MEDICATION(S)
ACTEMRA 200 MG/10 ML VIAL, ACTEMRA 400 MG/20 ML VIAL, ACTEMRA 80 MG/4 ML 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: 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 Actemra therapy. Systemic Juvenile Idiopathic arthritis (SJIA) (Initial): Diagnosis of active SJIA. Trial and failure, contraindication, or intolerance to one NSAID 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 Actemra therapy. Cytokine Release Syndrome (CRS) Risk due to CAR T-cell Therapy: Patient will receive or is receiving chimeric antigen receptor (CAR) T-cell immunotherapy [i.e., Kymria (tisagenlecleucel), Yescarta (axicabtagene ciloleucel)].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RA, SJIA, PJIA (Initial): Prescribed by or in consultation with a rheumatologist. CRS Risk due to CAR T-cell Therapy: Prescribed by or in consultation with an oncologist or hematologist.

COVERAGE DURATION
RA, SJIA, PJIA (Initial, reauth): 12 months. CRS risk due to CAR T-cell therapy: 2 months

OTHER CRITERIA
RA, SJIA, PJIA (Reauth): Documentation of positive clinical response to Actemra therapy.
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: 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 Actemra therapy. Giant Cell Arteritis (GCA) (Initial): Diagnosis of GCA. Trial and failure, contraindication, or intolerance to a glucocorticoid (i.e., prednisone). Systemic Juvenile Idiopathic Arthritis (SJIA) (Initial): Diagnosis of active SJIA. Trial and failure, contraindication, or intolerance to one of the following: NSAID 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 Actemra therapy.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
RA, GC, SJIA, PJIA (initial, reauth): 12 months

OTHER CRITERIA
RA, GC, SJIA, PJIA (Reauth): Documentation of positive clinical response to Actemra therapy.
MEDICATION(S)
ACTIMMUNE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
ALYQ, TADALAFIL 20 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

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

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
ADEMPAS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

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

MEDICATION(S)
AFINITOR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
All 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.
MEDICATION(S)
AIMOVIG AUTOINJECTOR

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): Not used in combination with another calcitonin gene-related peptide (CGRP) inhibitor. 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.

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 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. 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
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.
ALIQOPA (S)

MEDICATION(S)
ALIQOPA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Relapsed Follicular Lymphoma: Diagnosis of relapsed follicular lymphoma AND patient has received at least two prior systemic therapies.

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
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(), or Pi()() 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). 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. Trial and failure, or intolerance to Prolastin.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
PROLASTIN C

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Alpha-1 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(), or Pi()() 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). One of the following: FEV1 level is between 30% and 65% of predicted OR the patient has experienced a rapid decline in lung function (i.e., reduction of FEV1 more than 120 mL/year) that warrants treatment.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
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). Trial and failure or intolerance to Xalkori (crizotinib).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
DEXTROAMPHETAMINE-AMPHELAMINE

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 ADHD, OR b) diagnosis of attention deficit disorder (ADD), OR c) diagnosis of narcolepsy as confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible).

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

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
AMPYRA, DALFAMPRIDINE ER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
MS (Reauth): Physician confirmation that the patient's walking improved with 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).
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 Anadrol-50 therapy as evidenced by an improvement in anemia (e.g., increased hemoglobin, increased reticulocyte count, reduction/elimination for need of blood transfusions).
MEDICATION(S)
APOKYN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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

REQUIRED MEDICAL INFORMATION
Parkinson's disease (PD) (Initial): Diagnosis of advanced PD. Patient is experiencing acute intermittent hypomobility (defined as off episodes characterized by muscle stiffness, slow movements, or difficulty starting movements). Patient is receiving Apokyn in combination with other medications for the treatment of PD (e.g., carbidopa/levodopa, pramipexole, ropinirole, 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 Apokyn therapy.
MEDICATION(S)
ARANESP 10 MCG/0.4 ML SYRINGE, ARANESP 100 MCG/0.5 ML SYRINGE, ARANESP 100 MCG/ML VIAL, ARANESP 150 MCG/0.3 ML SYRINGE, ARANESP 200 MCG/0.4 ML SYRINGE, ARANESP 200 MCG/ML VIAL, ARANESP 25 MCG/0.42 ML SYRING, ARANESP 25 MCG/ML VIAL, ARANESP 300 MCG/0.6 ML SYRINGE, ARANESP 300 MCG/ML VIAL, ARANESP 40 MCG/0.4 ML SYRINGE, ARANESP 40 MCG/ML VIAL, ARANESP 500 MCG/1 ML SYRINGE, ARANESP 60 MCG/0.3 ML SYRINGE, ARANESP 60 MCG/ML VIAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Anemia with Chronic Kidney Disease (CKD) (Initial): Diagnosis (Dx) of CKD. Anemia by lab values (Hct less than 30% or Hgb less than 10 g/dL) collected within 30 days of request. One of the following: a) both of the following: Patient is on dialysis, patient is without ESRD OR b) all of the following: patient is not on dialysis, the rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion, and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal. Anemia with chemo (Initial): Other causes of anemia have been ruled out. Anemia by lab values (Hct less than 30%, Hgb less than 10 g/dL) collected within the prior 2 weeks of request. Cancer is a non-myeloid malignancy. Patient is concurrently on chemo, or will receive concomitant chemo for a minimum of 2 months, or anemia is caused in part by cancer chemo. Will not be approved if patient is not receiving cancer chemotherapy. 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. Most recent or average (avg) Hct over 3 mo is 33% or less OR most recent or avg Hgb over 3 months is 11 g/dL or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Chemo (Reauth): Anemia by lab values (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 weeks of request. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Patient is concurrently on chemo, or will receive concomitant chemo for a minimum of 2 months, or anemia is caused in part by cancer chemo. Will not be approved if patient is not receiving cancer chemotherapy. MDS (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Off-label uses (except MDS, 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.

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

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

COVERAGE DURATION
CAPS (initial, reauth): 12 months

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
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
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 Austedo therapy.
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.
**MEDICATION(S)**
BAVENCIO

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

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Merkel Cell Carcinoma (MCC): Diagnosis of metastatic Merkel cell carcinoma. Urothelial Carcinoma (UC): Diagnosis of locally advanced or metastatic urothelial carcinoma. One of the following: 1) Patient has disease progression during or following platinum-containing chemotherapy, OR 2) Patient has disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

**AGE RESTRICTION**
MCC: Patient is 12 years of age or older.

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

**COVERAGE DURATION**
12 months

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Systemic lupus erythematous (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)]).

AGE RESTRICTION
N/A

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

COVERAGE DURATION
SLE (init, reauth): 6 months

OTHER CRITERIA
SLE (reauth): Documentation of positive clinical response to Benlysta therapy.
BENZODIAZEPINES (S)

**MEDICATION(S)**
ALPRAZOLAM 0.25 MG TABLET, ALPRAZOLAM 0.5 MG TABLET, ALPRAZOLAM 1 MG TABLET, ALPRAZOLAM 2 MG TABLET, ALPRAZOLAM ER, ALPRAZOLAM XR, CHLORDIAZEPoxide HCL, ESTAZOLAM, LORAZEPAM 0.5 MG TABLET, LORAZEPAM 1 MG TABLET, LORAZEPAM 2 MG TABLET, LORAZEPAM 2 MG/ML CARPUJECT, LORAZEPAM 2 MG/ML ORAL CONCENT, 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, LORAZEPAM INTENSOL, TEMAZEPAM

**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
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
BESPONSA (S)

MEDICATION(S)
BESPONSA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
B-cell precursor acute lymphoblastic leukemia (ALL): Diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL). Disease is relapsed or refractory.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
BLINCYTO 35MCG VIAL+STABILIZER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL): Diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia/acute lymphoblastic lymphoma. Minimal residual disease (MRD)-positive B-cell precursor ALL (MRD+ ALL): Diagnosis of B-cell precursor ALL. Patient is in their first or second complete remission. Documentation of MRD greater than or equal to 0.1%.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
ALL: 12 months. MRD+ ALL: 6 months

OTHER CRITERIA
Subject to Part B vs. Part D review. All Indications: Approve for continuation of prior therapy.
BORTEZOMIB (S)

MEDICATION(S)
BORTEZOMIB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Multiple myeloma (MM): Diagnosis of MM. Mantle cell lymphoma (MCL): Diagnosis of MCL AND patient has received at least one prior therapy for MCL.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

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

**MEDICATION(S)**
BOTOX

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

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

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

**AGE RESTRICTION**
N/A

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

**OTHER CRITERIA**
UI, OAB, CBP, Neuromuscular Disorders: (Reauth) Confirmed improvement in symptoms with initial Botox treatment. At least 3 months have or will have elapsed since the last treatment with Botox.

HH: (Reauth) At least a 2-point improvement in HDSS.

Migraine: (Reauth) Reduction in headache frequency or intensity. Confirmation of decreased utilization of pain medications (eg, narcotic analgesics, NSAIDs) or triptans, or a reduction in the number of ER visits.

Achalasia: (Reauth) Documentation of improvement or reduction in symptoms of achalasia (ie, dysphagia, regurgitation, chest pain). At least 6 months have or will have elapsed since last series of injections.

AF: (Reauth) Incomplete healing of fissure or recurrence of fissure. Improved symptoms with prior treatment with Botox.
MEDICATION(S)
BRAFTOVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
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).

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 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.
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 thrombocytic 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.

COVERAGE DURATION
3 months

OTHER CRITERIA
N/A
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 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.
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.

**AGE RESTRICTION**
N/A

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

**COVERAGE DURATION**
12 months

**OTHER CRITERIA**
Approve for continuation of prior therapy.
MEDICATION(S)
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.
MEDECATION(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).
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): Patients condition has not progressed, as defined by ALL of the following: A) Hemoglobin level decreased greater than 1.5 g/dL from baseline, AND B) Platelet count decreased greater than 25% from baseline, AND C) Spleen volume increased greater than 25% from baseline, AND D) Liver volume increased greater than 20% from baseline.
MEDICATION(S)
CEREZYMÉ 400 UNITS VIAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Gaucher disease: 12 months

OTHER CRITERIA
N/A
MEDICATION(S)
CHOLBAM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

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

MEDICATION(S)
CHORIONIC GONAD 10,000 UNIT VL, NOVAREL 5,000 UNIT VIAL, PREGNYL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
Excluded if used to promote fertility. MHH (Reauth): Documentation of positive clinical response to therapy.
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. TF/C/I to both Enbrel and Humira, or attestation demonstrating a trial may be inappropriate, OR for continuation of prior Cimzia therapy. Crohn's Disease (CD, initial): Dx of moderately to severely active CD. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine (Purinethol), Azathioprine (Imuran), Corticosteroid (eg, prednisone, methylprednisolone), Methotrexate (Rheumatrex, Trexall). TF/C/I to Humira OR for continuation of prior Cimzia therapy. Psoriatic Arthritis (PsA, initial): Dx of active PsA. TF/C/I to both Enbrel and Humira, or attestation demonstrating a trial may be inappropriate, OR for continuation of prior Cimzia 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 Cimzia therapy. Plaque Psoriasis (initial): Dx of moderate to severe plaque psoriasis. TF/C/I to Cosentyx AND either Humira or Enbrel OR for continuation of prior Cimzia 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).

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**

**OTHER CRITERIA**
Reauth (all indications): Documentation of positive clinical response to Cimzia therapy.
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
MEDECATION(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.
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.
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 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 or ARB.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
CHF (initial, reauth): 12 months

OTHER CRITERIA
CHF (reauth): Documentation of positive clinical response to Corlanor therapy.
MEDICATION(S)
COSENTYX (2 SYRINGES), COSENTYX PEN, COSENTYX PEN (2 PENS), COSENTYX SYRINGE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: Trial and failure, contraindication, or intolerance to Enbrel (etanercept) OR Humira (adalimumab), OR for continuation of prior Cosentyx therapy. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: Trial and failure, contraindication, or intolerance to Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior Cosentyx therapy. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. One of the following: Trial and failure, contraindication, or intolerance to Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior Cosentyx 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 rheumatologist or dermatologist. AS (initial): Prescribed by or in consultation with a rheumatologist.

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

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
All indications: Excluded if for fertility uses.

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
CYRAMZA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
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 AND Patient is concomitantly receiving treatment with oral cysteamine.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
DACOGEN (S)

MEDICATION(S)
DECITABINE

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.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
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 moderate to very severe COPD. COPD is associated with chronic bronchitis. 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.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
COPD (init, reauth): 12 months

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

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.
MEDICATION(S)
DEFERASIROX, EXJADE, JADENU, 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): 6 mo.

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

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

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
DEXTROAMPHETAMINE (S)

MEDICATION(S)
DEXTROAMPHETAMINE SULFATE, DEXTROAMPHETAMINE SULFATE ER, ZENZEDI 10 MG TABLET, ZENZEDI 5 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

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

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
DOXEPIN TOPICAL (S)

MEDICATION(S)
DOXEPIN 5% CREAM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of moderate pruritus. Patient has atopic dermatitis or lichen simplex chronicus. Trial and failure, contraindication, or intolerance to at least one medium potency topical corticosteroid, or is not a candidate for topical corticosteroids (e.g., treatment is on face, axilla, or groin).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
14 days

OTHER CRITERIA
N/A
MEDICATION(S)
DUOBRII

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
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
MEDICATION(S)
DUPIXENT

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 moderate to severe atopic dermatitis. Trial and failure, contraindication, or intolerance to one medium to high potency topical corticosteroid. One of the following: A) Trial and failure or intolerance to pimecrolimus topical cream, unless the patient is not a candidate for pimecrolimus therapy (e.g., immunocompromised, severe atopic dermatitis), B) Trial and failure or intolerance to tacrolimus topical ointment, unless the patient is not a candidate for tacrolimus ointment therapy (e.g., immunocompromised), or C) Eucrisa (crisaborole). Eosinophilic Asthma (initial): Diagnosis of moderate 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 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, 2) Any prior intubation for an asthma exacerbation, or 3) Prior asthma-related hospitalization within the past 12 months. Corticosteroid Dependent Asthma (initial): Diagnosis of moderate to severe asthma. Patient is currently dependent on oral corticosteroids for the treatment of asthma. Eosinophilic Asthma, Corticosteroid Dependent Asthma (initial): 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), theophylline], OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)].

AGE RESTRICTION
Asthma (initial): Age greater than or equal to 12 years. Atopic dermatitis: 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.

COVERAGE DURATION

OTHER CRITERIA
Atopic dermatitis (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in body surface area involvement, reduction in pruritus severity). Eosinophilic Asthma (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). Patient is currently being treated with ONE of the following unless there is a contraindication or intolerance to these medications: 1) Inhaled corticosteroid (ICS) and additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline] OR 2) A combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Dulera [mometasone/formoterol], Symbicort [budesonide/formoterol]). Corticosteroid Dependent Asthma (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in exacerbations, improvement in FEV1, reduction in oral corticosteroid dose). Patient is currently being treated with ONE of the following unless there is a contraindication or intolerance to these medications: 1) Inhaled corticosteroid (ICS) and additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline] OR 2) A combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Dulera [mometasone/formoterol], Symbicort [budesonide/formoterol]).
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
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) (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): Not used in combination with another calcitonin gene-related peptide (CGRP) inhibitor. One of the following: trial and failure, contraindication, or intolerance to Aimovig OR for prior continuation of therapy.

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

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

**COVERAGE DURATION**
EM, CM (initial): 6 months. ECH (initial): 3 months. EM, CM, ECH (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. CM (reauth): Patient continues to be monitored for medication overuse headache.
MEDICATION(S)
EMPLICITI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Multiple myeloma: Diagnosis of multiple myeloma. One of the following: 1) Both of the following: a) Patient has received at least one prior therapy for multiple myeloma [eg, Revlimid (lenalidomide), Thalomid (thalidomide), Velcade (bortezomib)]. and b) Used in combination with both of the following: Revlimid (lenalidomide) and dexamethasone., OR 2) Both of the following: a) Patient has received at least two prior therapies including Revlimid (lenalidomide) and a proteasome inhibitor and b) Used in combination with both of the following: Pomalyst (pomalidomide) and dexamethasone.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

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

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
All indications (Reauth): Documentation of positive clinical response to Enbrel therapy.
**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. One of the following: (a) Patient is using Endari with concurrent hydroxyurea therapy, OR (b) Patient has a contraindication or intolerance to hydroxyurea. 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 Endari therapy.
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]. UC, CD (init, reauth): Patient is not receiving Entyvio in combination with Tysabri (natalizumab), or a TNF inhibitor [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), 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 Entyvio therapy.
MEDICATION(S)
EPCLUSA

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. One of the following: 1) Trial and failure, contraindication or intolerance to Mavyret (except patients with decompensated cirrhosis) AND sofosbuvir/velpatasvir, OR 2) For continuation of prior brand Epclusa therapy. Patient is not receiving Epclusa 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
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. Patient is not receiving sofosbuvir/velpatasvir 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
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.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
EPOPROSTENOL SODIUM, VELETRI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

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

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

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

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

**AGE RESTRICTION**
N/A

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

**COVERAGE DURATION**
12 months
OTHER CRITERIA
Approve for continuation of prior therapy.
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
18 years of age or older

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
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. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog OR 2) Patient received bilateral orchiectomy. 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.
**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): Both of the following: 1) diagnosis of IPF as documented by all of the following: a) exclusion of other known causes of interstitial lung disease (ILD) (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity), AND b) one of the following: i) in patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF, AND 2) not used in combination with Ofev (nintedanib).

**AGE RESTRICTION**
N/A

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

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

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial: 6 months, Reauth: 12 months

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of one of the following: A) Neovascular (wet) age-related macular degeneration OR B) Macular edema following retinal vein occlusion, OR C) Diabetic macular edema OR D) Diabetic retinopathy in patients with diabetic macular edema.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Fabry Disease: Diagnosis of Fabry disease.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Fabry Disease: 12 months

OTHER CRITERIA
N/A
MEDICATION(S)
FARYDAK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

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

MEDICATION(S)
FASENRA

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), theophylline], OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)].

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) and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline], OR b) A combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)].
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)
FERRIPROX 100 MG/ML SOLUTION, FERRIPROX 500 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Transfusional iron overload due to thalassemia syndromes (Initial): Diagnosis of transfusional iron overload due to thalassemia syndromes. 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 Desferal (deferoxamine), Exjade (deferasirox) or Jadenu (deferasirox) OR B) History of contraindication or intolerance to Desferal (deferoxamine), Exjade (deferasirox) or Jadenu (deferasirox).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
All uses (reauth): Patient has experienced greater than or equal to 20% decline in serum ferritin levels from baseline. ANC greater than 1.5 x 10^9/L.
MEDICATION(S)
FIRAZYR, 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
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. Patient has moderate to severe weakness that interferes with function.

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 Firdapse therapy (e.g., improvement in dynamometry, Timed 25-Foot Walk Test, Timed Up and Go Test).
MEDICATION(S)
FIRMAGON

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of advanced or metastatic prostate cancer.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

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

MEDICATION(S)
FORTEO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Postmenopausal osteoporosis or osteopenia or men with primary or hypogonadal osteoporosis or osteopenia: 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. Treatment duration of parathyroid hormones [e.g., Forteo (teriparatide), Tymlos (abaloparatide)] has not exceeded a total of 24 months during the patient's lifetime. Glucocorticoid-Induced Osteoporosis: See Other Criteria section.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A
COVERAGE DURATION
All uses: 24 months (max 24 months of therapy per lifetime)

OTHER CRITERIA
Glucocorticoid-Induced Osteoporosis: 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). Treatment duration of parathyroid hormones [e.g., Forteo (teriparatide), Tymlos (abaloparatide)] has not exceeded a total of 24 months during the patient's lifetime.
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 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
N/A
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): Galafold 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 Galafold 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.
**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 Gattex therapy.
MEDICATION(S)
GAZYVA

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 chlorambucil. Patient is previously untreated for CLL. Follicular lymphoma (FL): One of the following: 1)All of the following: 1.2)Diagnosis of FL. 1.3)Patient has relapsed after or is refractory to a rituximab-containing regimen. 1.4)Both of the following: Used in combination with bendamustine and followed by Gazyva monotherapy. OR 2)All of the following: 2.1) Diagnosis of stage II bulky, III, or IV follicular lymphoma 2.2) Patient has not been treated with prior therapy 2.3) Both of the following: Used in combination with chemotherapy until patient has at least achieved a partial remission and followed by Gazyva monotherapy.

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.
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, relapsing-remitting MS, secondary-progressive MS with relapses).

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 IIIIB 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.
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, relapsing-remitting MS, secondary-progressive MS with relapses).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
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

REQURED MEDICAL INFORMATION
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 and Osmolex (amantadine ER).

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Parkinson's Disease (reauthorization): Documentation of positive clinical response to Gocovri therapy (e.g., decreased off periods or decreased on time with troublesome dyskinesia).
GROWTH HORMONE, PREFERRED (S)

MEDICATION(S)
GENOTROPIN, NUTROPIN AQ NUSPIN

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 growth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.25SD below population(pop) mean (below 1.2 percentile for age and gender), or growth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg, delayed more than 2yrs compared w/chronological age)].

PWS(reauth): evidence of positive response to tx (eg, incr in total LBM, decr in fat mass) and expctd adult ht not attained and doc of expctd adult ht goal.

GFSGA(initial): SGA dx based on catchup growth failure in 1st 24mo of life using 0-36mo growth chart confirmed by birth wt or length below 3rd percentile for gestational age (more than 2SD below pop mean) and ht remains at or below 3rd percentile (more than 2SD below pop mean).

TS,NS(initial): ped growth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on growth charts for age and gender.

SHOX(initial): ped growth failure dx w/SHOX gene deficiency confirmed by genetic testing.

GFCRI(initial): ped growth failure dx assoc w/CRI. ISS(initial): ISS dx, diagnostic eval excluded other causes assoc w/short stature (eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender 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, GFGSA, 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 1 GH stim test (insulin tolerance test [ITT], arginine/GHRH,glucagon,arginine) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L],[GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2],[glucagon at or below 3mcg/L],[Arg at or below 0.4mcg/L]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IFG-1/somatomedinC below age and gender adj std rmnl 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 std rmnl range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,GHRH+ARG,ARG,glucagon) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L]. TPAP(reauth): evidence of positive response to therapy (eg, incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3). IGHDA(initial): doc GHD by failure to produce peak serum GH greater than 5 mcg/L after 2 provocative pharmacol stim tests(insulin,L-ARG,glucagon).
MEDICATION(S)
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 erythematosus, systemic dermatomyositis (polymyositis). Dermatologic diseases: Severe erythema multiforme, Stevens-Johnson syndrome. Allergic states: Serum sickness. Ophthalmic diseases: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa, such as: keratitis, iritis and iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation. Respiratory diseases: Symptomatic sarcoidosis. Edematous state: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus. All indications except for infantile spasms: Trial and failure, contraindication, or intolerance to treatment with two corticosteroids. 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
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
HALAVEN (S)

MEDICATION(S)
HALAVEN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria will be applied consistent with current AASLD/IDSA guideline. All (including patients with genotype 5 or 6 infection AND decompensated cirrhosis): A) Diagnosis of chronic hepatitis C, B) Patient is not receiving ledipasvir/sofosbuvir in combination with another HCV direct acting antiviral agent [eg, Sovaldi (sofosbuvir)]. ONE of the following: Trial and failure, intolerance, or contraindication to a) Mavyret (except patients with decompensated cirrhosis, or pediatric patients younger than 12 years of age and weighing between 35-44 kg) and b) sofosbuvir/velpatasvir (except pediatric patients 12 to 17 years of age or weighing at least 35 kg, OR patients with GT 1, 4, 5, or 6, a liver transplant and compensated or decompensated cirrhosis), OR for continuation of prior ledipasvir/sofosbuvir therapy. Pediatric patients 12 to 17 years of age weighing at least 45 kg: One of the following: 1) Trial and failure, contraindication or intolerance to Mavyret OR 2) For continuation of prior ledipasvir/sofosbuvir therapy.

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
N/A
MEDICATION(S)
HERCEPTIN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
Non-24 (reauth): Documentation of positive clinical response to Hetlioz therapy.
MEDICATION(S)
CYPROHEPTADINE 4 MG TABLET, DEXCHLORPHENIRAMINE MALEATE, HYDROXYZINE 10 MG/5 ML SOLN, HYDROXYZINE 10 MG/5 ML SYRUP, HYDROXYZINE 100 MG/2 ML VIAL, HYDROXYZINE 25 MG/ML VIAL, HYDROXYZINE 50 MG/25 ML SYRUP, HYDROXYZINE 50 MG/ML VIAL, HYDROXYZINE 500 MG/10 ML VIAL, HYDROXYZINE HCL 10 MG TABLET, HYDROXYZINE HCL 25 MG TABLET, HYDROXYZINE HCL 50 MG TABLET, HYDROXYZINE PAM 100 MG CAP, HYDROXYZINE PAM 25 MG CAP, HYDROXYZINE PAM 50 MG CAP, PHENADOZ, PROMETHAZINE 12.5 MG SUPPOS, PROMETHAZINE 12.5 MG TABLET, PROMETHAZINE 25 MG SUPPOSITORY, PROMETHAZINE 25 MG TABLET, PROMETHAZINE 25 MG/ML AMPUL, PROMETHAZINE 25 MG/ML VIAL, PROMETHAZINE 50 MG SUPPOSITORY, PROMETHAZINE 50 MG TABLET, PROMETHAZINE 50 MG/ML AMPUL, PROMETHAZINE 50 MG/ML VIAL, PROMETHAZINE 6.25 MG/5 ML SOLN, PROMETHAZINE 6.25 MG/5 ML SYRP, PROMETHEGAN

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)
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.
MEDICATION(S)
MEGESTROL 20 MG TABLET, MEGESTROL 40 MG TABLET, MEGESTROL 625 MG/5 ML SUSP,
MEGESTROL ACET 40 MG/ML SUSP, MEGESTROL ACET 400 MG/10 ML

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
PA applies to patients 65 years or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Applies to New Starts only.
MEDICATION(S)
PENTOBARBITAL 1,000 MG/20 ML, PENTOBARBITAL 2,500 MG/50 ML, PHENOBARBITAL 100 MG TABLET, PHENOBARBITAL 15 MG TABLET, PHENOBARBITAL 16.2 MG TABLET, PHENOBARBITAL 20 MG/5 ML ELIX, PHENOBARBITAL 20 MG/5 ML SOLN, PHENOBARBITAL 30 MG TABLET, PHENOBARBITAL 32.4 MG TABLET, PHENOBARBITAL 60 MG TABLET, PHENOBARBITAL 64.8 MG TABLET, PHENOBARBITAL 97.2 MG TABLET, 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.
MEDICATION(S)
CHLORZOXAZONE 250 MG TABLET, 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
MEDICATION(S)
CHLORDIAZEPoxide-AMITRIPTYLINE, 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.
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 40 MG/0.4 ML, HUMIRA(CF) PEN CROHN'S-UC-HS, 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. 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 REstricted
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, Plaque psoriasis, AS, CD, Hidradenitis suppurativa (HS), Uveitis (Reauth): Documentation of positive clinical response to Humira therapy. UC (Reauth): For patients who initiated Humira 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 Humira therapy for longer than 12 weeks: Documentation of positive clinical response to Humira therapy.
HYDROXYPROGESTERONE (S)

MEDICATION(S)
HYDROXYPROGESTERONE 1.25 G/5ML

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
All uses (initial): Pregnant patients.

REQUIRED MEDICAL INFORMATION
Amenorrhea/Abnormal Uterine Bleeding: Diagnosis of one of the following: 1) primary or secondary amenorrhea or 2) abnormal uterine bleeding. Amenorrhea is due to hormonal imbalance in the absence of organic pathology (e.g., submucous fibroids or uterine cancer) Secretory endometrium and desquamation: Used for production of secretory endometrium and desquamation in patients with endometrial disorder. Adenocarcinoma: Diagnosis of Stage III or IV adenocarcinoma of the uterine corpus. Estrogen production test: Used for the testing of endogenous estrogen production.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Breast Cancer: Diagnosis of 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, resistance, relapse, 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
All Uses: 18 years of age or older

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

COVERAGE DURATION
All uses: 12 months

OTHER CRITERIA
All uses: Approve for continuation of prior therapy.
MEDICATION(S)
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.
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 Autoinflammatory 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
Periodic Fever Syndrome (CAPS, TRAPS, HIDS/MKD, FMF) ((Reauth) and SJIA (Reauth): Documentation of positive clinical response to therapy.
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 Enbrel (etanercept) or Humira (adalimumab) AND 2) Trial and failure, contraindication, or intolerance to Cosentyx (secukinumab), or set B) For continuation of prior Ilumya 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 Ilumya therapy.
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.
MEDITATION(S)
IMFINZI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Urothelial carcinoma: 1) Diagnosis of locally advanced or metastatic urothelial carcinoma AND 2) One of the following: a) Patient has experienced disease progression during or following platinum-containing chemotherapy OR b) Patient has experienced disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Non-Small Cell Lung Cancer (NSCLC): 1) Diagnosis of NSCLC AND 2) Disease is stage III and unresectable AND 3) Disease has not progressed following concurrent platinum-based chemotherapy and radiation 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
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. Patient is receiving Inbrija in combination with carbidopa/levodopa. Trial and failure, contraindication or intolerance to one 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 Inbrija therapy. Patient is receiving Inbrija 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.
MEDICATION(S)
INFLECTRA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

OTHER CRITERIA
Reauthorization for all indications: Documentation of positive clinical response to infliximab therapy. All indications (re-auth): Excluded if patient is receiving infliximab in combination with a Biologic Disease Modifying Antirheumatic Drug (DMARD) [eg, Enbrel (etanercept), Oencia (abatacept), Rituxan (rituximab), Kineret (anakinra), Cimzia (certolizumab)].
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 Ingrezza 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 cancer (RCC): Diagnosis of RCC. One of the following: (1) disease has relapsed or (2) both of the following: medically or surgically unresectable tumor and diagnosis of stage IV disease.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
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 Kaposis sarcoma, diagnosis of malignant melanoma, diagnosis of Stage III or IV follicular Non-Hodgkins 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.
MEDICATION(S)
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 both of the following conventional therapy regimens: a) topical retinoid or retinoid-like agent [eg, Retin-A/Retin-A Micro (tretinoin)] AND b) combination therapy with benzoyl peroxide and one of the following: 1) oral antibiotic [eg, Ery-Tab (erythromycin), Minocin (minocycline)] OR 2) topical antibiotic [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.
MEDICATION(S)
ISTODAX, ROMIDEPSIN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months.

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

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

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 Juxtapid therapy. Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor.
**MEDICATION(S)**
KADCYLA

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

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

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

**AGE RESTRICTION**
N/A

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

**COVERAGE DURATION**
12 months

**OTHER CRITERIA**
Approve for continuation of prior therapy.
MEDICATION(S)
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
Patient is greater than or equal to 12 years of age

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

COVERAGE DURATION
12 months

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

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

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**

**AGE RESTRICTION**
CF (Initial): 6 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) to Kalydeo therapy.
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
**KEVEYS (S)**

**MEDICATION(S)**
KEVEYS

**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 Keveyis 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) Trial and failure, contraindication, or intolerance (TF/C/I) to both Enbrel (etanercept) and Humira (adalimumab), b) or attestation demonstrating a trial may be inappropriate, OR c) For continuation of prior Kevzara 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 Kevzara therapy.
MEDICATION(S)
KEYTRUDA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
cHL, PMBCL: Prescribed by or in consultation with a hematologist/oncologist. All Other Uses: Prescribed by or in consultation with an oncologist.
COVERAGE DURATION
12 months

OTHER CRITERIA
Urothelial Carcinoma: Dx of locally advanced or metastatic urothelial carcinoma AND one of the following: 1) Patient is not eligible for cisplatin-containing chemotherapy and tumors express PD-L1 (Combined Positive Score [CPS] greater than or equal to 10), 2) Disease progression during or following platinum-containing chemotherapy, or 3) Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Microsatellite Instability-High Cancer (MSI-H): One of the following: 1) Dx of unresectable or metastatic, MSI-H or mismatch repair deficient solid tumors AND disease progression following prior treatment AND patient has no satisfactory alternative treatment options, OR 2) Dx of unresectable or metastatic, MSI-H or mismatch repair deficient colorectal cancer AND patient has experienced progression following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. Gastric Cancer: Dx of gastric or gastroesophageal junction adenocarcinoma AND disease is locally advanced, recurrent, or metastatic AND tumors express PD-L1 (Combined Positive Score [CPS] greater than or equal to 1) as determined by an FDA-approved test and disease progression following two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy AND HER2/neu-targeted therapy if the patient is HER2/neu positive. Cervical Cancer (CC): Dx of CC. Disease is recurrent or metastatic. Disease progression on or after chemotherapy. Tumor(s) express PD-L1 (CPS greater than or equal to 1) as determined by an FDA-approved test. All Indications: Approve for continuation of prior therapy.
**MEDICATION(S)**
KINERET

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

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior Kineret therapy.

Neonatal-Onset Multisystem Inflammatory Disease (NOMID) (initial): Diagnosis of NOMID AND dx of NOMID has been confirmed by one of the following: 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]).

**AGE RESTRICTION**
N/A

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

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

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

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

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
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) Kisqali is used in combination with an aromatase inhibitor [e.g., Femara (letrozole)] OR B) Both of the following: 1) Used in combination with Faslodex (fulvestrant) and 2) patient is a postmenopausal woman.

**AGE RESTRICTION**
N/A

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

**COVERAGE DURATION**
12 months

**OTHER CRITERIA**
Approve for continuation of prior therapy
MEDICATION(S)
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. Cancer is hormone receptor (HR)-positive and 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.
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 Cushings 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 Korlym therapy or patient has stable glucose tolerance while on Korlym therapy.
MEDICATION(S)
KRYSTEXXA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Gout (initial): Diagnosis of gout. Trial, failure, contraindication or intolerance to two of the following conventional therapies: allopurinol, febuxostat, or probenecid

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Gout (initial, reauth): 12 months

OTHER CRITERIA
Gout (reauth): Serum urate level has decreased since initiating therapy. Clinical improvement in the signs and symptoms of gout (e.g., decrease in tophi size or frequency of gouty flares per year from baseline or improvement in chronic arthropathy or quality of life).
MEDICATION(S)
KUVAN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Phenylketonuria (PKU) (initial): Diagnosis of PKU. Patient 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.
**MEDICATION(S)**
KYNAMRO

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

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Homozygous familial hypercholesterolemia (HoFH) (initial): Submission of medical records (eg, chart notes, laboratory values) documenting diagnosis of HoFH as confirmed by one of the following: a) genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (ie, LDLRAP1 or ARH), or b) both of the following: 1) either untreated LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL AND 2) either xanthoma before 10 years of age or evidence of heterozygous FH in both parents. Patient is receiving other lipid-lowering therapy. Trial and failure, contraindication, or intolerance to Repatha therapy. Not used in combination with Juxtapid (lomitapide). 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 Kynamro therapy. Not used in combination with Juxtapid (lomitapide). Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor.
**MEDICATION(S)**
KYPROLIS

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

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

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

**AGE RESTRICTION**
N/A

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

**COVERAGE DURATION**
12 months

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

MEDICATION(S)
LARTRUVO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy
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, progressive-relapsing 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 one of the following: Ocrevus (daclizumab) or Tysabri (natalizumab), and 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), Plegridy (peginterferon beta-1a), Rebif (interferon beta-1a), Tecfidera (dimethyl fumarate), or 2) Patient has previously received treatment with alemtuzumab, and at least 12 months have or will have elapsed since the first treatment with alemtuzumab, and patient has not already received the FDA-recommended lifetime limit of two (2) treatment courses of 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, max 2 yrs of therapy.

OTHER CRITERIA
N/A
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.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
DTC/RCC: 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, LETAIRIS

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

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

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

**AGE RESTRICTION**
N/A

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

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

**OTHER CRITERIA**
PAH (Reauth): Documentation of positive clinical response to therapy.
LEUKINE (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 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 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): 3 mo or duration of tx. HIVN: 6 mo. ARS: 1 mo.

OTHER CRITERIA
N/A
MEDICATION(S)
LIDOCAINE 5% OINTMENT, LIDOCAINE HCL 2% JELLY, LIDOCAINE HCL 4% SOLUTION, LIDOCAINE-PRILOCAINE, LIPROZONEPAK, MEDOLOR PAK

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
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
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: fluoropyrimidine-based chemotherapy (e.g. fluorouracil), Platinum-based chemotherapy (e.g., carboplatin, cisplatin, oxaliplatin), Taxane (e.g., docetaxel, paclitaxel) or irinotecan-based chemotherapy, HER2/neu-targeted therapy (e.g., trastuzumab) (if HER2 overexpression).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
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 NSCLC. Disease is metastatic and anaplastic lymphoma kinase (ALK)-positive. Metastatic disease has progressed on one of the following: 1) Xalkori (crizotinib) and at least one other ALK inhibitor [e.g., Alunbrig (brigatinib)], 2) Alecensa (alectinib) as the first ALK inhibitor therapy, or 3) Zykadia (ceritinib) as the first ALK inhibitor therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
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.
**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.
MEDICATION(S)
LEUPROLIDE 2WK 1 MG/0.2 ML KT, LEUPROLIDE 2WK 14 MG/2.8 ML KT, LEUPROLIDE 2WK 14
MG/2.8 ML VL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
LUPRON DEPOT-PED 11.25 MG 3MO, 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.
MEDICATION(S)
LYNPARZA 100 MG TABLET, LYNPARZA 150 MG TABLET

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.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
All uses: Prescribed by or in consultation with an oncologist
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). Lynparza will be used as first-line maintenance treatment. 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 MS, secondary-progressive MS with relapses). 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), Betaseron (interferon beta-1b), Copaxone/Glatopa (glatiramer acetate), Extavia (interferon beta-1b), Gilenya (fingolimod), Lemtrada (alemtuzumab), Mayzent (siponimod), Ocrevus (ocrelizumab), Plegridy (peginterferon beta-1a), Rebif (interferon beta-1a), Tecfidera (dimethyl fumarate), Tysabri (natalizumab), Zinbryta (daclizumab), 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

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 patient is not receiving Mavyret 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
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
MEDICATION(S)
METADATE ER, METHYLPHENIDATE ER 10 MG TAB, METHYLPHENIDATE ER 20 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

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

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
RASUVO 10 MG/0.2 ML AUTOINJ, RASUVO 12.5 MG/0.25 ML AUTOINJ, RASUVO 15 MG/0.3 ML AUTOINJ, RASUVO 17.5 MG/0.35 ML AUTOINJ, RASUVO 20 MG/0.4 ML AUTOINJ, RASUVO 22.5 MG/0.45 ML AUTOINJ, RASUVO 25 MG/0.5 ML AUTOINJ, RASUVO 30 MG/0.6 ML AUTOINJ, RASUVO 7.5 MG/0.15 ML AUTOINJ

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 rheumatologist. 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.
METHYLIN CHEW (S)

MEDICATION(S)
METHYLPHENIDATE 10 MG CHEW TAB, METHYLPHENIDATE 2.5 MG CHEW TB, METHYLPHENIDATE 5 MG CHEW TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

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

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
METHYLPHENIDATE (S)

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

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

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
METHYLPHENIDATE ER (S)

MEDICATION(S)
METHYLPHENIDATE ER 18 MG TAB, METHYLPHENIDATE ER 27 MG TAB, METHYLPHENIDATE ER 36 MG TAB, METHYLPHENIDATE ER 54 MG TAB, METHYLPHENIDATE ER 72 MG TAB, METHYLPHENIDATE ER (LA), METHYLPHENIDATE HCL CD, METHYLPHENIDATE HCL ER (CD), METHYLPHENIDATE LA, RELEXXII

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

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

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
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 Mirvaso therapy.
MEDICATION(S)
MOZOBIL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
One course of therapy up to 4 days

OTHER CRITERIA
N/A
MEDICATION(S)
AVONEX, AVONEX PEN, BETASERON 0.3 MG KIT, 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, relapsing-remitting MS, secondary-progressive MS with relapses). One of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to Rebif, or 2) for continuation of prior therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
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, relapsing-remitting MS, secondary-progressive MS with relapses).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
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
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.
MEDICATION(S)
MYLOTARG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Acute myeloid leukemia (AML): One of the following diagnoses: Newly diagnosed AML or relapsed/refractory (R/R) AML. Disease is CD33-positive.

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.
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
MEDICATION(S)
NATPARA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Hypocalcemia (Initial): Diagnosis of hypocalcemia due to chronic hypoparathyroidism. NATPARA is not being used in the setting of acute post-surgical hypoparathyroidism. Patient does not have a known calcium-sensing receptor mutation. Patient 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. NATPARA 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: 4 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
Breast cancer: Diagnosis (dx) of early stage breast cancer. Disease is human epidermal growth factor receptor 2 (HER2)-positive. Patient has received adjuvant Herceptin (trastuzumab)-based 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.
NEULASTA (S)

MEDICATION(S)
NEULASTA

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). 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. One of the following: Relapsed disease OR both medically/surgically unresectable tumor and dx of Stage IV disease. Hepatocellular carcinoma (HCC): Diagnosis of HCC. One of the following: patient has metastatic disease, or patient has extensive liver tumor burden, or patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only), or disease is unresectable. Differentiated thyroid carcinoma (DTC): Diagnosis of DTC (ie, follicular carcinoma, Hurthle cell carcinoma, or papillary carcinoma). One of the following: locally recurrent disease or metastatic disease. One of the following: patient has symptomatic disease or patient has progressive disease. Disease is refractory to radioactive iodine (RAI) treatment. Medullary thyroid carcinoma (MTC): Diagnosis of MTC. 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.
MEDICATION(S)
NINLARO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
MEDICATION(S)
NORTHERA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Neurogenic orthostatic hypotension (NOH) (init): Diagnosis of symptomatic NOH. NOH is caused by one of the following conditions: primary autonomic failure (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. Disease progression despite one of the following therapies: Avonex, Aubagio, Betaseron, Copaxone/Glatopa, Extavia, Gilenya, Lemtrada, Ocrevus, Plegridy, Rebif, Tecfidera, Tysabri, Zinbryta. 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**
N/A

**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
Chronic immune (idiopathic) thrombocytopenic purpura (ITP) (Initial): Diagnosis of relapsed/refractory chronic ITP for greater than 6 months. Baseline platelet count is less than 50,000/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 or immunoglobulins 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 Nplate therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding.
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. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog (e.g., Zoladex [goserelin], Vantas [histrelin], Lupron [leuprolide], Trelstar [triptorelin]) OR 2) Patient received bilateral orchiectomy. Trial and failure, contraindication, 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.
**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), theophylline], OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)].

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 12 years

**PRESCRIBER RESTRICTION**
Asthma (init, reauth): Prescribed by or in consultation with a pulmonologist or allergist/immunologist. EGPA (init): Prescribed by or in consultation with a pulmonologist, rheumatologist or allergist/immunologist.
COVERAGE DURATION
Asthma (init): 6 mo, Asthma (reauth): 12 months. EGPA (init, reauth): 12 months

OTHER CRITERIA
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) and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline], OR b) A combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)]. EGPA (reauth): Documentation of positive clinical response to therapy (e.g., increase in remission time).
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. (Reauthorization): Documentation of clinical benefit from ongoing therapy with Nuedexta.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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.
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. Patients with moderate to severe hepatic impairment (Child-Pugh class B or C) will be subject to a quantity limit of 5 mg or 10 mg twice weekly (MDD = 0.34).

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 (i.e., prior Ocaliva therapy) while on Ocaliva therapy. Patients with moderate to severe hepatic impairment (Child-Pugh class B or C) will be subject to a quantity limit of 5 mg or 10 mg twice weekly (MDD = 0.34).
**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, progressive-relapsing MS with relapses). One of the following: a) Failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following: Aubagio (teriflunomide), Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone/Glatopa (glatiramer acetate), Extavia (interferon beta-1b), Gilenya (fingolimod), Plegridy (peginterferon beta-1a), Rebif (interferon beta-1a), Tecfidera (dimethyl fumarate), 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): 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). Hepatitis B virus (HBV) screening has been performed.

**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 Ocrevus 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], ofatumumab [Arzerra]). Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone).
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.
MEDICATION(S)
OFEV

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
IPF (initial): Prescribed by a pulmonologist

COVERAGE DURATION
Initial, reauth: 12 months

OTHER CRITERIA
IPF (reauth): Documentation of positive clinical response to Ofev therapy.
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: Trial and failure, contraindication, or intolerance to both 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-IV-TR F40.2 for specific phobia diagnostic criteria), OR for continuation of prior Olumiant therapy. Patient is not receiving Olumiant 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 Olumiant therapy. Patient is not receiving Olumiant in combination with a potent immunosuppressant (e.g., azathioprine, cyclosporine).
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.
OPDIVO (S)

MEDICATION(S)
OPDIVO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Melanoma: Diagnosis (dx) of melanoma and one of the following: a) disease is unresectable, or b) disease is metastatic, or c) Opdivo will be used in the adjuvant setting following complete resection of Stage IIIIB/C or Stage IV disease. Non-small cell lung cancer (NSCLC): Dx of NSCLC, disease is metastatic, trial and failure, contraindication, or intolerance (TF/C/I) to platinum-based chemotherapy (eg, cisplatin, carboplatin), and one of the following: 1) absence of epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) rearrangement, OR 2) presence of EGFR or ALK genomic tumor aberrations AND TF/C/I to FDA-approved therapy for these aberrations [e.g., Gilotrif (afatinib), Iressa (gefitinib), Tarceva (erlotinib), Xalkori (crizotinib)]. Renal cell carcinoma (RCC): Dx of RCC. Disease is advanced, relapsed, or Stage IV disease that is surgically unresectable. One of the following: A) TF/C/I to at least one anti-angiogenic or tyrosine kinase inhibitor therapy (eg, Inlyta [axitinib], Votrient [pazopanib], Sutent [sorafenib], Nexavar [sunitinib]) or B) All of the following: 1) intermediate- or poor-prognosis risk, 2) previously untreated disease, and 3) used in combination with Yervoy (ipilimumab). Classical Hodgkin Lymphoma (cHL): Dx of cHL. One of the following: A) Patient has had relapse or progression after autologous hematopoietic stem cell transplantation and Adcetris (brentuximab vedotin), OR B) Patient has had relapse or progression after 3 or more lines of systemic therapy that includes autologous HSCT, OR C) Used as palliative therapy and patient is greater than 60 years of age. Head and Neck Squamous Cell Carcinoma (HNSCC): Dx of recurrent or metastatic HNSCC. Patient has disease progression on or after platinum-containing therapy.

AGE RESTRICTION
Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Metastatic Colorectal Cancer: Patient is 12 years of age or older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist.
COVERAGE DURATION
12 months.

OTHER CRITERIA
Urothelial Carcinoma: Diagnosis of urothelial carcinoma. Disease is locally advanced or metastatic. One of the following: Patient has disease progression during or following platinum-containing chemotherapy OR Patient has disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Metastatic Colorectal Cancer: Dx of microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (CRC). Patient has experienced progression following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. Hepatocellular Carcinoma (HCC): Dx of HCC AND previously treated with Nexavar (sorafenib). All indications: Approve for continuation of prior therapy.
MEDICATION(S)
OPSUMIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
PAH (Reauth): Documentation of positive clinical response to therapy.
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. Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. All indications (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. All indications (Initial, reauth): Patient is not receiving Orencia in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].

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 indications (Initial, reauth): 12 months

OTHER CRITERIA
All indications (Reauth): Documentation of positive clinical response to Orencia 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. Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. All indications (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 Orencia 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.
MEDIICATION(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 of Orilissa has not exceeded a total of 24 months.
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).
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.
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. Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. PsA, plaque psoriasis (initial): Trial and failure, contraindication, or intolerance to both Humira and Enbrel, or attestation demonstrating a trial may be inappropriate, OR for continuation of prior Otezla therapy.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial, Reauth: 12 months

OTHER CRITERIA
Reauth (all indications): Documentation of positive clinical response to Otezla therapy.
MEDICATION(S)
OXANDROLONE 10 MG TABLET, OXANDROLONE 2.5 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Promote weight gain (initial): 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.
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 | 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-PF | AMPHOTERICIN B 50 MG VIAL | APREPITANT, AZASAN, AZATHIOPRINE 50 MG TABLET | BETHKIS | BUDESONIDE 0.25 MG/2 ML SUSP | BUDESONIDE 0.5 MG/2 ML SUSP | BUDESONIDE 1 MG/2 ML INH SUSP | CLINIMIX 4.25%-10% SOLUTION | CLINIMIX 4.25%-5% SOLUTION | CLINIMIX 5%-15% SOLUTION | CLINIMIX 5%-20% SOLUTION | CLINIMIX E 2.75%-5% SOLUTION | CLINIMIX E 4.25%-10% SOLUTION | CLINIMIX E 4.25%-5% SOLUTION | CLINIMIX E 5%-15% SOLUTION | CLINIMIX E 5%-20% SOLUTION | CROMOLYN 20 MG/2 ML NEB SOLN | CYCLOPHOSPHAMIDE 25 MG CAPSULE | CYCLOPHOSPHAMIDE 50 MG CAPSULE | CYCLOSPORINE 100 MG CAPSULE | CYCLOSPORINE 5 MG/ML SYRN | ENGERIX-B 20 MCG/ML SYRN | ENGERIX-B PEDIATRIC-adolescent | FREAMINE HBC | GENGRAF 100 MG SOLUTION | GENGRAF 25 MG CAPSULE | GRANISETRON HCL 1 MG TABLET | HEPATAMINE | IMOVAX RABIES VACCINE | INTRALIPID 20% IV FAT EMUL | IPRATROPIUM BR 0.02% SOLN | IPRATROPIUM-Labetalol | LEVALBUTEROL CONCENTRATE | LEVALBUTEROL HCL | MYCOPHENOLATE 200 MG/ML SUSP | MYCOPHENOLATE 250 MG CAPSULE | MYCOPHENOLATE 500 MG TABLET | MYCOPHENOLIC ACID | NEBUPENT | NEPHRAMINE | NUTRILIPID | ONDANSETRON 4 MG/5 ML SOLUTION | ONDANSETRON HCL 24 MG TABLET | ONDANSETRON HCL 4 MG TABLET | ONDANSETRON HCL 8 MG TABLET | ONDANSETRON ODT | PERFOROMIST | PREMASOL | PROCALAMINE | PROGRAF 0.2 MG GRANULE PACKET | PROGRAF 1 MG GRANULE PACKET | PROSOL | RABAVERT | RECOMBIVAX HB 10 MCG/ML SYR | RECOMBIVAX HB 10 MCG/ML VIAL | RECOMBIVAX HB 40 MCG/ML VIAL | RECOMBIVAX HB 5 MCG/0.5 ML SYR | SANDIMMUNE 100 MG/ML SOLN | SIROLIMUS 0.5 MG TABLET | SIROLIMUS 1 MG TABLET | SIROLIMUS 1 MG/ML SOLUTION | SIROLIMUS 2 MG TABLET | TACROLIMUS 0.5 MG CAPSULE | TACROLIMUS 1 MG CAPSULE | TACROLIMUS 5 MG CAPSULE | TOBRAMYCIN 300 MG/5 ML AMPULE | TRAVASOL | TROPHAMINE 10% IV SOLUTION | YUPELRI |

### DETAILS

This drug may be covered under Medicare Part B or D depending on the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.
MEDICATION(S)
PEG.INTRON 50 MCG KIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chronic Hepatitis C: Criteria will be applied consistent with current AASLD-IDSA guidance.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

OTHER CRITERIA
HepC (reauth): patient has an undetectable HCV RNA at week 24, additional treatment weeks of peginterferon are required to complete treatment regimen, and patient has not exceeded 48 wks of therapy with peginterferon.
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

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
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 oral non-steroidal anti-inflammatory drugs (NSAIDs) OR 2) Documented swallowing disorder OR 3) History of peptic ulcer disease/gastrointestinal bleed OR 4) Patient is older than 65 years of age with one additional risk factor for gastrointestinal adverse events (e.g. use of anticoagulants, chronic corticosteroids).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial, reauth: 12 months

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

MEDICATION(S)
PERJETA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

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

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): All of the following: A) Diagnosis of metastatic squamous NSCLC AND B) Portrazza will be used in combination with gemcitabine and cisplatin AND C) Portrazza will be used as first-line treatment.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
1 year of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
**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 thrombocytopenia. One of the following: 1) Planning to initiate and maintain interferon-based treatment, or 2) currently receiving interferon-based treatment. First-line for severe aplastic anemia (SAA): Diagnosis of SAA. Used for first-line treatment (i.e., patient has not received prior immunosuppressive therapy). Used in combination with standard immunosuppressive therapy. Patient meets at least two of the following: 1) absolute neutrophil count less than 500/mcL, 2) platelet count less than 20,000/mcL, 3) absolute reticulocyte count less than 60,000/mcL. Refractory SAA (initial): Diagnosis of refractory severe aplastic anemia. Patient has a platelet count less than 30,000/mcL. Insufficient response to immunosuppressive therapy.

**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 Promacta 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 Promacta prior to initiation of treatment with interferon, Promacta 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 Promacta treatment by week 9, OR 2) For patients that started treatment with Promacta while on concomitant treatment with interferon, Promacta 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 Promacta therapy as evidenced by an increase in platelet count.
MEDICATION(S)
MODAFINIL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Obstructive sleep apnea/hypopnea syndrome (OSAHS) (Initial): Diagnosis (dx) of OSAHS defined by one of the following: 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), or both of the following: 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), and 1 of the following symptoms: unintentional sleep episodes during wakefulness, daytime sleepiness, unrefreshing sleep, fatigue, insomnia, waking up breath holding/gasping/choking, loud snoring, or breathing interruptions during sleep. Shift-work sleep disorder (SWSD) (Initial): Dx of SWSD confirmed by 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). No other medical condition or medication accounts for the symptoms. 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
MEDICATION(S)
PULMOZYME

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
CF (initial, reauth): 12 months

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

MEDICATION(S)
QUININE SULFATE 324 MG CAPSULE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
7 days

OTHER CRITERIA
N/A
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 and 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.
**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 Ravicti therapy.
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. Psoriatic arthritis (PsA) (Initial): Dx of active PsA. Plaque psoriasis (Initial): Dx of chronic severe (ie, extensive and/or disabling) plaque psoriasis. Sarcoidosis (Initial): TF/C/I to one immunosuppressant [eg, methotrexate (Rheumatrex/Trexall), cyclophosphamide, or azathioprine (Imuran)] AND TF/C/I to one corticosteroid (eg, prednisone). All indications (Initial): Patient is not receiving Remicade in combination with a biologic DMARD [eg, Enbrel (etanercept), Rituxan (rituximab), Ocrenza (abatacept), Kineret (anakinra)].

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 a dermatologist. Plaque Psoriasis (Initial): Prescribed by or in consultation with a dermatologist. Sarcoidosis (Initial): Prescribed by or in consultation with a pulmonologist, dermatologist, ophthalmologist.
COVERAGE DURATION
All indications (initial, reauth): 12 months

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

MEDICATION(S)
REMODULIN, TREPROSTINIL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
Subject to Part B vs. D Review. PAH (Reauth): Documentation of positive clinical response to therapy.
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): Diagnosis (Dx) of moderately to severely active CD or FCD. Ulcerative colitis (UC) (initial): Dx of moderately to severely active UC. Rheumatoid arthritis (RA) (initial): 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. Reauthorization for all indications: Documentation of positive clinical response to infliximab 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. CD, FCD, UC (initial): Prescribed by or in consultation with a gastroenterologist. Plaque Psoriasis (initial): Prescribed by or in consultation with a dermatologist.

COVERAGE DURATION
All indications (Initial, reauth): 12 months
OTHER CRITERIA
CD, FCD (initial): Trial and failure, contraindication or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine (Purinethol), azathioprine (Imuran), corticosteroids (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex, Trexall). UC (initial): TF/C/I to one of the following conventional therapies: corticosteroids, aminosalicylate [eg, mesalamine (Asacol/Pentasa/Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine/Sulfazine)], azathioprine (Imuran), 6-mercaptopurine (Purinethol). RA (initial): Receiving concurrent therapy with methotrexate (Rheumatrex/Trexall), or TF/C/I to methotrexate. AS (initial): TF/C/I to two or more NSAIDs. All indications (initial): One of the following: 1) Trial and failure or intolerance to Remicade or 2) For continuation of prior Renflexis therapy. All indications (Initial and re-auth): Excluded if patient is receiving infliximab in combination with a Biologic Disease Modifying Antirheumatic Drug (DMARD) [eg, Enbrel (etanercept), Orencia (abatacept), Rituxan (rituximab), Kineret (anakinra), Cimzia (certolizumab)].
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 (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 (e.g., chart notes, laboratory 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. HoFH (initial): 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 LDRAP1 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 (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 consecutive weeks of one high-intensity (HI) statin therapy (tx) and will continue to receive a HI statin [ie, atorvastatin 40-80 mg, Crestor (rosuvastatin) 20-40 mg] at max tolerated dose.

AGE RESTRICTION
N/A
**PREScriber Restriction**
HeFH/ASCVD/HoFH (init, reauth): Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist

**Coverage Duration**
HeFH/ASCVD/HoFH (init): 6 mon. HeFH/ASCVD/HoFH (reauth): 12 mons

**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 consec 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, Crestor (rosuvastatin) 5-10 mg, simvastatin 10-40 mg, pravastatin 10-80 mg, lovastatin 20-40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1-4 mg] at 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 statin 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 consec 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 consecutive 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): Pt is receiving other lipid-lowering tx (eg statin, ezetimibe). HeFH/ASCVD (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): Pt continues to receive other lipid-lowering tx (eg statin, ezetimibe). HeFH/ASCVD/HoFH (reauth): Sub of MR (eg, lab values) documenting LDL reduction while on Repatha tx. HeFH/ASCVD/HoFH (Init, reauth): Prescriber attests that the info provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical info necessary to verify the accuracy of the info provided. HoFH (Init, reauth): Not used in combo w/ Juxtapid.
**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 concurrently on chemo, or will receive concomitant chemo for a minimum of 2 mos, or anemia is caused in part by cancer chemo. Will not be approved if patient is not receiving cancer chemotherapy. Preoperative for reduction of allogeneic blood transfusion: Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery. Hgb is greater than 10 to less than or equal to 13 g/dL. Patient is at high risk for perioperative transfusions. Patient is unwilling or unable to donate autologous blood pre-operatively. Anemia in hepatitis C virus (HCV)-infected pts due to ribavirin in combination with interferon/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

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

MEDICATION(S)
SILDENAFIL, 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 INJECTION (S)

MEDICATION(S)
SILDENAFIL 10 MG/12.5 ML VIAL

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. Patient is unable to take oral medications.

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
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.
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
MEDICATION(S)
RINVOQ ER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Rheumatoid arthritis (RA) (initial): Diagnosis of moderately to severely active RA. One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or 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 Rinoq therapy. Patient is not receiving Rinvoq 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. Patient is not receiving Rinoq in combination with a potent immunosuppressant (e.g., azathioprine, cyclosporine).
MEDICATION(S)
RITUXAN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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

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

AGE RESTRICTION
N/A
PRESCRIBER RESTRICTION
ITP: Prescribed by or in consultation with a hematologist or oncologist. RA: Prescribed by or in consultation with a rheumatologist. WG, MPA: Prescribed by or in consultation with a nephrologist, pulmonologist, or rheumatologist. 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
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: 1) Diagnosis of follicular CD20-positive lymphoma AND 2) One of the following: 2.1) Disease is relapsed or refractory OR 2.2) Patient exhibited complete or partial response to prior treatment with rituximab in combination with chemotherapy OR 2.3) Disease is non-progressing or stable following prior treatment with first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy OR 2.4) Both of the following: 2.4.1) Disease is previously untreated AND 2.4.2) Medication is used in combination with first-line chemotherapy AND 3) Patient receives a full induction dose of intravenous rituximab prior to initiation of therapy. 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 AND 4) Patient receives a full induction dose of intravenous rituximab prior to initiation of therapy. Chronic Lymphocytic Leukemia: 1) Diagnosis of chronic lymphocytic leukemia AND 2) Medication is being used in combination with fludarabine and cyclophosphamide (FC) therapy AND 3) Patient receives a full induction dose of intravenous rituximab prior to initiation of 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.
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).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy
MEDICATION(S)
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
**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. Patient has moderate to severe weakness that interferes with function.

**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).
**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.
MEDICATION(S)
VIGABATRIN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Acromegaly (initial): Diagnosis of acromegaly. 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 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.
MEDICATION(S)
SANDOSTATIN LAR DEPOT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
Acromegaly (reauth): Patient has had a clinical response to therapy (e.g., reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size). Carcinoid tumor (reauth): patient has improvement in number of diarrhea or flushing episodes. Vasoactive intestinal peptide tumor (reauth): patient has improvement in number of diarrhea episodes.
MEDICATION(S)
CUTAQUIG, CUVITRU 1 GRAM/5 ML VIAL, CUVIDRU 2 GRAM/10 ML VIAL, CUVIDRU 4 GRAM/20 ML VIAL, CUVIDRU 8 GRAM/40 ML VIAL

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). Hizentra only: Patient does not have hyperprolinemia.

REQUIRED MEDICAL INFORMATION
Initial: 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). Chronic inflammatory demyelinating polyneuropathy (CIDP): Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis AND Ig is being used subcutaneously (SC).

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, etc.).

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.
SEROSTIM (S)

MEDICATION(S)
SEROSTIM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial: 3 months. Reauth: 6 months

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
Acromegaly (reauth): patient’s growth hormone (GH) level or insulin-like growth factor 1 (IGF-1) level for age and gender has normalized/improved
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 greater than 2 years of age

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
12 months

**OTHER CRITERIA**
N/A
**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) or Humira (adalimumab), OR b) for continuation of prior Siliq 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 Siliq therapy.
MEDICATION(S)
SIMPONI ARIA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Rheumatoid arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: Receiving concurrent therapy with methotrexate (Rheumatrex/Trexall), OR trial and failure, contraindication, or intolerance (TF/C/I) to methotrexate (Rheumatrex/Trexall). 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. 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 Simponi therapy. All indications (initial): Patient is not receiving Simponi Aria in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)].

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 (Initial, reauth): 12 months
OTHER CRITERIA
All Indications (Reauth): Documentation of positive clinical response to Simponi therapy. Patient is not receiving Simponi Aria in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Oeneric (abatacept)].
**SKYRIZI (S)**

**MEDICATION(S)**
SKYRIZI (2 SYRINGES) KIT

**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) or Humira (adalimumab), OR b) for continuation of prior Skyrizi 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 Skyrizi therapy.
**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): The member has diagnosis of PNH or aHUS. 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 immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus), and TF/C/I to chronic plasmapheresis/plasma exchange (PE) or intravenous immunoglobulin (IVIG).

**AGE RESTRICTION**
N/A

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

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

**OTHER CRITERIA**
All indications (reauth): Documentation of positive clinical response to Soliris therapy.
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.
MEDICATION(S)
SOMAVERET

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).
MEDICATION(S)
SPINRAZA

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 either of the following: 1) Invasive ventilation or tracheostomy or 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). Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
SMA (initial, reauth): Prescribed by or in consultation with a neurologist with expertise in the diagnosis of SMA

COVERAGE DURATION
Initial: 3 months. Reauth: 6 months.
OTHER CRITERIA
SMA (reauth): Documentation of positive clinical response to Spinraza therapy from pretreatment baseline status as demonstrated by the most recent results (less than 1 month prior to request) from one of the following exams: A) Both of the following HINE milestones: 1) One of the following: a) Improvement or maintenance of a previous improvement of at least a 2 point (or maximal score) increase in ability to kick or b) Improvement or maintenance of a previous improvement of at least a 1 point increase in any other HINE milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp AND 2) One of the following: a) Improvement or maintenance of a previous improvement in more HINE motor milestones than worsening from pretreatment baseline (net positive improvement) or b) Patient has achieved and maintained any new motor milestones from pretreatment baseline 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 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 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. Patient continues to not be dependent on either of the following: 1) Invasive ventilation or tracheostomy or 2) use of non-invasive ventilation beyond use for naps and nighttime sleep. Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures.
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

OTHER CRITERIA
N/A
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.
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
Diagnosis of moderately to severely active Crohn's disease. 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)]. Patient is not receiving Stelara in combination a biologic DMARD [e.g, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].

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: 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.
MEDICATION(S)
STELARA 45 MG/0.5 ML SYRINGE, STELARA 45 MG/0.5 ML VIAL, STELARA 90 MG/ML SYRINGE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

PAGE 309
LAST UPDATED 10/2019
OTHER CRITERIA
Reauth (all indications): Documentation of positive clinical response to Stelara therapy.
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, AND 3) trial and failure, contraindication or intolerance to an anti-VEGF therapy (e.g., Avastin [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.
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)
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.
MEDICATION(S)
SYLATRON, SYLATRON 4-PACK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
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 Sylvant therapy. Patient is HIV negative and HHV-8 negative.
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 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 one of the following mutations on at least one allele 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): E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D579G, 711+3A-G, E831X, S945L, S977F, F1052V, K1060T, A1067T, R1070W, F1074L, D1152H, D1270N, 2789+5G-A, 3272-26A-G, 3849+10kbC-T.

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 Symdeko (tezacaftor/ivacaftor) therapy (e.g., improvement in lung function or decreased number of pulmonary exacerbations).
**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).
**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
12 months

OTHER CRITERIA
Approve 5 doses based on patient body weight for all other indications.
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
CML: 18 years of age or older

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
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
MEDICATION(S)
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.
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) AND medication is used in combination with Mekinist (trametinib). 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): 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).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
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
MEDICATION(S)
TALTZ AUTOINJECTOR, TALTZ AUTOINJECTOR (2 PACK), TALTZ AUTOINJECTOR (3 PACK), TALTZ SYRINGE, TALTZ SYRINGE (2 PACK)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: 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 Taltz 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 Taltz 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
Initial, reauth: 12 months

OTHER CRITERIA
All indications (Reauth): Documentation of positive clinical response to Taltz therapy.
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.
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.
MEDICATION(S)
BEXAROTENE, TARGRETIN 1% GEL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chronic myelogenous leukemia (CML): Diagnosis of Ph+/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.
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 Tavalisse therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding.
TECENTRIQ (S)

MEDICATION(S)
TECENTRIQ

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Urothelial Carcinoma: Diagnosis of locally advanced or metastatic urothelial carcinoma. One of the following: A) Both of the following: Tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] covering greater than or equal to 5% of the tumor area), as determined by an FDA-approved test (e.g., Ventana PD-L1 Assay) and Patient is not eligible for cisplatin-containing chemotherapy, B) Patient is not eligible for any platinum-containing chemotherapy regardless of PD-L1 status, C) Patient has disease progression during or following any platinum-containing chemotherapy, OR D) Patient has disease progression within 12 months of neoadjuvant or adjuvant chemotherapy. Non-Small Cell Lung Cancer: All of the following: A) Diagnosis of metastatic non-small cell lung cancer (NSCLC), and B) Patient has disease progression during or following platinum-containing chemotherapy, and C) One of the following: 1) Patient does not have epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) rearrangement OR 2) Both of the following: patient has an EGFR mutation AND trial and failure, contraindication, or intolerance to at least one anti-EGFR therapy (e.g., Gilotrif [afatinib], Iressa [gefitinib], Tarceva [erlotinib]) OR 3) Both of the following: patient has ALK rearrangement AND trial and failure, contraindication, or intolerance to at least one ALK inhibitor (e.g., Xalkori [crizotinib]).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A
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.
TESTOSTERONE (S)

**MEDICATION(S)**
ANDRODERM, TESTOSTERONE 1.62% (2.5 G) PKT, TESTOSTERONE 1.62% GEL PUMP, TESTOSTERONE 1.62%(1.25 G) PKT, TESTOSTERONE 12.5 MG/1.25 GRAM, TESTOSTERONE 25 MG/2.5 GM PKT, TESTOSTERONE 30 MG/1.5 ML PUMP, 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 100 MG/ML, TESTOSTERONE CYP 200 MG/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.
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
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.
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. 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). Newly-Diagnosed AML: Diagnosis of newly-diagnosed AML. Patient has an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). 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.

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.
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
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
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.
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 Lupron Depot (7.5 mg, 22.5 mg, 30 mg, and 45 mg).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
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) 1) Trial and failure, contraindication, or intolerance (TF/C/I) to Enbrel (etanercept) or Humira (adalimumab) AND 2) TF/C/I to Cosentyx (secukinumab), OR set B) for continuation of prior Tremfya 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 Tremfya therapy.
**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): 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.
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)
TYKERB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.
MEDICATION(S)
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., Forteo [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
MEDITATION(S)
TYSABRI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses). One of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following: Aubagio (teriflunomide), Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone or Glatopa (glatiramer acetate), Extavia (interferon beta-1b), Gilenya (fingolimod), Lemtrada (alemtuzumab), Ocrevus (ocrelizumab), Plegridy (peginterferon beta-1a), Rebif (interferon beta-1a), Tecfidera (dimethyl fumarate), or Zinbryta (daclizumab), 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. Patient is not taking Tysabri in combination with another MS agent [eg, Aubagio (teriflunomide), Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone (glatiramer acetate), Glatopa (glatiramer acetate), Extavia (interferon beta-1b), Gilenya (fingolimod), Lemtrada (alemtuzumab), Rebif (interferon beta-1a), or Tecfidera (dimethyl fumarate)]. Crohn’s Disease (CD) (initial): Diagnosis of moderate to severe CD with evidence of inflammation (eg, elevated C-reactive protein [CRP], elevated erythrocyte sedimentation rate, presence of fecal leukocytes). Inadequate response or intolerance to one of the following conventional therapies: corticosteroids, 6-mercaptopurine (6MP [Purinethol], azathioprine [Imuran], methotrexate, aminosalicylates (eg, sulfasalazine, mesalamine, olsalazine). Inadequate response or intolerance to a TNF-inhibitor (eg, Cimzia [certolizumab pegol], Humira [adalimumab], Remicade [infliximab]). CD (initial and reauth): Patient is not taking Tysabri in combination with an immunosuppressant (eg, 6-MP, azathioprine, cyclosporine, or methotrexate) or a TNF-inhibitor (eg, Enbrel [etanercept], Humira [adalimumab], or Remicade [infliximab]).

AGE RESTRICTION
N/A

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

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

MEDICATION(S)
ULTOMIRIS

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.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
PNH (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 Ultomiris therapy.
MEDICATION(S)
UPTRAVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Pulmonary arterial hypertension (PAH) (initial): Diagnosis of PAH AND Patient is symptomatic AND One of the following: a) Diagnosis of PAH was confirmed by right heart catheterization OR b) patient is currently on any therapy for the diagnosis of PAH. One of the following: a) 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 Uptravi 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 Uptravi therapy. Not taken in combination with a prostanoid/prostacyclin analogue [e.g., Flolan (epoprostenol), Ventavis (iloprost), Tyvaso/Remodulin/Orenitram (treprostinil)].
MEDICATION(S)
VALCHLOR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL) (initial): All of the following: 1) diagnosis of Stage IA MF-CTCL, OR diagnosis of Stage IB MF-CTCL, AND 2) patient has received at least one prior skin-directed therapy [e.g., topical corticosteroids, bexarotene topical gel (Targretin topical gel), 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 125 UNIT/1.2 ML VIAL

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
VELCADE (S)

MEDICATION(S)
VELCADE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL): Diagnosis of CLL or SLL.
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.
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 Vimizim 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.
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.
**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 patient is not receiving Vosevi 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
MEDICATION(S)
VOTRIENT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Gaucher disease: 12 months

OTHER CRITERIA
N/A
MEDICATION(S)
VYXEOS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Newly diagnosed therapy related acute myeloid leukemia (t-AML): Diagnosis of t-AML. Acute myeloid leukemia myelodysplasia-related changes (AML-MRC): Diagnosis of AML-MRC.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy
MEDICATION(S)
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 rearrangements-positive tumor 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
NSCLC: Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

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

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

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Xeljanz/Xeljanz XR: Rheumatoid arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Psoriatic arthritis (PsA) (Initial): Diagnosis of active PsA. RA/PsA (initial): One of the following: Failure, contraindication, or intolerance to both 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-IV-TR 300.29 for specific phobia diagnostic criteria), OR for continuation of prior tofacitinib therapy.

Xeljanz only: 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 Xeljanz therapy. All indications: Patient is not receiving tofacitinib in combination with a potent immunosuppressant (eg, azathioprine, cyclosporine).

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
RA (initial): Prescribed by or in consultation with a rheumatologist. 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/PsA (initial, reauth): 12 months. UC (init): 4 mo. UC (reauth): 12 mo.

OTHER CRITERIA
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).
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.
**MEDICATION(S)**
XEOMIN 200 UNIT VIAL

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

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
All indications (init, reauth): 3 months (for 1 dose)

**OTHER CRITERIA**
All indications CD, blepharospasm, ULS (reauth): Confirmed improvement in symptoms with initial Xeomin treatment. At least 3 months have elapsed or will have elapsed since the last treatment with Xeomin. CS (reauth): Confirmed improvement in symptoms with initial Xeomin treatment. At least 4 months have elapsed or will have elapsed since the last treatment with Xeomin.
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 Xermelo therapy AND Xermelo will continue to be used in combination with SSA therapy.
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.
MEDICATION(S)
XIAFLEX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Dupuytren's contracture (DC) (initial, reauth): Diagnosis of Dupuytren's contracture with a palpable cord AND Prescriber is enrolled in the Xiaflex REMS program for Dupuytren's contracture AND Patient has a positive “table top test” (defined as the inability to simultaneously place the affected finger and palm flat against a table top) AND Patient has a documented contracture of at least 20 degrees flexion for a metacarpophalangeal joint or a proximal interphalangeal joint AND Patient has a flexion deformity that results in functional limitations. Peyronie’s disease (PD) (initial, reauth): Diagnosis of Peyronie’s disease AND Prescriber is enrolled in the Xiaflex REMS program for Peyronie’s disease AND Patient has a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy AND The plaques do not involve the penile urethra AND Patient has a curvature deformity that results in pain (e.g., pain upon erection or intercourse).

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

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
DC, PD (Initial and reauth): 12 months

OTHER CRITERIA
Peyronie’s disease (reauth): patient has a new plaque that results in a curvature deformity.
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.
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), theophylline], OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)]. 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, 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, leukotriene receptor antagonist, H1 antihistamine, hydroxyzine, doxepin. Used concurrently with an H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamines.

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
COVERAGE DURATION
Asthma (init): 6 months, Asthma (reauth): 12 months. CIU (init): 3 months, (reauth) 6 months

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) and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline], OR b) A combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)]. 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.
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.
**MEDICATION(S)**
XPOVIO

**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 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.

**AGE RESTRICTION**
N/A

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

**COVERAGE DURATION**
12 months

**OTHER CRITERIA**
Approve for continuation of prior therapy.
MEDICATION(S)
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. One of the following: 1) use in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g. Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)] OR 2) patient has had bilateral orchiectomy.

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.
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 Xuriden 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, irrepresensible 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, irrepresensible need to sleep or daytime lapses into sleep) are present, AND trial and failure, contraindication, or intolerance to one of the following: 1) amphetamine-based stimulant (eg, amphetamine, dextroamphetamine), OR 2) methylphenidate-based stimulant.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
All uses (initial, reauth): 12 months
OTHER CRITERIA
Narcolepsy Type 1 (reauth): Documentation demonstrating a reduction in the frequency of cataplexy attacks associated with Xyrem therapy, OR documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with Xyrem therapy. Narcolepsy Type 2 (reauth): Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with Xyrem therapy.
MEDICATION(S)
YERVOY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Unresectable or metastatic melanoma: Diagnosis of unresectable, metastatic melanoma. Cutaneous melanoma: Diagnosis of cutaneous melanoma with pathologic involvement of regional lymph nodes of more than 1 mm. Patient has undergone resection, including total lymphadenectomy. Renal Cell Carcinoma (RCC): Diagnosis of renal cell carcinoma. Disease is advanced, relapsed, or stage IV disease that is surgically unresectable. Intermediate- or poor-prognosis risk. Previously untreated disease. Used in combination with Opdivo (nivolumab). Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Metastatic Colorectal Cancer (CRC): Diagnosis of MSI-H or dMMR metastatic colorectal cancer. Disease has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. Used in combination with Opdivo (nivolumab).

AGE RESTRICTION
MSI-H/dMMR CRC: Patient is 12 years of age or older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Prostate Cancer: Diagnosis of metastatic castration-resistant (chemical or surgical) or recurrent prostate cancer. Used in combination with methylprednisolone. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog or 2) Patient received a bilateral orchiectomy. 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
MEDICATION(S)
ZALTRAP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Colon and/or rectal cancer: Diagnosis of metastatic colon and/or rectal cancer. Ziv-aflibercept is being used in combination with 5-fluorouracil, leucovorin, and irinotecan (FOLFIRI) regimen. Patient has disease that is resistant to or has progressed following an oxaliplatin-containing regimen [e.g., 5-fluorouracil, leucovorin, and oxaliplatin (FOLFOX)].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

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

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

**OFF LABEL USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of recurrent epithelial ovarian cancer, recurrent fallopian tube cancer, or recurrent primary peritoneal cancer. Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin).

**AGE RESTRICTION**
N/A

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

**COVERAGE DURATION**
12 months

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma. Cancer is BRAFV600 mutant type (MT) as detected by 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.
MEDICATION(S)
ZOLINZA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Cutaneous T-cell lymphoma (CTCL): Diagnosis of CTCL. Progressive, persistent or recurrent disease on or contraindication or intolerance to two systemic therapies (e.g., bexarotene, romidepsin, etc.).

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Short Bowel Syndrome (SBS): Diagnosis of SBS. Patient is currently receiving specialized nutritional support (eg, intravenous parenteral nutrition, fluid, and micronutrient supplements). Patient has not previously received 4 weeks of treatment with Zorbtive.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a gastroenterologist.

COVERAGE DURATION
SBS: 4 weeks.

OTHER CRITERIA
N/A
ZORTESS (S)

MEDICATION(S)
ZORTESS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Prevention of kidney transplant organ rejection: The medication is being used for prevention of kidney transplant organ rejection. Patient is at low-to-moderate immunologic risk. Patient is prescribed concurrent therapy with reduced doses of cyclosporine AND corticosteroids. Prevention of liver transplant organ rejection: The medication is being used for prevention of liver transplant organ rejection. Thirty (30) or more days have passed since the transplant procedure. Patient is prescribed concurrent therapy with reduced doses of tacrolimus and corticosteroids.

AGE RESTRICTION
All indications: 18 years of age or older

PRESCRIBER RESTRICTION
All uses: Prescriber is experienced in immunosuppressive therapy and management of transplant patients.

COVERAGE DURATION
12 months

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chronic lymphocytic leukemia (CLL): Diagnosis of CLL. Used in combination with Rituxan (rituximab). The patient has relapsed on at least one prior therapy (eg, purine analogues [fludarabine, pentostatin, cladribine], alkylating agents [chlorambucil, cyclophosphamide], or monoclonal antibodies [rituximab]). Patient is a candidate for Rituxan (rituximab) monotherapy due to presence of other comorbidities (eg, coronary artery disease, peripheral vascular disease, diabetes mellitus, pulmonary disease [COPD]).
Follicular Lymphoma (FL): Diagnosis of FL. The patient has relapsed on at least two prior systemic therapies (eg, rituximab, alkylating agents [cyclophosphamide, chlorambucil], anthracyclines [doxorubicin, daunorubicine], purine analogs [fludarabine]). Small lymphocytic lymphoma (SLL): Diagnosis of SLL. The patient has relapsed on at least two prior systemic therapies (eg, rituximab, alkylating agents [cyclophosphamide, chlorambucil], anthracyclines [doxorubicin, daunorubicine], purine analogs [fludarabine]).

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC that is metastatic or recurrent. Tumor is anaplastic lymphoma kinase (ALK)-positive as detected by 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. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog or 2) Patient received a bilateral orchiectomy. 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. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog or 2) Patient received a bilateral orchiectomy.

**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.
**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. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog or 2) Patient received a bilateral orchiectomy. Metastatic Castration-Sensitive Prostate Cancer (mCSPC): Diagnosis of metastatic high-risk castration-sensitive prostate cancer. Used in combination with prednisone. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog or 2) Patient received a bilateral orchiectomy.

**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