 MCG/10 ML VIAL, FLUOROURACIL 1 GRAM/20 ML VIAL, FLUOROURACIL 2.5 GRAM/50 ML VL, FLUOROURACIL 5 GRAM/100 ML VL, FLUOROURACIL 500 MG/10 ML VIAL, FORMOTEROL FUMARATE, GANCICLOVIR SODIUM, GENGRAF, GRANISETRON HCL 1 MG TABLET, HEPAGAM B, HYPERHEP B, HYPERRAB, IMOVAX RABIES VACCINE, INTRALIPID 20% IV FAT EMUL, IPRATROPIUM BR 0.02% SOLN, IPRATROPIUM-ALBUTEROL, LEUCOVORIN CAL 100 MG/10 ML VL, LEUCOVORIN CAL 500 MG/50 ML VL, LEVALBUTEROL CONCENTRATE, LEVALBUTEROL HCL, MORPHINE SULFATE 1 MG/ML VIAL, MORPHINE SULFATE 10 MG/ML VIAL, MORPHINE SULFATE 4 MG/ML VIAL, MORPHINE SULFATE 5 MG/ML VIAL, MORPHINE SULFATE 8 MG/ML VIAL, MYCOPHENOLATE 200 MG/ML SUSP, MYCOPHENOLATE 250 MG CAPSULE, MYCOPHENOLATE 500 MG TABLET, MYCOPHENOLIC ACID, NABI-HB, NUTRILIPID, ONDANSETRON 4 MG/5 ML SOLUTION, ONDANSETRON HCL 24 MG TABLET, ONDANSETRON HCL 4 MG TABLET, ONDANSETRON HCL 8 MG TABLET, ONDANSETRON ODT, PENTAMIDINE 300 MG INHAL POWDR, PERFOROMIST, PLENAMINE, PROGRAF 0.2 MG GRANULE PACKET, PROGRAF 1 MG GRANULE PACKET, RABAVERT, RECOMBIVAX HB, 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 (IR), TACROLIMUS 1 MG CAPSULE (IR), TACROLIMUS 5 MG CAPSULE (IR), TOBRAMYCIN 300 MG/4 ML AMPULE, TOBRAMYCIN 300

MG/5 ML AMPULE, YUPELRI, ZORTRESS 1 MG TABLET

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.

PEGASYS (S)

MEDICATION(S)
PEGASYS, PEGASYS PROCLICK 180 MCG/0.5

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
HepB: 48 wks. HepC: Initial: 28 wks. Reauth: 20 wks.

OTHER CRITERIA
N/A

PEMAZYRE (S)

MEDICATION(S)
PEMAZYRE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of cholangiocarcinoma. Disease is one of the following: unresectable locally advanced or metastatic. Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement. Patient has been previously treated.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hepatologist, gastroenterologist, or oncologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

PENNSAID (S)

MEDICATION(S)
DICLOFENAC 1.5% TOPICAL SOLN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Osteoarthritis of the knees (initial): Diagnosis of osteoarthritis of the knees. Patient meets one of the following: 1) Treatment failure with at least two prescription strength non-steroidal anti-inflammatory drugs (NSAIDs) OR 2) History of peptic ulcer disease/gastrointestinal bleed OR 3) Patient is older than 65 years of age with one additional risk factor for gastrointestinal adverse events (e.g. use of anticoagulants, chronic corticosteroids).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial, reauth: 12 months

OTHER CRITERIA
Osteoarthritis of the knees (reauth): Documentation of positive clinical response to therapy (e.g., improvement in pain symptoms of osteoarthritis).

PHESGO (S)

MEDICATION(S)
PHESGO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Early Breast Cancer (EBC): Diagnosis of breast cancer. Used in combination with chemotherapy. Disease is human epidermal growth factor receptor 2 (HER2)-positive. One of the following: a) Used for neoadjuvant treatment and disease is one of the following: locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive), OR b) Used for adjuvant treatment and disease is early breast cancer at high risk of recurrence. Metastatic Breast Cancer (MBC): Diagnosis of breast cancer. Used in combination with docetaxel. Disease is human epidermal growth factor receptor 2 (HER2)-positive metastatic breast cancer. Patient has not received prior anti-HER2 therapy or chemotherapy for metastatic disease.

AGE 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.

PIQRAY (S)

MEDICATION(S)
PIQRAY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Breast Cancer (BC): Diagnosis of advanced or metastatic BC. Disease is hormone receptor (HR)-positive, and human epidermal growth factor receptor 2 (HER2)-negative. Cancer is PIK3CA-mutated as detected by an FDA-approved test (therascreen PIK3CA RGQ PCR Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient is a postmenopausal woman or male. Used in combination with fulvestrant. Disease has progressed on or after an endocrine-based regimen.

AGE 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.

POMALYST (S)

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. Kaposi sarcoma (KS): One of the following: 1) Both of the following: a) Diagnosis of AIDS-related KS and b) Patient has failed highly active antiretroviral therapy (HAART), OR 2) Both of the following: a) Diagnosis of KS and b) Patient is HIV-negative.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

PROCYSBI (S)

MEDICATION(S)
PROCYSBI DR 25 MG CAPSULE, PROCYSBI DR 75 MG CAPSULE

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
1 year of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

PROMACTA (S)

MEDICATION(S)
PROMACTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chronic immune (idiopathic) thrombocytopenic purpura (ITP) (initial): Diagnosis of one of the following: relapsed/refractory ITP or chronic ITP. Baseline platelet count is less than 30,000/mcL. Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding. Trial and failure, intolerance, contraindication to corticosteroids or immunoglobulins or splenectomy. Chronic hepatitis C (initial): Diagnosis of chronic hepatitis C-associated thrombocytpenia. One of the following: 1) Planning to initiate and maintain interferon-based treatment, or 2) currently receiving interferon-based treatment. First-line for severe aplastic anemia (SAA): Diagnosis of SAA. Used for first-line treatment (i.e., patient has not received prior immunosuppressive therapy). Used in combination with standard immunosuppressive therapy. Patient meets at least two of the following: 1) absolute neutrophil count less than 500/mcL, 2) platelet count less than 20,000/mcL, 3) absolute reticulocyte count less than 60,000/mcL. Refractory SAA (initial): Diagnosis of refractory severe aplastic anemia. Patient has a platelet count less than 30,000/mcL. Insufficient response to immunosuppressive therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Chronic ITP and SAA: Prescribed by or in consultation with a hematologist/oncologist. Chronic hepatitis C associated thrombocytopenia: Prescribed by or in consultation with a hematologist/oncologist, gastroenterologist, hepatologist, infectious disease specialist, or HIV specialist certified through the American Academy of HIV Medicine.

COVERAGE DURATION

ITP(init,reauth):12mo.HepC:3mo(init),12mo(reauth).1stline SAA:6mo.RefractSAA:16wk-init,12mo-reauth

OTHER CRITERIA

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

PROVIGIL (S)

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Narcolepsy: Init, Reauth: 12 mo. All other indications: Init, Reauth: 6 mo.

OTHER CRITERIA

OSA, Narcolepsy, Idiopathic Hypersomnia (Reauth): Documentation of positive clinical response to modafinil therapy. SWD (Reauth): Documentation of positive clinical response to modafinil therapy. MS Fatigue (reauth): Patient is experiencing relief of fatigue with modafinil therapy. Depression (reauth): Documentation of positive clinical response to modafinil therapy. Used as adjunctive therapy.

PULMOZYME (S)

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).

QINLOCK (S)

MEDICATION(S)
QINLOCK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Gastrointestinal Stromal Tumor (GIST): Diagnosis of gastrointestinal stromal tumor (GIST). Disease is advanced. Patient has received prior treatment with three or more kinase inhibitors (e.g., sunitinib, regorafenib), one of which must include imatinib.

AGE 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.

QUALAQUIN (S)

MEDICATION(S)
QUININE SULFATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Excluded if used solely for the treatment or prevention of nocturnal leg cramps.

REQUIRED MEDICAL INFORMATION
Malaria: Diagnosis of uncomplicated malaria. One of the following: 1) Treatment in areas of chloroquine-sensitive malaria, and trial and failure, contraindication, or intolerance to chloroquine or hydroxychloroquine, OR 2) Treatment in areas of chloroquine-resistant malaria.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
7 days

OTHER CRITERIA
N/A

RADICAVA (S)

MEDICATION(S)
RADICAVA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Amyotrophic lateral sclerosis (ALS) (initial): Submission of medical records (e.g., chart notes, previous medical history, diagnostic testing including: imaging, nerve conduction studies, laboratory values) to support a diagnosis of “definite” or “probable” ALS per the revised El Escorial diagnostic criteria. Patient has scores of greater than or equal to 2 in all items of the ALS Functional Rating Scale-Revised (ALSFRS-R) criteria at the start of treatment. Patient has a percent forced vital capacity (%FVC) of greater than or equal to 80% at the start of treatment.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
ALS (initial): Prescribed by or in consultation with a neurologist.

COVERAGE DURATION
Initial, reauth: 6 months

OTHER CRITERIA
ALS (reauthorization): Documentation of a benefit from therapy (e.g., slowing in the decline of functional abilities), and Patient is not dependent on invasive ventilation or tracheostomy.

RAVICTI (S)

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
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
UCDs (Initial, reauth): 12 months

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

REBLOZYL (S)

MEDICATION(S)
REBLOZYL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Beta Thalassemia (initial): One of the following: a) Diagnosis of beta thalassemia major AND patient requires regular red blood cell (RBC) transfusions, OR b) Diagnosis of transfusion-dependent beta thalassemia. MDS-RS, MDS/MPN-RS-T (initial): One of the following diagnoses: a) Very low-to intermediate-risk myelodysplastic syndrome with ring sideroblasts (MDS-RS), OR b) Myelodysplastic or myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T). Patient has failed an erythropoiesis stimulating agent [e.g., Epogen (epoetin alfa), Aranesp (darbepoetin)]. Patient requires transfusions of 2 or more red blood cell (RBC) units over 8 weeks.

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
Beta Thalassemia (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in RBC transfusion burden). MDS-RS, MDS/MPN-RS-T (reauth): Documentation of a positive clinical response to therapy (e.g., RBC transfusion independence, improvement in hemoglobin levels).

REMICADE (S)

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 (e.g., diclofenac, ibuprofen, meloxicam, naproxen). Psoriatic arthritis (PsA) (Initial): Dx of active PsA. Plaque psoriasis (Initial): Dx of chronic severe (ie, extensive and/or disabling) plaque psoriasis. Sarcoidosis (initial): TF/C/I to one immunosuppressant [eg, methotrexate (Rheumatrex/Trexall), cyclophosphamide, or azathioprine (Imuran)] AND TF/C/I to one corticosteroid (eg, prednisone).

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 uses (initial, reauth): 12 months

OTHER CRITERIA

Reauth (CD, UC, AS, PsA, RA): Documentation of positive clinical response to therapy. Reauth (plaque psoriasis): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline.

RENFLEXIS (S)

MEDICATION(S)
RENFLEXIS

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 (e.g., diclofenac, ibuprofen, meloxicam, naproxen). All indications (initial): One of the following: 1) Trial and failure or intolerance to Remicade or 2) For continuation of prior Renflexis therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Initial: RA, AS: Prescribed by or in consultation with a rheumatologist. PsA: Prescribed or in consultation with a rheumatologist or dermatologist. Crohn's Disease, Fistulizing Crohn's Disease, UC: Prescribed by or in consultation with a gastroenterologist. Plaque Psoriasis: Prescribed by or in consultation with a dermatologist.

COVERAGE DURATION

All indications (initial, reauth): 12 months

OTHER CRITERIA

Reauthorization for CD, UC, AS, PsA, RA: Documentation of positive clinical response to therapy. Reauthorization (plaque psoriasis): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline.

REPATHA (S)

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

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

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

RETACRIT (S)

MEDICATION(S)
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 chemo (Initial):Other causes of anemia have been ruled out. Anemia by lab values (Hct less than 30%, Hgb less than 10 g/dL) collected within the prior 2 weeks of request. Cancer is a non-myeloid malignancy. Patient is receiving chemo. Preoperative for reduction of allogeneic blood transfusion: Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery. Hgb is greater than 10 to less than or equal to 13 g/dL. Patient is at high risk for perioperative transfusions. Patient is unwilling or unable to donate autologous blood pre-operatively. Anemia in hepatitis C virus (HCV)-infected pts due to ribavirin in combination with interferon/peg-interferon (Initial): Dx of HCV infection. Anemia by labs (Hct less than 36% or Hgb less than 12 g/dL) collected within 30 days of request. Patient is receiving ribavirin and one of the following: interferon alfa or peginterferon alfa. Anemia with HIV (Initial): Anemia by lab values (Hgb less than 12 g/dL or Hct less than 36%) collected within 30 days of request. Serum erythropoietin level less than or equal to 500 mU/mL. Receiving zidovudine therapy or dx of HIV. Anemia in Myelodysplastic Syndrome (MDS) (Initial): Dx of MDS. Serum erythropoietin level is 500 mU/mL or less, or dx of transfusion-dependent MDS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

CKD,HIV(Init):6mo. CKD,HIV(reauth):12mo. Chemo,HCV(all):3mo. MDS:(init) 3mo,(reauth)12mo. Preop:1mo.

OTHER CRITERIA

Subject to ESRD review. CKD (Reauth): Dx of CKD. One of the following: 1) Most recent or average (avg) Hct over 3 months is 33% or less (Hgb is 11 g/dL or less) for patients on dialysis, without ESRD, 2) Most recent or avg Hct over 3 mo is 30% or less (Hgb 10 g/dL or less) for patients not on dialysis, OR 3) Most recent or avg Hct over 3 mo is 36% or less (Hgb 12 g/dL or less) for pediatric patients. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. HIV (Reauth): Most recent or avg Hct over 3 months is below 36% or most recent or avg Hgb over 3 months is below 12 g/dl. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Chemo (Reauth): Anemia by lab values (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 weeks of request. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Patient is receiving chemo. HCV (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. If patient has demonstrated response to therapy, authorization will be issued for the full course of ribavirin therapy. MDS (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Other Off-label uses (except MDS, HCV): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%. CKD (init, reauth), HIV (init), Chemo (init), Preop, MDS (init), HCV (init): Verify iron evaluation for adequate iron stores.

RETEVMO (S)

MEDICATION(S)
RETEVMO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Lung Cancer: Diagnosis of metastatic non-small cell lung cancer (NSCLC). Disease has presence of RET gene fusion-positive tumor(s). Medullary Thyroid Cancer (MTC): Diagnosis of medullary thyroid cancer (MTC). Disease is advanced or metastatic. Disease has presence of RET gene mutation tumor(s). Disease requires treatment with systemic therapy. Thyroid Cancer: Diagnosis of thyroid cancer. Disease is advanced or metastatic. Disease has presence of RET gene fusion-positive tumor(s). Disease requires treatment with systemic therapy. Patient is radioactive iodine-refractory or radioactive iodine therapy is not appropriate.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Lung Cancer, MTC: Prescribed by or in consultation with an oncologist. Thyroid Cancer: Prescribed by or in consultation with an endocrinologist or an oncologist.

COVERAGE DURATION
Lung Cancer, MTC, Thyroid Cancer: 12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

REVATIO (S)

MEDICATION(S)
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.

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.

REVATIO SUSPENSION (S)

MEDICATION(S)
SILDENAFIL 10 MG/ML ORAL SUSP

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. 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.

REVCOVI (S)

MEDICATION(S)
REVCOVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of adenosine deaminase deficiency (ADA) with severe combined immunodeficiency (SCID).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

REVLIMID (S)

MEDICATION(S)
REVLIMID

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): Diagnosis of transfusion-dependent anemia due to low- or intermediate-1-risk MDS associated with a deletion 5q. Mantle cell lymphoma (MCL): Diagnosis of MCL. Disease has relapsed after, is refractory to, or progressed after at least one prior therapy (eg, bortezomib, bendamustine, cladribine, rituximab). Follicular Lymphoma (FL): Diagnosis of FL that has been previously treated. Used in combination with a rituximab product. Marginal Zone Lymphoma (MZL): Diagnosis of MZL that has been previously treated. Used in combination with a rituximab product.

AGE 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.

REZUROCK (S)

MEDICATION(S)
REZUROCK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chronic graft versus host disease (cGVHD) (initial): Diagnosis of cGVHD. Trial and failure of two or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
cGVHD (initial): Prescribed by or in consultation with one of the following: hematologist, oncologist, or physician experienced in the management of transplant patients.

COVERAGE DURATION
cGVHD (initial, reauth): 12 months

OTHER CRITERIA
cGVHD (reauth): Patient does not show evidence of progressive disease while on therapy.

RILUTEK (S)

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

RINVOQ (S)

MEDICATION(S)
RINVOQ

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 (TF/C/I) to one disease modifying antirheumatic drug (DMARD) [eg, methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)], OR for continuation of prior therapy. Not used in combination with a potent immunosuppressant (e.g., azathioprine, cyclosporine).

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 therapy. Not used in combination with a potent immunosuppressant (e.g., azathioprine, cyclosporine).

RITUXAN (S)

MEDICATION(S)
RITUXAN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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 for the treatment of follicular, CD20-positive, B-cell NHL in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, used as monotherapy for maintenance therapy, 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): Diagnosis of moderately to severely active RA. 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). Not received in combination with a biologic DMARD [e.g., Enbrel (etanercept), Orencia (abatacept), Kineret (anakinra)]. Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA): Diagnosis of WG or MPA. Patient is concurrently on glucocorticoids (eg, prednisone) OR contraindication or intolerance to glucocorticoids (eg, prednisone). Immune or idiopathic thrombocytopenic purpura (ITP): Diagnosis of ITP. TF/C/I to one of the following: glucocorticoids (e.g., prednisone, methylprednisolone), immune globulins (e.g., IVIG), or splenectomy. Documented platelet count of less than 50x10^9 /L.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

ITP, CLL, NHL: 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. PV: Prescribed by or in consultation with a dermatologist

COVERAGE DURATION

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

OTHER CRITERIA

Chronic Lymphocytic Leukemia (CLL): Diagnosis of CLL. Used in combination with fludarabine and cyclophosphamide. Pemphigus Vulgaris (PV): Diagnosis of moderate to severe PV. All uses: Approve for continuation of prior therapy.

RITUXAN HYCELA (S)

MEDICATION(S)
RITUXAN HYCELA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Follicular Lymphoma: Diagnosis of follicular lymphoma. One of the following: 1) Disease is relapsed or refractory OR 2) Patient exhibited complete or partial response to prior treatment with rituximab in combination with chemotherapy OR 3) Disease is non-progressing or stable following prior treatment with first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy OR 4) Both of the following: a) Disease is previously untreated AND b) Medication is used in combination with first-line chemotherapy. Diffuse Large B-Cell Lymphoma: 1) Diagnosis of diffuse large B-cell lymphoma AND 2) Disease is previously untreated AND 3) Medication is being used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy. Chronic Lymphocytic Leukemia: 1) Diagnosis of chronic lymphocytic leukemia AND 2) Medication is being used in combination with fludarabine and cyclophosphamide (FC) therapy.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

ROZLYTREK (S)

MEDICATION(S)
ROZLYTREK

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 non-small cell lung cancer (NSCLC). Patient has ROS1 rearrangement positive tumor(s). Solid Tumors: Patient has solid tumors with a neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, TPR-NTRK1, etc.). Disease is without a known acquired resistance mutation (e.g., TRKA G595R, TRKA G667C or TRKC G623R substitutions). Disease is one of the following: metastatic or unresectable (including cases where surgical resection is likely to result in severe morbidity). One of the following: disease has progressed following previous treatment (e.g., surgery, radiation therapy, or systemic therapy) or disease has no satisfactory alternative treatments.

AGE 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.

RUBRACA (S)

MEDICATION(S)
RUBRACA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Ovarian cancer: Diagnosis of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. One of the following: 1) Both of the following: a) Presence of deleterious BRCA mutation as detected by a U.S. Food and Drug Administration (FDA)-approved diagnostic test (e.g., FoundationFocus CDxBRCA Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) and b) Trial and failure, contraindication, or intolerance to two or more chemotherapies (e.g., cisplatin, carboplatin), OR 2) Both of the following: a) Disease is recurrent and b) Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin). Prostate cancer: Diagnosis of metastatic castration-resistant prostate cancer. Presence of deleterious BRCA mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has received previous treatment with both of the following: 1) Androgen receptor-directed therapy [e.g., Erleada (apalutamide), Xtandi (enzalutamide), Zytiga (abiraterone)], AND 2) A taxane-based chemotherapy [e.g., docetaxel, Jevtana (cabazitaxel)].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Ovarian cancer: Prescribed by or in consultation with an oncologist. Prostate cancer: Prescribed by or in consultation with an oncologist or urologist

COVERAGE DURATION
12 months

OTHER CRITERIA

Approve for continuation of prior therapy

RUCONEST (S)

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.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

RUXIENCE (S)

MEDICATION(S)
RUXIENCE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Non-Hodgkin's Lymphoma (NHL): One of the following: 1) Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma. Used as first-line treatment in combination with chemotherapy, 2) Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma. Patient achieved a complete or partial response to a rituximab product in combination with chemotherapy. Used as monotherapy for maintenance therapy, 3) Diagnosis of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma. One of the following: a) Patient has stable disease following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy or, b) Patient achieved a partial or complete response following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy, 4) Diagnosis of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin's lymphoma OR, 5) Diagnosis of diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma. Used as first-line treatment in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens. Chronic Lymphocytic Leukemia (CLL): Diagnosis of chronic lymphocytic leukemia. Used in combination with fludarabine and cyclophosphamide. Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA): Diagnosis of WG or MPA. Patient is concurrently on glucocorticoids (eg, prednisone) OR contraindication or intolerance to glucocorticoids (eg, prednisone).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
NHL, CLL: Prescribed by or in consultation with a hematologist/oncologist. WG, MPA: Prescribed by or in consultation with a nephrologist, pulmonologist, or rheumatologist.

COVERAGE DURATION

NHL, CLL: 12 months. WG, MPA: 3 months.

OTHER CRITERIA

Approve for continuation of prior therapy.

RUZURGI (S)

MEDICATION(S)
RUZURGI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Lambert-Eaton Myasthenic Syndrome (LEMS) (initial): Diagnosis of LEMS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
LEMS (initial): Prescribed by or in consultation with a neurologist.

COVERAGE DURATION
LEMS (initial): 3 months. LEMS (reauth): 12 months.

OTHER CRITERIA
LEMS (reauth): Documentation of positive clinical response to therapy (e.g., improvement in dynamometry, Timed 25-Foot Walk Test, Timed Up and Go Test).

RYDAPT (S)

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 (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA), used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation. Aggressive Systemic Mastocytosis (ASM), Systemic Mastocytosis with Associated Hematological Neoplasm (SM-AHN), Mast Cell Leukemia (MCL): Diagnosis of one of the following: aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL).

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

SABRIL (S)

MEDICATION(S)
VIGABATRIN, VIGADRONE

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.

SANDOSTATIN (S)

MEDICATION(S)
OCTREOTIDE ACETATE

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

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

SANDOSTATIN LAR (S)

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. One of the following: A) Inadequate response to surgical resection and/or pituitary irradiation OR B) Patient is not a candidate for surgical resection or pituitary irradiation. Trial and failure, contraindication or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses. 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 or flushing episodes. Patient had a trial of short-acting octreotide and responded to and tolerated therapy. Vasoactive intestinal peptide tumor (initial): Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea. 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, reauth): 12 months

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

peptide tumor (reauth): Patient has improvement in number of diarrhea episodes.

SARCLISA (S)

MEDICATION(S)
SARCLISA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of multiple myeloma. Patient has received at least two prior treatment regimens which included lenalidomide and a proteasome inhibitor (e.g., bortezomib, carfilzomib). Used in combination with pomalidomide and dexamethasone.

AGE 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.

SCIG (S)

MEDICATION(S)
CUTAQUIG, CUVITRU, HIZENTRA, XEMBIFY

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).

REQUIRED MEDICAL INFORMATION
Initial: Immune globulin will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. Medication is being used subcutaneously. Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) OR one of the following FDA-approved or literature supported diagnoses: 1) Common variable immunodeficiency (CVID), OR 2) Congenital agammaglobulinemia (X-linked or autosomal recessive), OR 3) Severe combined immunodeficiencies (SCID), OR 4) Wiskott-Aldrich syndrome, OR 5) Other primary immunodeficiency with an immunologic evaluation including IgG levels below the normal laboratory value for the patient's age at the time of diagnosis and the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine).

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial, reauth: 12 months

OTHER CRITERIA
Subject to Part B vs. Part D review. All uses (reauth): Patient has experienced an objective

improvement on immune globulin therapy and the immune globulin will be administered at the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both strategies) for maintenance therapy.

SECUADO (S)

MEDICATION(S)
SECUADO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of schizophrenia. Both of the following: 1) Trial and failure of Saphris (asenapine) and 2) Trial and failure, contraindication, or intolerance to one of the following generic formulary atypical antipsychotic agents: aripiprazole, olanzapine, paliperidone, quetiapine, risperidone, or ziprasidone.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

SIGNIFOR (S)

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. One of the following: a) Pituitary surgery has not been curative for the patient or b) Patient is not a candidate for pituitary surgery.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Cushing's disease (initial): Prescribed by or in consultation with an endocrinologist.

COVERAGE DURATION
Cushing's disease (initial, reauth): 12 months

OTHER CRITERIA
Cushing's disease (reauth): Documentation of positive clinical response to therapy (e.g., a clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs or symptoms of the disease).

SIGNIFOR LAR (S)

MEDICATION(S)
SIGNIFOR LAR

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. One of the following: a) Inadequate response to surgery or b) Patient is not a candidate for surgery. Cushing's disease (initial): Diagnosis of Cushing’s disease. One of the following: a) Pituitary surgery has not been curative for the patient or b) Patient is not a candidate for pituitary surgery.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Cushing's disease (initial): Prescribed by or in consultation with an endocrinologist.

COVERAGE DURATION
Acromegaly: Initial: 6 months, Reauth: 12 months. Cushing's disease (init, reauth): 12 months

OTHER CRITERIA
Acromegaly (reauth): Documentation of positive clinical response to therapy (e.g., patient’s growth hormone (GH) level or insulin-like growth factor 1 (IGF-1) level for age and gender has normalized/improved). Cushing's disease (reauth): Documentation of positive clinical response to therapy (e.g., a clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs or symptoms of the disease).

SIKLOS (S)

MEDICATION(S)
SIKLOS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Sickle Cell Anemia: Diagnosis of sickle cell anemia. Patient has moderate to severe painful crises. One of the following: 1) Patient is less than 18 years of age or 2) Trial and failure, or intolerance to Droxia.

AGE RESTRICTION
Patient is 2 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

SILIQ (S)

MEDICATION(S)
SILIQ

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: a) Trial and failure, contraindication, or intolerance to Cosentyx (secukinumab) AND one of the following: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab), OR b) for continuation of prior therapy.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Plaque psoriasis (Initial, reauth): 12 months

OTHER CRITERIA
Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline.

SIMPONI ARIA (S)

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 (TF/C/I) to methotrexate (Rheumatrex/Trexall). One of the following: a) Trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), or Xeljanz/Xeljanz XR (tofacitinib), or b) attestation demonstrating a trial may be inappropriate, OR c) For continuation of prior therapy. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: TF/C/I to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior therapy. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. One of the following: TF/C/I to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior therapy.

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.

COVERAGE DURATION
RA, AS, PsA (Initial, reauth): 12 months

OTHER CRITERIA

All Indications (Reauth): Documentation of positive clinical response to therapy.

SKYRIZI (S)

MEDICATION(S)

SKYRIZI 150 MG/ML SYRINGE, SKYRIZI (2 SYRINGES) KIT, SKYRIZI PEN

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.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Plaque psoriasis (initial): Prescribed by or in consultation with a dermatologist.

COVERAGE DURATION

Plaque psoriasis (Initial, reauth): 12 months

OTHER CRITERIA

Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline.

SOLIRIS (S)

MEDICATION(S)
SOLIRIS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Paroxysmal Nocturnal Hemoglobinuria (PNH), Atypical Hemolytic Uremic Syndrome (aHUS) (initial): Diagnosis of PNH or aHUS. Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab). Generalized Myasthenia Gravis (gMG) (initial): Diagnosis of gMG. Patient is anti-acetylcholine (AChR) antibody positive. One of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus), or 2) TF/C/I to one immunsuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus), and TF/C/I to chronic plasmapheresis/plasma exchange (PE) or intravenous immunoglobulin (IVIG). Neuromyelitis Optica Spectrum Disorder (NMOSD) (initial): Diagnosis of NMOSD. Patient is anti-aquaporin-4 (AQP4) antibody positive.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
gMG, NMOSD (initial): Prescribed by or in consultation with a neurologist.

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

OTHER CRITERIA
PNH (reauth): Documentation of positive clinical response (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to therapy. aHUS (reauth): Documentation of positive clinical

response (e.g., increase in mean platelet counts, hematologic normalization) to therapy. gMG, NMOSD (reauth): Documentation of positive clinical response to therapy.

SOMATULINE DEPOT (S)

MEDICATION(S)
SOMATULINE DEPOT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Acromegaly: Diagnosis of acromegaly. One of the following: A) Inadequate response to one of the following: surgery or radiotherapy, OR B) Not a candidate for one of the following: surgery or radiotherapy. Gastroenteropancreatic neuroendocrine tumors (GEP-NETs) (120mg/0.5mL strength only): Diagnosis of GEP-NETs. Disease is one of the following: (a) unresectable, locally advanced or (b) metastatic. Carcinoid syndrome (120mg/0.5mL strength only): Diagnosis of carcinoid syndrome. Used to reduce the frequency of short-acting somatostatin analog rescue therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
All uses: 12 months

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

SOMAVERT (S)

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
Prescribed by or in consultation with an endocrinologist

COVERAGE DURATION
Initial and reauth: 12 months

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

SPORANOX (S)

MEDICATION(S)
ITRACONAZOLE 10 MG/ML SOLUTION, ITRACONAZOLE 100 MG CAPSULE

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) all of the following: a) patient has a diagnosis of onychomycosis confirmed by one of the following (CAPSULE ONLY): i) positive potassium hydroxide (KOH) preparation, OR ii) fungal culture, OR iii) nail biopsy, AND b) patient has had a trial and failure, contraindication, or intolerance to oral terbinafine, OR 3) 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 infxn:6mo.Candidiasis:1mo.Fingernail onycho:5wks.Toenail onycho, other:3mo.

OTHER CRITERIA
N/A

SPRAVATO (S)

MEDICATION(S)
SPRAVATO 56 MG DOSE PACK, SPRAVATO 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-resistant depression (TRD): Diagnosis of major depressive disorder (treatment-resistant). Patient has not experienced a clinical meaningful improvement after treatment with at least two antidepressants from different classes for an adequate duration (at least 4 weeks each) in the current depressive episode. Used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
TRD: Prescribed by or in consultation with a psychiatrist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

SPRYCEL (S)

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+)/BCR ABL chronic myelogenous leukemia (CML): Diagnosis of Ph+/BCR ABL CML. Ph+/BCR ABL acute lymphoblastic leukemia (ALL): Diagnosis of Ph+/BCR ABL ALL.

AGE 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.

STELARA (IV) (S)

MEDICATION(S)
STELARA 130 MG/26 ML VIAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Crohn's Disease (CD): Diagnosis of moderately to severely active CD. One of the following: a) trial and failure, contraindication, or intolerance to Humira (adalimumab), or (b) trial and failure, contraindication, or intolerance to treatment with at least one immunomodulator or corticosteroid [e.g., Purinethol (6-mercaptopurine), Imuran (azathioprine), Sandimmune (cyclosporine A), Prograf (tacrolimus), MTX (methotrexate)]. Ulcerative Colitis (UC): Diagnosis of moderately to severely active UC. One of the following: a) trial and failure, contraindication, or intolerance to Humira (adalimumab), or (b) trial and failure, contraindication, or intolerance to treatment with at least one immunomodulator or corticosteroid (e.g., Purinethol [6-mercaptopurine], Imuran [azathioprine], aminosalicylates [e.g., mesalamine {Asacol, Pentasa, Rowasa}, olsalazine {Dipentum}, sulfasalazine {Azulfidine, Sulfazine}]).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a gastroenterologist.

COVERAGE DURATION
One time

OTHER CRITERIA
Stelara is to be administered as an intravenous induction dose. Stelara induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for Crohn's Disease/ulcerative colitis: 260 mg for patients weighing 55 kg or less, 390 mg for patients weighing

more than 55 kg to 85 kg, or 520 mg for patients weighing more than 85 kg.

STELARA (S)

MEDICATION(S)

STELARA 45 MG/0.5 ML SYRINGE, STELARA 45 MG/0.5 ML VIAL, 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). Plaque psoriasis (Initial): One of the following: a) Trial and failure, contraindication, or intolerance (TF/C/I) to Cosentyx (secukinumab) AND one of the following: Enbrel (etanercept), Humira (adalimumab), or Skyrizi (risankizumab), OR b) for continuation of prior therapy. Psoriatic arthritis (PsA) (Initial - 45mg/0.5mL): Diagnosis of active PsA. PsA (Initial - 90mg/1mL): Diagnosis of active PsA. Patient's weight is greater than 100 kg (220 lbs). Diagnosis of co-existent moderate to severe psoriasis. PsA (Initial): One of the following: a) TF/C/I to Cosentyx (secukinumab) AND one of the following: Enbrel (etanercept) or Humira (adalimumab) OR b) for continuation of prior 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 therapy. Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. 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], aminosalicylates [e.g., mesalamine {Asacol, Pentasa, Rowasa}, olsalazine {Dipentum}, sulfasalazine {Azulfidine, Sulfazine}]), OR c) for continuation of prior 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 and UC (initial): Prescribed by or in consultation with a gastroenterologist.

COVERAGE DURATION

All uses (Initial, reauth): 12 months

OTHER CRITERIA

Reauth (PsA, CD, UC): Documentation of positive clinical response to therapy. Reauth (plaque psoriasis): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline.

STIVARGA (S)

MEDICATION(S)
STIVARGA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Metastatic colorectal cancer (mCRC): All of the following: 1) diagnosis of mCRC, AND 2) trial and failure, contraindication or intolerance to fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI), AND 3) trial and failure, contraindication or intolerance to an anti-VEGF therapy (e.g., bevacizumab), AND 4) one of the following: a) RAS mutation, OR b) both of the following: RAS wild-type (RAS mutation negative tumor) and trial and failure, contraindication or intolerance to an anti-EGFR therapy [e.g., Vectibix (panitumumab), Erbitux (cetuximab)]. Gastrointestinal stromal tumor (GIST): All of the following: 1) diagnosis of locally advanced, unresectable or metastatic GIST, AND 2) trial and failure, contraindication or intolerance to both of the following: a) Gleevec (imatinib mesylate), AND b) Sutent (sunitinib malate). Hepatocellular Carcinoma (HCC): Diagnosis of HCC. Trial and failure or intolerance to Nexavar (sorafenib tosylate).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
mCRC, GIST: Prescribed by or in consultation with an oncologist. HCC: Prescribed by or in consultation with an oncologist, hepatologist, or gastroenterologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

STRENSIQ (S)

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

SUPPRELIN LA (S)

MEDICATION(S)
SUPPRELIN LA

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.

SUTENT (S)

MEDICATION(S)
SUNITINIB MALATE, 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 contraindication or intolerance to Gleevec (imatinib). Pancreatic neuroendocrine tumors: Diagnosis of progressive, well-differentiated pancreatic neuroendocrine tumor that is unresectable locally advanced or metastatic disease. Adjuvant treatment of renal cell carcinoma: Diagnosis of renal cell carcinoma (RCC). Used as adjuvant therapy. Patient is at high risk of recurrent RCC following nephrectomy.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
All uses: 12 months

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

SYLATRON (S)

MEDICATION(S)
SYLATRON 200 MCG KIT, SYLATRON 300 MCG KIT

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 or dermatologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

SYLVANT (S)

MEDICATION(S)
SYLVANT

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 therapy. Patient is HIV negative and HHV-8 negative.

SYMDEKO (S)

MEDICATION(S)
SYMDEKO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of cystic fibrosis. One of the following: 1) Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by a U.S. Food and Drug Administration (FDA)-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) OR 2) Patient has at least one mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence as detected by a U.S. Food and Drug Administration (FDA)-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).

AGE RESTRICTION
Initial: Patient is 6 years of age or older

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Reauth: Documentation of a positive clinical response to therapy (e.g., improvement in lung function or decreased number of pulmonary exacerbations).

SYMLIN (S)

MEDICATION(S)
SYMLINPEN 120, SYMLINPEN 60

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: One of the following diagnoses: A) Type 1 diabetes OR B) Type 2 diabetes. Patient has failed to achieve desired glucose control despite optimal insulin therapy. Patient is taking concurrent mealtime insulin therapy (e.g., Humulin, Humalog, Novolin, Novolog).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Reauth: Patient has experienced an objective response to therapy demonstrated by an improvement in HbA1c from baseline. Patient is receiving concurrent mealtime insulin therapy (e.g., Humulin, Humalog, Novolin, Novolog).

SYNAGIS (S)

MEDICATION(S)
SYNAGIS

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

AGE 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

5 months (5 doses) during RSV season.

OTHER CRITERIA

N/A

SYNDROS (S)

MEDICATION(S)
SYNDROS

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 (TF/C/I) to a 5HT-3 receptor antagonist (eg, Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]). TF/C/I to one of the following: Compazine (prochlorperazine), Decadron (dexamethasone), Haldol (haloperidol), Zyprexa (olanzapine). AIDS anorexia: Diagnosis of anorexia with weight loss in patients with AIDS. Patient is on antiretroviral therapy.

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 chemotherapy.

SYNRIBO (S)

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
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

SYPRINE (S)

MEDICATION(S)
CLOVIQUE, TRIENTINE HCL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration). Trial and failure, contraindication, or intolerance to a penicillamine product (e.g., Depen, Cuprimine)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Reauth: Documentation of a positive clinical response to therapy

TABRECTA (S)

MEDICATION(S)
TABRECTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of non-small cell lung cancer (NSCLC). Disease is one of the following: recurrent, advanced, metastatic. Presence of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).

AGE 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.

TAFAMIDIS (S)

MEDICATION(S)
VYNDAMAX, VYNDAQEL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM) (initial): Diagnosis of transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM). One of the following: 1) Patient has a transthyretin (TTR) mutation (e.g., V122I), 2) Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of TTR amyloid deposits, OR 3) All of the following: i) echocardiogram or cardiac magnetic resonance imaging suggestive of amyloidosis, ii) scintigraphy scan suggestive of cardiac TTR amyloidosis, and iii) absence of light-chain amyloidosis. One of the following: 1) History of heart failure (HF), with at least one prior hospitalization for HF, OR 2) Presence of clinical signs and symptoms of HF (e.g., dyspnea, edema). Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
ATTR-CM (initial, reauth): Prescribed by or in consultation with a cardiologist

COVERAGE DURATION
ATTR-CM (initial, reauth): 12 months

OTHER CRITERIA
ATTR-CM (reauth): Documentation of positive clinical response to therapy. Patient continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure.

TAFINLAR (S)

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 or metastatic melanoma AND cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) OR both of the following: cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) and medication is used in combination with Mekinist (trametinib). Adjuvant Treatment for Melanoma: Diagnosis of melanoma. Cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Involvement of lymph nodes following complete resection. Used as adjunctive therapy. Medication is used in combination with Mekinist (trametinib). Non-small Cell Lung Cancer (NSCLC): Diagnosis of metastatic non-small cell lung cancer AND cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) AND medication is used in combination with Mekinist (trametinib). Anaplastic Thyroid Cancer (ATC): Diagnosis of locally advanced or metastatic anaplastic thyroid cancer. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Cancer may not be treated with standard locoregional treatment options. Medication is used in combination with Mekinist (trametinib) .

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.

TAGRISSO (S)

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): One of the following: A) All of the following: Diagnosis of metastatic NSCLC. One of the following: 1) Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA), OR 2) Both of the following: a) Patient has known active EGFR T790M mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) and b) Patient has experienced disease progression on or after one of the following EGFR Tyrosine Kinase Inhibitors (TKIs): Gilotrif (afatinib), Iressa (gefitinib), Tarceva (erlotinib). OR B) All of the following: Diagnosis of NSCLC. Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Both of the following: 1) Patient is receiving as adjuvant therapy, and 2) Patient has had a complete surgical resection of the primary NSCLC tumor.

AGE 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.

TAKHZYRO (S)

MEDICATION(S)
TAKHZYRO

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.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
HAE (prophylaxis): Prescribed by or in consultation with an immunologist, allergist, or rheumatologist

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

TALTZ (S)

MEDICATION(S)
TALTZ AUTOINJECTOR, TALTZ AUTOINJECTOR (2 PACK), TALTZ AUTOINJECTOR (3 PACK), TALTZ 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: a) Trial and failure, contraindication, or intolerance to Cosentyx (secukinumab) AND one of the following: Enbrel (etanercept), Humira (adalimumab), or Skyrizi (risankizumab), OR b) for continuation of prior therapy. Psoriatic Arthritis (PsA) (initial): Diagnosis of active PsA. One of the following: a) Trial and failure, contraindication, or intolerance to Cosentyx (secukinumab) AND one of the following Enbrel (etanercept) or Humira (adalimumab), OR b) for continuation of prior therapy. Ankylosing spondylitis (AS) (initial): Diagnosis of active AS. One of the following: a) Trial and failure, contraindication, or intolerance to Cosentyx (secukinumab) AND one of the following: Enbrel (etanercept) or Humira (adalimumab), OR b) for continuation of prior therapy. Non-radiographic axial spondyloarthritis (nr-axSpA, initial): Dx of active nr-axSpA with objective signs of inflammation (eg, C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) TF/C/I to one non-steroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, meloxicam, naproxen). One of the following: a) Trial and failure, contraindication, or intolerance to Cosentyx (secukinumab), OR b) for continuation of prior therapy.

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. AS, nr-axSpA (initial): Prescribed by or in

consultation with a rheumatologist.

COVERAGE DURATION

Initial, reauth: 12 months

OTHER CRITERIA

PsA, AS, nr-axSpA (Reauth): Documentation of positive clinical response to therapy. Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline.

TALZENNA (S)

MEDICATION(S)
TALZENNA

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 one of the following: a) locally advanced or b) metastatic. Presence of a deleterious or suspected deleterious germline BRCA-mutation (gBRCAm) as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Disease is human epidermal growth factor receptor 2 (HER2)-negative.

AGE 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.

TARCEVA (S)

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 a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Pancreatic Cancer: Diagnosis of locally advanced, unresectable, or metastatic pancreatic cancer AND erlotinib will be used in combination with gemcitabine.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
All uses: 12 months

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

TARGRETIN (S)

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.

TASIGNA (S)

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+/BCR ABL 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.

TAVALISSE (S)

MEDICATION(S)
TAVALISSE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chronic Idiopathic Thrombocytopenic Purpura (ITP) (initial): Diagnosis of chronic immune ITP or relapsed/refractory ITP. Baseline platelet count is less than 30,000/mcL. Trial and failure, contraindication, or intolerance to at least one of the following: corticosteroids, immunoglobulins, splenectomy, thrombopoietin receptor agonists (e.g., Nplate, Promacta), or Rituxan (rituximab). Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
ITP (initial): Prescribed by or in consultation with a hematologist/oncologist.

COVERAGE DURATION
ITP (initial, reauth): 12 months

OTHER CRITERIA
ITP (reauth): Documentation of positive clinical response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding.

TAZVERIK (S)

MEDICATION(S)
TAZVERIK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Epithelioid sarcoma: Diagnosis of epithelioid sarcoma. Disease is one of the following: metastatic or locally advanced. Patient is not eligible for complete resection. Follicular lymphoma: Diagnosis of follicular lymphoma. Disease is one of the following: relapsed or refractory.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Epithelioid sarcoma: Prescribed by or in consultation with an oncologist. Follicular lymphoma: Prescribed by or in consultation with an oncologist or hematologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

TECFIDERA (S)

MEDICATION(S)
DIMETHYL FUMARATE, 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, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

TEGSEDI (S)

MEDICATION(S)
TEGSEDI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) (initial): Diagnosis of hATTR amyloidosis with polyneuropathy. Patient has a transthyretin (TTR) mutation (e.g., V30M). One of the following: 1) Patient has a baseline polyneuropathy disability (PND) score less than or equal to IIIb, 2) Patient has baseline familial amyloidotic polyneuropathy (FAP) stage of 1 or 2, OR 3) Patient has a baseline neuropathy impairment score (NIS) between 10 and 130. Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
hATTR amyloidosis (initial): Prescribed by or in consultation with a neurologist

COVERAGE DURATION
hATTR amyloidosis (initial, reauth): 12 months

OTHER CRITERIA
hATTR amyloidosis (reauth): Patient has demonstrated a benefit from therapy (e.g., improved neurologic impairment, slowing of disease progression, quality of life assessment). One of the following: 1) Patient continues to have a PND score less than or equal to IIIb, 2) Patient continues to have a FAP stage of 1 or 2, OR 3) Patient continues to have a NIS between 10 and 130.

TEPMETKO (S)

MEDICATION(S)
TEPMETKO

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. Disease is metastatic. Presence of mesenchymal-epithelial transition (MET) exon 14 skipping alterations.

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.

TERIPARATIDE (S)

MEDICATION(S)
FORTEO, TERIPARATIDE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

All uses (initial): 24 months. All uses (reauth): 12 months.

OTHER CRITERIA

Glucocorticoid-Induced Osteoporosis (initial): Diagnosis of glucocorticoid-induced osteoporosis. History of prednisone or its equivalent at a dose greater than or equal to 5mg/day for greater than or equal to 3 months. One of the following: 1) BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site), or 2) One of the following FRAX 10-year probabilities: a) Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions, or b) Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions, or 3) History of one of the following fractures resulting from minimal trauma: vertebral compression fx, fx of the hip, fx of the distal radius, fx of the pelvis, or fx of the proximal humerus. TF/C/I to one bisphosphonate (e.g., alendronate). All uses (initial, reauth): One of the following: 1) Treatment duration of parathyroid hormones [e.g., teriparatide, Tymlos (abaloparatide)] has not exceeded a total of 24 months during the patient's lifetime, or 2) Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones [e.g., teriparatide, Tymlos (abaloparatide)].

TESTOSTERONE (S)

MEDICATION(S)

ANDRODERM, TESTOSTERONE 1% (25MG/2.5G) PK, TESTOSTERONE 1% (50 MG/5 G) PK, TESTOSTERONE 1.62% GEL PUMP, TESTOSTERONE 12.5 MG/1.25 GRAM, TESTOSTERONE 50 MG/5 GRAM GEL, TESTOSTERONE 50 MG/5 GRAM PKT, TESTOSTERON CYP 1,000 MG/10 ML, TESTOSTERON CYP 2,000 MG/10 ML, TESTOSTERONE CYP 1,000 MG/5 ML, TESTOSTERONE CYP 100 MG/ML, TESTOSTERONE CYP 200 MG/ML, TESTOSTERONE CYP 500 MG/2.5 ML, TESTOSTERONE CYP 500 MG/5 ML, TESTOSTERONE CYP 6,000 MG/30ML

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 300 ng/dL (10.4 nmol/L) or less than the reference range for the lab OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome). Gender Dysphoria (GD) (off-label): Dx of GD. Patient is a female-to-male transsexual.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

HG(init): (New to T tx:6 mo. New to plan and cont T tx:12 mo), (reauth): 12 mo. GD: 12 mo.

OTHER CRITERIA

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

TESTOSTERONE ENANTHATE (S)

MEDICATION(S)
TESTOSTERON 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 300 ng/dL (10.4 nmol/L) or less than the reference range for the lab OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome). Delayed puberty (DP): Dx of DP AND male patient at birth. Breast cancer (BC): Dx of inoperable BC AND used for palliative treatment AND female patient at birth. Gender Dysphoria (GD) (off-label): Dx of GD. Patient is a female-to-male transsexual.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
HG(init): (New to T tx:6 mo. Cont T tx:12 mo), (reauth): 12 mo. BC, GD: 12 mo. DP: 6 mo.

OTHER CRITERIA
HG (Reauth): 1) Follow-up total serum T level within or below the normal limits of the reporting lab, or 2) Follow-up total serum T level outside of upper limits of normal for the reporting lab and the dose is

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

THALOMID (S)

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.

TIBSOVO (S)

MEDICATION(S)
TIBSOVO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Relapsed or refractory Acute Myeloid Leukemia (AML): Diagnosis of AML. Disease is relapsed or refractory. Newly-Diagnosed AML: Diagnosis of newly-diagnosed AML. One of the following: 1) patient is greater than or equal to 75 years old OR 2) patient has comorbidities that preclude use of intensive induction chemotherapy. Locally Advanced or Metastatic Cholangiocarcinoma: Diagnosis of cholangiocarcinoma. Disease is locally advanced or metastatic. Patient has been previously treated. All indications: Patient has an isocitrate dehydrogenase-1 (IDH1) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Relapsed or refractory AML, Newly-Diagnosed AML: Prescribed by or in consultation with a hematologist/oncologist. Locally Advanced or Metastatic Cholangiocarcinoma: Prescribed by or in consultation with a hepatologist, gastroenterologist, or oncologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

TIGLUTIK (S)

MEDICATION(S)
TIGLUTIK

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 ALS. Trial and failure or intolerance to generic riluzole tablets.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

TOLSURA (S)

MEDICATION(S)
TOLSURA

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: Blastomycosis, Histoplasmosis, or Aspergillosis. Trial and failure or intolerance to generic itraconazole capsules.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 months

OTHER CRITERIA
N/A

TOPICAL RETINOID (S)

MEDICATION(S)

AVITA, 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

Acne vulgaris: Diagnosis of acne vulgaris (i.e., 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

TRACLEER (S)

MEDICATION(S)
BOSENTAN

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.

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.

TRELSTAR (S)

MEDICATION(S)
TRELSTAR

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 any brand Lupron formulation.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

TREMFYA (S)

MEDICATION(S)
TREMFYA

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: set A) Both of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following: Enbrel (etanercept), Humira (adalimumab), or Skyrizi (risankizumab), AND 2) TF/C/I to Cosentyx (secukinumab), OR set B) for continuation of prior therapy. Psoriatic Arthritis (PsA) (initial): Diagnosis of active PsA. One of the following: set A) 1) TF/C/I to Enbrel (etanercept) or Humira (adalimumab) AND 2) TF/C/I to Cosentyx (secukinumab), OR set B) for continuation of prior 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.

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

OTHER CRITERIA
Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. PsA (Reauth): Documentation of positive clinical response to therapy.

TRIKAFTA (S)

MEDICATION(S)
TRIKAFTA

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 has at least one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected by an FDA-cleared cystic fibrosis mutation test or a test performed at a Clinical Laboratory Improvement Amendments (CLIA)-approved facility: F508del mutation OR a mutation in the CFTR gene that is responsive based on in vitro data.

AGE RESTRICTION
CF (initial): 6 years of age or older.

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

COVERAGE DURATION
CF (initial, reauth): 12 months

OTHER CRITERIA
CF (reauth): Documentation of positive clinical response to therapy (e.g., improvement in lung function [percent predicted forced expiratory volume in one second {PPFEV1}] or decreased number of pulmonary exacerbations).

TRIPTODUR (S)

MEDICATION(S)
TRIPTODUR

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. Trial and failure or intolerance to Lupron Depot-Ped.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
CPP (Initial, reauth): 12 months

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

TRODELVY (S)

MEDICATION(S)
TRODELVY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Triple Negative Breast Cancer (TNBC): Diagnosis of TNBC. Disease is metastatic. Patient has received at least two prior therapies for metastatic disease (e.g., carboplatin, cisplatin, gemcitabine, paclitaxel, docetaxel, capecitabine, etc.).

AGE 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.

TRUSELTIQ (S)

MEDICATION(S)
TRUSELTIQ

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of cholangiocarcinoma. Disease is one of the following: a) unresectable locally advanced or b) metastatic. Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has been previously treated.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hepatologist, gastroenterologist, or oncologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

TUKYSA (S)

MEDICATION(S)
TUKYSA

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 one of the following: a) advanced unresectable or b) metastatic. Disease is human epidermal growth factor receptor 2 (HER2)-positive. Used in combination with trastuzumab and capecitabine. Patient has received one or more prior anti-HER2 based regimens (e.g., trastuzumab, pertuzumab, ado-trastuzumab emtansine).

AGE 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.

TURALIO (S)

MEDICATION(S)
TURALIO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Tenosynovial Giant Cell Tumor (TGCT): Diagnosis of TGCT. Patient is symptomatic. Patient is not a candidate for surgery due to worsening functional limitation or severe morbidity with surgical removal.

AGE 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.

TYKERB (S)

MEDICATION(S)
LAPATINIB, 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: 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.

TYMLOS (S)

MEDICATION(S)
TYMLOS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
24 months (max 24 months of therapy per lifetime)

OTHER CRITERIA

N/A

TYSABRI (S)

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). One of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following disease-modifying therapies for MS: Aubagio (teriflunomide), Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone/Glatopa (glatiramer acetate), Extavia (interferon beta-1b), Gilenya (fingolimod), Lemtrada (alemtuzumab), Mavenclad (cladribine), Mayzent (siponimod), Ocrevus (ocrelizumab), Plegridy (peginterferon beta-1a), Rebif (interferon beta-1a), Tecfidera (dimethyl fumarate), 2) Patient is not a candidate for any of the drugs listed as prerequisites due to the severity of their MS, or 3) for continuation of prior therapy. Not used in combination with another disease-modifying therapy for MS. 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). TF/C/I to one of the following conventional therapies: corticosteroids, 6-mercaptopurine (6MP [Purinethol], azathioprine (Imuran), methotrexate, aminosalicylates (eg, sulfasalazine, mesalamine, olsalazine). TF/C/I to a TNF-inhibitor (eg, Cimzia [certolizumab pegol], Humira [adalimumab], Remicade [infliximab]). CD (initial and reauth): Not used in combination with an immunosuppressant (eg, 6-MP, azathioprine, cyclosporine, or methotrexate). Not used in combination with a TNF-inhibitor (eg, Enbrel [etanercept], Humira [adalimumab], or 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): Documentation of positive clinical response (eg, improved disease activity index) to therapy.

UBRELVY (S)

MEDICATION(S)
UBRELVY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of migraine with or without aura. Will be used for the acute treatment of migraine. Will not be used for preventive treatment of migraine. Patient has fewer than 15 headache days per month. Trial and failure or intolerance to one triptan (e.g., eletriptan, rizatriptan, sumatriptan) or a contraindication to all triptans. If patient has 4 or more headache days per month, patient must meet one of the following: a) currently being treated with Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications, OR b) currently being treated with Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications, OR c) currently being treated with a beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications. Medication will not be used in combination with another oral CGRP inhibitor.

AGE RESTRICTION
Initial: 18 years of age or older.

PRESCRIBER RESTRICTION
Initial, Reauth: Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.

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

OTHER CRITERIA
Reauth: Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia,

phonophobia, nausea). Will not be used for preventive treatment of migraine. Medication will not be used in combination with another oral CGRP inhibitor.

UDENYCA (S)

MEDICATION(S)
UDENYCA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Febrile neutropenia (FN) prophylaxis: Patient will be receiving prophylaxis for FN due to one of the following: 1) Patient is receiving National Cancer Institute¿s Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown, 3) patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN, 4) both of the following: a) patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN, AND b) patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia, OR 5) Both of the following: a) patient is receiving myelosuppressive anticancer drugs associated with neutropenia, AND b) patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis). Treatment of FN (off-label): Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia. Diagnosis of FN. Patient is at high risk for infection-associated complications. Acute radiation syndrome (ARS) (off-label): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS).

AGE RESTRICTION
N/A

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

COVERAGE DURATION
ARS: 1 mo. FN (prophylaxis, treatment): 3 mo or duration of tx.

OTHER CRITERIA

N/A

UKONIQ (S)

MEDICATION(S)
UKONIQ

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Marginal zone lymphoma (MZL): Diagnosis of MZL. Disease is one of the following: relapsed or refractory. Patent has received at least one prior anti-CD20-based regimen (e.g., bendamustine + rituximab, bendamustine + obinutuzumab, etc.). Follicular lymphoma (FL): Diagnosis of FL. Disease is one of the following: relapsed or refractory. Patient has received at least three prior lines of systemic therapy (e.g., bendamustine + rituximab, bendamustine + obinutuzumab, etc.).

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

ULTOMIRIS (S)

MEDICATION(S)
ULTOMIRIS 300 MG/30 ML VIAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Paroxysmal nocturnal hemoglobinuria (PNH) (initial): Diagnosis of PNH. Atypical hemolytic uremic syndrome (aHUS) (initial): Diagnosis of aHUS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
PNH, aHUS (initial, reauth): 12 months

OTHER CRITERIA
PNH, aHUS (reauth): Documentation of positive clinical response (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to therapy.

UPTRAVI (S)

MEDICATION(S)

UPTRAVI 1,000 MCG TABLET, UPTRAVI 1,200 MCG TABLET, UPTRAVI 1,400 MCG TABLET, UPTRAVI 1,600 MCG TABLET, UPTRAVI 200 MCG TABLET, UPTRAVI 200-800 TITRATION PACK, UPTRAVI 400 MCG TABLET, UPTRAVI 600 MCG TABLET, UPTRAVI 800 MCG 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 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) trial and failure, contraindication, or intolerance to a PDE5 inhibitor [i.e., Adcirca (tadalafil), Revatio (sildenafil)] or Adempas (riociguat), and 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 therapy. Not taken in combination with a prostanoid/prostacyclin analogue [e.g., Flolan (epoprostenol), Ventavis (iloprost), Tyvaso/Remodulin/Orenitram (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 therapy. Not taken in combination with a prostanoid/prostacyclin analogue [e.g., Flolan (epoprostenol), Ventavis (iloprost),

Tyvaso/Remodulin/Orenitram (treprostinil)].

VALCHLOR (S)

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), 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.

VARIZIG (S)

MEDICATION(S)
VARIZIG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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

REQUIRED MEDICAL INFORMATION
Immune globulin is being used intramuscularly. The immune globulin is being used for passive immunization or post exposure-prophylaxis of varicella. Patient is considered a high risk individual (i.e., immune compromised, pregnant woman, newborn of mother with varicella, premature infant, and infant less than 1 year old).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 months (approve one dose only)

OTHER CRITERIA
N/A

VASCEPA (S)

MEDICATION(S)
ICOSAPENT ETHYL, VASCEPA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Severe Hypertriglyceridemia (init): Diagnosis (dx) of hypertriglyceridemia and patient has a pre-treatment triglyceride (TG) level greater than or equal to 500 mg/dL. Prevention of CV Events (init): Dx of hypertriglyceridemia and patient has a pre-treatment TG level of 150 to 499 mg/dL. One of the following: 1) Patient has established cardiovascular disease (CVD) (e.g., coronary artery disease, cerebrovascular or carotid disease, peripheral artery disease, etc.) OR 2) Both of the following: a) Dx of diabetes mellitus AND b) Patient has two or more risk factors for developing CVD. Medication will be used as an adjunct to maximally tolerated statin therapy unless there is a contraindication or intolerance to statin therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial/Reauth: 12 months

OTHER CRITERIA
Severe Hypertriglyceridemia (reauth):Documentation of positive clinical response to therapy. Prevention of CV Events (Reauth): Documentation of positive clinical response to therapy. Medication continues to be used as an adjunct to maximally tolerated statin therapy unless there is a contraindication or intolerance to statin therapy.

VENCLEXTA (S)

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. Acute Myeloid Leukemia (AML): Diagnosis of newly diagnosed AML. Used in combination with azacitidine, or decitabine, or low-dose cytarabine. One of the following: 1) age 75 years or older OR 2) comorbidities that preclude use of intensive induction chemotherapy.

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.

VENTAVIS (S)

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.

VERZENIO (S)

MEDICATION(S)
VERZENIO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Breast Cancer: Diagnosis of advanced or metastatic breast cancer. Disease is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative. One of the following: a) used in combination with an aromatase inhibitor (e.g., Arimidex [anastrozole], Aromasin [exemestane], Femara [letrozole]) and patient is a postmenopausal woman, OR b) used in combination with Faslodex (fulvestrant) and disease has progressed following endocrine therapy, OR c) used as monotherapy and disease has progressed following endocrine therapy and patient has already received at least one prior chemotherapy regimen.

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.

VIMIZIM (S)

MEDICATION(S)
VIMIZIM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Mucopolysaccharidosis (initial): Diagnosis of Mucopolysaccharidosis type IVA (MPS IVA, Morquio A syndrome) confirmed by both of the following: a) documented clinical signs and symptoms of the disease (e.g., kyphoscoliosis, genu valgum, pectus carinatum, gait disturbance, growth deficiency, etc.) and b) documented reduced fibroblast or leukocyte GALNS enzyme activity or molecular genetic testing of GALNS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial, reauth: 12 months

OTHER CRITERIA
Reauth: Documentation of positive clinical response to therapy.

VIMOVO (S)

MEDICATION(S)
NAPROXEN-ESOMEPRAZOLE MAG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(initial): All of the following: 1) diagnosis of one of the following: a) osteoarthritis, OR b) rheumatoid arthritis, OR c) ankylosing spondylitis, OR d) juvenile idiopathic arthritis, AND 2) one of the following: a) history of peptic ulcer disease, OR b) history of gastrointestinal (GI) bleeding, obstruction, or perforation, OR c) erosive esophagitis, OR d) used in combination with aspirin, AND 3) trial and failure, or intolerance to esomeprazole and naproxen sodium administered together as separate components.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
All uses (initial, reauth): 3 months.

OTHER CRITERIA
All uses (reauth): documentation of positive clinical response to therapy.

VITRAKVI (S)

MEDICATION(S)
VITRAKVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Presence of solid tumors (e.g., salivary gland, soft tissue sarcoma, infantile fibrosarcoma, thyroid cancer, lung, melanoma, colon, etc.). Disease is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion (e.g. ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.). Disease is without a known acquired resistance mutation [e.g., TRKA G595R substitution, TRKA G667C substitution, or other recurrent kinase domain (solvent front and xDFG) mutations]. Disease is one of the following: metastatic or unresectable (including cases where surgical resection is likely to result in severe morbidity). One of the following: Disease has progressed on previous treatment (e.g., surgery, radiotherapy, or systemic therapy) OR Disease has no satisfactory alternative treatments.

AGE 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.

VIZIMPRO (S)

MEDICATION(S)
VIZIMPRO

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. Disease is metastatic. Disease is positive for one of the following epidermal growth factor receptor (EGFR) mutations: exon 19 deletion or exon 21 L858R substitution.

AGE 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.

VOSEVI (S)

MEDICATION(S)
VOSEVI

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 patients: Diagnosis of chronic hepatitis C, patient is without decompensated liver disease (defined as Child-Pugh Class B or C), and not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni, Zepatier].

AGE 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 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.

OTHER CRITERIA
N/A

VOTRIENT (S)

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.

VPRIV (S)

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

VUMERITY (S)

MEDICATION(S)
VUMERITY

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, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: a) Failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS: 1) Aubagio (teriflunomide), 2) Gilenya (fingolimod), or 3) Brand Tecfidera/generic dimethyl fumarate, OR b) for continuation of prior therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

WAKIX (S)

MEDICATION(S)
WAKIX

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). Symptoms of cataplexy are present. Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present. Narcolepsy without cataplexy (Narcolepsy Type 2) (initial): Diagnosis (Dx) of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible). Trial and failure, contraindication or intolerance to both generic modafinil and generic armodafinil.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
Narcolepsy with cataplexy (Narcolepsy Type 1) (reauth): Documentation demonstrating a reduction in the frequency of cataplexy attacks associated with therapy, OR documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy. Narcolepsy without cataplexy (Narcolepsy Type 2) (reauth): Documentation of positive clinical response to therapy.

WELIREG (S)

MEDICATION(S)
WELIREG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of von Hippel-Lindau (VHL) disease. Patient requires therapy for one of the following: a) renal cell carcinoma (RCC), b) central nervous system (CNS) hemangioblastoma, or c) pancreatic neuroendocrine tumor (pNET). Patient does not require immediate surgery.

AGE 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.

XALKORI (S)

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 advanced or metastatic NSCLC AND One of the following: A) Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) or B) Patient has MET amplification- or ROS1 rearrangement-positive tumor as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Anaplastic Large Cell Lymphoma (ALCL): Diagnosis of systemic ALCL. Disease is relapsed or refractory. Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

XCOPRI (S)

MEDICATION(S)
XCOPRI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of partial onset seizures.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

XELJANZ (S)

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
Xeljanz tab/Xeljanz XR tab: Rheumatoid arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Trial and failure, contraindication, or intolerance (TF/C/I) to one disease modifying antirheumatic drug (DMARD) [eg, methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)]. Psoriatic arthritis (PsA) (Initial): Diagnosis of active PsA. PsA (initial): One of the following: TF/C/I to Enbrel (etanercept) or Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-IV-TR 300.29/F40.2 for specific phobia diagnostic criteria), OR for continuation of prior tofacitinib therapy. Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. Trial and failure, contraindication or intolerance to one of the following conventional therapies: 6-mercaptopurine (Purinethol), aminosalicylate [e.g., mesalamine (Asacol, Pentasa, Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine, Sulfazine)], azathioprine (Imuran), or corticosteroids (e.g., prednisone, methylprednisolone). Trial and failure, contraindication, or intolerance to 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-V-TR F40.2 for specific phobia diagnostic criteria), OR for continuation of prior tofacitinib therapy. All indications: Patient is not receiving tofacitinib in combination with a potent immunosuppressant (eg, azathioprine, cyclosporine).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RA, PJIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or

in consultation with a dermatologist or rheumatologist. UC (initial): Prescribed by or in consultation with a gastroenterologist.

COVERAGE DURATION

RA/PJIA/PsA (initial, reauth): 12 months. UC (init): 4 mo. UC (reauth): 12 mo.

OTHER CRITERIA

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

XENAZINE (S)

MEDICATION(S)
TETRABENAZINE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chorea associated with Huntington's Disease (HD) (Initial): Diagnosis of chorea in patients with Huntington's disease. Tardive dyskinesia (Initial): Diagnosis of tardive dyskinesia. One of the following: 1) Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication, OR 2) Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication. Tourette's syndrome (Initial): Patient has tics associated with Tourette's syndrome. Failure, contraindication, or intolerance to Haldol (haloperidol).

AGE RESTRICTION
N/A

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 uses: (initial) 3 months. (Reauth) 12 months.

OTHER CRITERIA
All indications (Reauth): Documentation of clinical response and benefit from therapy.

XERMELO (S)

MEDICATION(S)
XERMELO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Carcinoid syndrome diarrhea (Initial): Diagnosis of carcinoid syndrome diarrhea AND diarrhea is inadequately controlled by a stable dose of somatostatin analog (SSA) therapy (e.g., octreotide [Sandostatin, Sandostatin LAR], lanreotide [Somatuline Depot]) for at least 3 months AND used in combination with SSA therapy.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial: 6 months. Reauth: 12 months

OTHER CRITERIA
Carcinoid syndrome diarrhea (Reauthorization): Documentation of a positive clinical response to therapy AND drug will continue to be used in combination with SSA therapy.

XGEVA (S)

MEDICATION(S)
XGEVA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Multiple Myeloma (MM)/Bone metastasis from solid tumors (BMST): One of the following: 1) Diagnosis of multiple myeloma OR 2) diagnosis of solid tumors (eg, breast cancer, kidney cancer, lung cancer, prostate cancer, thyroid cancer), AND documented evidence of one or more metastatic bone lesions. Giant cell tumor of bone (GCTB): Both of the following: 1) diagnosis of giant cell tumor of bone AND 2) One of the following: a) tumor is unresectable, OR b) surgical resection is likely to result in severe morbidity. Hypercalcemia of malignancy (HCM): Both of the following: 1) diagnosis of hypercalcemia of malignancy, AND 2) Trial and failure, contraindication, or intolerance to one intravenous bisphosphonate (eg, pamidronate, Zometa (zoledronic acid).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
GCTB, HCM: Prescribed by or in consultation with an oncologist

COVERAGE DURATION
MM/BMST, GCTB: 12 mo. HCM: 2 mo.

OTHER CRITERIA
Approve for continuation of prior therapy.

XIFAXAN (S)

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. Treatment of HE: Used for the treatment of HE. Trial and failure, contraindication, or intolerance to lactulose. Irritable bowel syndrome with diarrhea (IBS-D) (550mg strength only) (initial): Diagnosis of IBS-D, AND trial and failure, contraindication or intolerance to an antidiarrheal agent [eg, loperamide].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
TD: 14 days. HE (prophylaxis, treatment): 12 months. IBS-D (initial, reauth): 2 weeks.

OTHER CRITERIA
IBS-D (reauth): Patient experiences IBS-D symptom recurrence.

XOLAIR (S)

MEDICATION(S)
XOLAIR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

Asthma (init/reauth): Prescribed by or in consultation with an allergist/immunologist, or pulmonologist. CIU (init): Prescribed by or in consultation with an allergist/immunologist, or dermatologist. NP (init/reauth): Prescribed by or in consultation with an allergist/immunologist, otolaryngologist, or pulmonologist.

COVERAGE DURATION

Asthma, init: 6 mo, reauth: 12 mo. CIU, init: 3 mo, reauth: 6 mo. NP, init/reauth: 12 mo.

OTHER CRITERIA

Asthma (reauth): Documentation of positive clinical response to therapy (e.g., Reduction in number of asthma exacerbations, improvement in forced expiratory volume in 1 second (FEV1), or decreased use of rescue medications). Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), tiotropium], OR b) A combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone/vilanterol)]. CIU (reauth): Patients disease status has been re-evaluated since the last authorization to confirm the patients condition warrants continued treatment. Patient has experienced one or both of the following: Reduction in itching severity from baseline or Reduction in the number of hives from baseline. NP (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS: 0-8 scale], improvement in nasal congestion/obstruction score [NCS: 0-3 scale]). Used in combination with another agent for nasal polyps (e.g., intranasal corticosteroid).

XOSPATA (S)

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 (AML). Disease is relapsed or refractory. Patient has a FMS-like tyrosine kinase (FLT3) mutation as determined by a U.S. Food and Drug Administration (FDA)-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).

AGE 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.

XPOVIO (S)

MEDICATION(S)
XPOVIO

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 multiple myeloma. Patient has received at least one prior therapy. Used in combination with bortezomib and dexamethasone. Relapsed/Refractory Multiple Myeloma (RRMM): Diagnosis of relapsed or refractory multiple myeloma (RRMM). Patient has received at least four prior therapies. Disease is refractory to all of the following: 1) Two proteasome inhibitors (e.g., bortezomib, carfilzomib), 2) Two immunomodulatory agents (e.g., lenalidomide, thalidomide), and 3) An anti-CD38 monoclonal antibody (e.g. daratumumab). Used in combination with dexamethasone. Diffuse large B-cell lymphoma (DLBCL): Diagnosis of one of the following: 1) Relapsed or refractory DLBCL not otherwise specified OR 2) Relapsed or refractory DLBCL arising from follicular lymphoma. Patient has previously received at least two lines of systemic therapy.

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.

XTANDI (S)

MEDICATION(S)
XTANDI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Castration-resistant or castration-recurrent prostate cancer (CRPC): Diagnosis of castration-resistant (chemical or surgical) or recurrent prostate cancer. Metastatic castration-sensitive prostate cancer (M-CSPC): Diagnosis of metastatic castration-sensitive prostate cancer.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
CRPC, M-CSPC: Prescribed by or in consultation with an oncologist or urologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

XURIDEN (S)

MEDICATION(S)
XURIDEN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Hereditary orotic aciduria (Initial): Diagnosis of hereditary orotic aciduria.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Initial: Prescribed by or in consultation with a medical geneticist or other specialist that treats inborn errors of metabolism

COVERAGE DURATION
Initial, reauth: 12 months

OTHER CRITERIA
Hereditary orotic aciduria (reauth): Documentation of positive clinical response to therapy.

XYREM (S)

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
All uses (initial): Prescribed by or in consultation with one of the following: neurologist, psychiatrist, or sleep medicine specialist.

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 therapy, OR documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy. Narcolepsy Type 2 (reauth): Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy.

XYWAV (S)

MEDICATION(S)
XYWAV

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 (e.g., safety concerns, not indicated for patient's age/weight) or intolerance to both of the following: 1) generic modafinil, AND 2) generic armodafinil.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
All uses (initial): Prescribed by or in consultation with one of the following: neurologist, psychiatrist, or sleep medicine specialist.

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

OTHER CRITERIA
Narcolepsy with cataplexy (Narcolepsy Type 1)(reauth): Documentation demonstrating a reduction in

the frequency of cataplexy attacks associated with therapy, OR documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy. Narcolepsy without Cataplexy (Narcolepsy Type 2)(reauth): Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy.

YONSA (S)

MEDICATION(S)
YONSA

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) or recurrent prostate cancer. Used in combination with methylprednisolone. Trial and failure or intolerance to Xtandi (enzalutamide).

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy

ZAVESCA (S)

MEDICATION(S)
MIGLUSTAT

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 (S)

MEDICATION(S)
ZEJULA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: advanced epithelial ovarian cancer, advanced fallopian tube cancer, or advanced primary peritoneal cancer. Used for maintenance treatment in patients who are in a complete or partial response to first-line platinum-based chemotherapy (e.g., cisplatin, carboplatin). Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: recurrent epithelial ovarian cancer, recurrent fallopian tube cancer, or recurrent primary peritoneal cancer. Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin). Treatment of advanced ovarian cancer after three or more chemotherapies: Diagnosis of advanced ovarian cancer, advanced fallopian tube cancer, or advanced primary peritoneal cancer. Patient has been treated with three or more prior chemotherapy regimens. Patient's cancer is associated with homologous recombination deficiency (HRD) positive status defined by one of the following: (a) a deleterious or suspected deleterious BRCA mutation or (b) both of the following: (1) genomic instability and (2) cancer has progressed more than 6 months after response to the last platinum-based chemotherapy (e.g., cisplatin, carboplatin).

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.

ZELBORAF (S)

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 a U.S. Food and Drug Administration (FDA)-approved test (eg, cobas 4600 BRAFV600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Erdheim-Chester Disease: Diagnosis of Erdheim-Chester disease AND Disease is BRAFV600 mutant type (MT).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Melanoma: Prescribed by or in consultation with an oncologist. Erdheim-Chester Disease: Prescribed by or in consultation with a hematologist/oncologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
All indications: Approve for continuation of therapy.

ZEPOSIA (S)

MEDICATION(S)
ZEPOSIA

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 (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: a) Failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS: 1) Aubagio (teriflunomide), 2) Gilenya (fingolimod), or 3) Brand Tecfidera/generic dimethyl fumarate, OR b) for continuation of prior therapy. Ulcerative Colitis (UC) (init): Diagnosis of moderately to severely active UC. One of the following: a) Trial and failure, contraindication, or intolerance to both of the following, or attestation demonstrating a trial may be inappropriate: Humira (adalimumab), Xeljanz IR (tofacitinib IR)/Xeljanz XR (tofacitinib XR), OR b) for continuation of prior therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
UC (init): Prescribed by or in consultation with a gastroenterologist.

COVERAGE DURATION
MS: 12 months. UC (init): 12 weeks, (reauth): 12 months.

OTHER CRITERIA
UC (reauth): Documentation of positive clinical response to therapy.

ZEPZELCA (S)

MEDICATION(S)
ZEPZELCA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of metastatic small cell lung cancer (SCLC). Disease has progressed on or after platinum-based chemotherapy (e.g., carboplatin, cisplatin, oxaliplatin).

AGE 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.

ZIEXTENZO (S)

MEDICATION(S)
ZIEXTENZO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Febrile neutropenia (FN) prophylaxis: Patient will be receiving prophylaxis for FN due to one of the following: 1) Patient is receiving National Cancer Institute¿s Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown, 3) patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN, 4) both of the following: a) patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN, AND b) patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia, OR 5) Both of the following: a) patient is receiving myelosuppressive anticancer drugs associated with neutropenia, AND b) patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis). Acute radiation syndrome (ARS): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS). Treatment of FN: Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia. Diagnosis of FN. Patient is at high risk for infection-associated complications.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
ARS: 1 mo. FN (prophylaxis, treatment): 3 mo or duration of tx.

OTHER CRITERIA

All Indications: Trial and failure or intolerance to both of the following: Neulasta/Neulasta Onpro AND Udenyca.

ZIRABEV (S)

MEDICATION(S)
ZIRABEV

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Non-Small Cell Lung Cancer: Excluded if squamous cell histology.

REQUIRED MEDICAL INFORMATION
Colorectal Cancer: Diagnosis of metastatic colorectal cancer. One of the following: 1) Both of the following: a) used as first- or second-line treatment and b) used in combination with an intravenous 5-fluorouracil-based chemotherapy, OR 2) All of the following: a) used as second-line treatment, b) used in combination with fluoropyrimidine-irinotecan-based chemotherapy or fluoropyrimidine-oxaliplatin-based chemotherapy, and c) patient has progressed on a first-line bevacizumab-containing regimen. Non-Small Cell Lung Cancer (NSCLC): Diagnosis of NSCLC. Disease is unresectable, locally advanced, recurrent, or metastatic. Used as first-line treatment. Used in combination with paclitaxel and carboplatin. Renal Cell Cancer: Diagnosis of metastatic renal cell cancer. Used in combination with interferon-alpha. Cervical Cancer: Diagnosis of carcinoma of the cervix. Disease is persistent, recurrent, or metastatic. Used in combination with one of the following: a) paclitaxel and cisplatin or b) paclitaxel and topotecan. Glioblastoma: Diagnosis of recurrent glioblastoma. Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer: Diagnosis of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. One of the following: 1) All of the following: a) disease is stage 3 or 4, b) patient has been treated with bevacizumab as a single agent, c) treatment is following surgical resection, and d) used in combination with carboplatin and paclitaxel, OR 2) All of the following: a) disease is platinum-resistant recurrent, b) patient has received no more than 2 prior chemotherapy regimens, and c) used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, OR 3) All of the following: a) disease is platinum-sensitive recurrent, b) patient has been treated with bevacizumab as a single agent, and c) used in combination with one of the following: i) carboplatin and paclitaxel or ii) carboplatin and gemcitabine.

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.

ZOLINZA (S)

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.

ZORBTIVE (S)

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 (somatropin).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a gastroenterologist.

COVERAGE DURATION
SBS: 4 weeks.

OTHER CRITERIA
N/A

ZYDELIG (S)

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.

ZYKADIA (S)

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 a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).

AGE 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 (NON-PREFERRED) (S)

MEDICATION(S)
ZYTIGA 500 MG TABLET

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 metastatic castration-resistant (chemical or surgical) or recurrent prostate cancer. Used in combination with prednisone. Trial and failure, or intolerance to Xtandi (enzalutamide). Metastatic Castration-Sensitive Prostate Cancer (mCSPC): Diagnosis of metastatic high-risk castration-sensitive prostate cancer. Used in combination with prednisone. Trial and failure, or intolerance to Xtandi (enzalutamide).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
mCRPC, mCSPC: Prescribed by or in consultation with an oncologist or urologist

COVERAGE DURATION
mCRPC, mCSPC: 12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

ZYTIGA (PREFERRED) (S)

MEDICATION(S)
ABIRATERONE ACETATE

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 metastatic castration-resistant (chemical or surgical) or recurrent prostate cancer. Used in combination with prednisone.
Metastatic Castration-Sensitive Prostate Cancer (mCSPC): Diagnosis of metastatic high-risk castration-sensitive prostate cancer. Used in combination with prednisone.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
mCRPC, mCSPC: Prescribed by or in consultation with an oncologist or urologist

COVERAGE DURATION
mCRPC, mCSPC: 12 months

OTHER CRITERIA
Approve for continuation of prior therapy