ACTIMMUNE (S)

MEDICATION(S)
ACTIMMUNE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

ADBRY (S)

MEDICATION(S)
ADBRY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of moderate to severe atopic dermatitis. One of the following: a) Involvement of at least 10% body surface area (BSA), or b) SCORing Atopic Dermatitis (SCORAD) index value of at least 25. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least two of the following: a) Medium or higher potency topical corticosteroid, b) Pimecrolimus cream, c) Tacrolimus ointment, or d) Eucrisa (crisaborole) ointment.

AGE RESTRICTION
Initial: Patient is 18 years of age or older.

PRESCRIBER RESTRICTION
Initial: Prescribed by or in consultation with a dermatologist or allergist/immunologist.

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

OTHER CRITERIA
Reauth: Documentation of a positive clinical response to therapy as evidenced by at least one of the following: a) Reduction in BSA involvement from baseline, or b) Reduction in SCORAD index value from baseline.

ADCIRCA (S)

MEDICATION(S)
ALYQ, TADALAFIL 20 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

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

ADEMPAS (S)

MEDICATION(S)
ADEMPAS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

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

AFINITOR (S)

MEDICATION(S)
EVEROLIMUS 10 MG TABLET, EVEROLIMUS 2.5 MG TABLET, EVEROLIMUS 5 MG TABLET, EVEROLIMUS 7.5 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Subependymal Giant Cell Astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC): Diagnosis of SEGA associated with TSC that requires therapeutic intervention. Renal cell carcinoma: Diagnosis of advanced 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. Breast Cancer: Diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer AND trial and failure, contraindication, or intolerance to FEMARA (letrozole) or ARIMIDEX (anastrozole). 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
SEGA associated with TSC: Patient is 1 year of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
All uses: 12 months

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

AFINITOR DISPERZ (S)

MEDICATION(S)
AFINITOR DISPERZ, EVEROLIMUS 2 MG TAB FOR SUSP, EVEROLIMUS 3 MG TAB FOR SUSP, EVEROLIMUS 5 MG TAB FOR SUSP

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. TSC-associated partial-onset seizures: Diagnosis of TSC-associated partial-onset seizures.

AGE RESTRICTION
SEGA associated with TSC: Patient is 1 year of age or older. TSC-associated partial-onset seizures: Patient is 2 years of age or older.

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

AIMOVIG (S)

MEDICATION(S)
AIMOVIG AUTOINJECTOR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

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

PRESCRIBER RESTRICTION
N/A

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] [e.g., ibuprofen, naproxen], triptans [e.g., eletriptan, rizatriptan, sumatriptan]) has decreased since the start of CGRP therapy. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. CM (reauth): Patient continues to be monitored for medication overuse headache.

ALDURAZYME (S)

MEDICATION(S)
ALDURAZYME

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

ALECENSA (S)

MEDICATION(S)
ALECENSA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

ALPHA-1 PROTEINASE INHIBITOR, PROLASTIN (S)

MEDICATION(S)
PROLASTIN C

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
AAT deficiency (initial, reauth): 12 months

OTHER CRITERIA
AAT deficiency (reauth): Documentation of positive clinical response to therapy. Continued conventional treatment for emphysema (e.g., bronchodilators).

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 NSCLC.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

AMPYRA (S)

MEDICATION(S)
DALFAMPRIDINE ER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

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

ARCALYST (S)

MEDICATION(S)
ARCALYST

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Cryopyrin-Associated Periodic Syndromes (CAPS) (Initial): Diagnosis of CAPS, including Familial Cold Auto-inflammatory Syndrome (FCAS) and/or Muckle-Wells Syndrome (MWS). The medication will not be used in combination with another biologic. Deficiency of Interleukin-1 Receptor Antagonist (DIRA): Diagnosis of DIRA. Patient weighs at least 10 kg. Patient is currently in remission (e.g., no fever, skin rash, and bone pain/no radiological evidence of active bone lesions/C-reactive protein [CRP] less than 5 mg/L). Recurrent Pericarditis (Initial): Diagnosis of recurrent pericarditis as evidenced by at least 2 episodes that occur a minimum of 4 to 6 weeks apart. Trial and failure, contraindication, or intolerance (TF/C/I) to at least one of the following: nonsteroidal anti-inflammatory drugs (e.g., ibuprofen, naproxen), colchicine, or corticosteroids (e.g., prednisone).

AGE RESTRICTION
N/A

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

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

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

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

AURYXIA (S)

MEDICATION(S)
AURYXIA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

AUSTEDO (S)

MEDICATION(S)
AUSTEDO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial: 3 months. Reauth: 12 months

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

AYVAKIT (S)

MEDICATION(S)
AYVAKIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Gastrointestinal stromal tumor (GIST): Diagnosis of GIST. Disease is one of the following: unresectable or metastatic. Presence of platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations. Advanced Systemic Mastocytosis (AdvSM): Diagnosis of AdvSM. Patient has one of the following: a) aggressive systemic mastocytosis (ASM), b) systemic mastocytosis with an associated hematological neoplasm (SM-AHN), or c) mast cell leukemia (MCL). Ayvakit 25 mg - Indolent Systemic Mastocytosis (ISM): Diagnosis of ISM. Platelet count is greater than 50 x 10^9/L.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

BAFIERTAM (S)

MEDICATION(S)
BAFIERTAM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
MS (initial, reauth): 12 months

OTHER CRITERIA
MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).

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 platinum-containing chemotherapy (e.g., gemcitabine with cisplatin or carboplatin, dose dense methotrexate vinblastine doxorubicin cisplatin [DDMVAC] with growth factor support, etc.) OR 2) Patient has progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy (e.g., [DDMVAC] with growth factor support, gemcitabine with cisplatin, etc.).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

BENLYSTA (S)

MEDICATION(S)
BENLYSTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

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

BESREMI (S)

MEDICATION(S)
BESREMI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of polycythemia vera as confirmed by all of the following: 1) One of the following: a) Hemoglobin greater than 16.5 g/dL for men or hemoglobin greater than 16.0 g/dL for women, b) Hematocrit greater than 49% for men or hematocrit greater than 48% for women, or c) Increased red cell mass, AND 2) Bone marrow biopsy showing hypercellularity for age with trilineage growth (panmyelosis) including prominent erythroid, granulocytic and megakaryocytic proliferation with pleomorphic, mature megakaryocytes, AND 3) One of the following: a) Presence of JAK2 or JAK2 exon 12 mutation or b) Subnormal serum erythropoietin level. Both of the following: 1) Trial and failure, contraindication or intolerance (TF/C/I) to hydroxyurea, AND 2) TF/C/I to one interferon therapy (e.g., Intron A, Pegasys, etc).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

BOSULIF (S)

MEDICATION(S)
BOSULIF 100 MG TABLET, BOSULIF 400 MG TABLET, BOSULIF 500 MG TABLET

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
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

BRAFTOVI (S)

MEDICATION(S)
BRAFTOVI 75 MG CAPSULE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy

BRIVIACT (S)

MEDICATION(S)
BRIVIACT 10 MG TABLET, BRIVIACT 10 MG/ML ORAL SOLN, BRIVIACT 100 MG TABLET, BRIVIACT 25 MG TABLET, BRIVIACT 50 MG TABLET, BRIVIACT 75 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Partial-onset seizures: Diagnosis of partial-onset seizures.

AGE RESTRICTION
Patient is 1 month of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

BRUKINSA (S)

MEDICATION(S)
BRUKINSA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Mantle Cell Lymphoma (MCL): Diagnosis of relapsed or refractory MCL. Trial and failure, contraindication, or intolerance to at least ONE combination treatment of rituximab and chemotherapy (e.g., BR, R-CHOP, R-CVP, R-FCM). Waldenstrom's Macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma (LPL): Diagnosis of WM/LPL. Marginal Zone Lymphoma (MZL): Diagnosis of MZL. Disease is relapsed or refractory. Patient has received at least one prior anti-CD20-based regimen for MZL (e.g., rituximab, obinutuzumab). Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): Diagnosis of ONE of the following: CLL or SLL.

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
3 months

OTHER CRITERIA
N/A

CABOMETYX (S)

MEDICATION(S)
CABOMETYX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Renal cell carcinoma (RCC): Diagnosis of RCC. Hepatocellular Carcinoma (HCC): Diagnosis of HCC. One of the following: a) Trial and failure, contraindication, or intolerance to Nexavar (sorafenib tosylate), or b) Patient has metastatic disease, or c) Patient has extensive liver tumor burden, or d) Patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only), or e) Disease is unresectable. Differentiated Thyroid Cancer (DTC): Diagnosis of DTC. Disease has progressed following prior VEGFR-targeted therapy (e.g., Lenvima [lenvatinib], Nexavar [sorafenib]). Disease or patient is refractory to radioactive iodine treatment or ineligible.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

CALQUENCE (S)

MEDICATION(S)
CALQUENCE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

CAMZYOS (S)

MEDICATION(S)
CAMZYOS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of obstructive hypertrophic cardiomyopathy (HCM). Patient has New York Heart Association (NYHA) Class II or III symptoms (e.g., shortness of breath, chest pain). Patient has a left ventricular ejection fraction of greater than or equal to 55%. Patient has valsalva left ventricular outflow tract (LVOT) peak gradient greater than or equal to 50 mmHg at rest or with provocation. Trial and failure, contraindication, or intolerance to both of the following at a maximally tolerated dose: a) non-vasodilating beta blocker (e.g., bisoprolol, propranolol) and b) calcium channel blocker (e.g., verapamil, diltiazem).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Initial, Reauth: Prescribed by or in consultation with a cardiologist.

COVERAGE DURATION
Initial: 6 months, Reauth: 12 months

OTHER CRITERIA
Reauthorization: Documentation of positive clinical response to therapy (e.g., improved symptom relief). Patient has a left ventricular ejection fraction of greater than or equal to 50%.

CAPLYTA (S)

MEDICATION(S)
CAPLYTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Schizophrenia: Diagnosis of schizophrenia. Trial and failure, contraindication, or intolerance to two of the following oral generic formulary atypical antipsychotic agents: asenapine, aripiprazole, olanzapine, paliperidone, quetiapine (IR or ER), risperidone, ziprasidone. Bipolar disorder: Diagnosis of bipolar I or II disorder (bipolar depression). Patient has depressive episodes associated with bipolar disorder. Used as monotherapy or as adjunctive therapy with lithium or valproate. Trial and failure, contraindication, or intolerance to quetiapine (IR or ER) or olanzapine.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy

CAPRELSA (S)

MEDICATION(S)
CAPRELSA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

CAYSTON (S)

MEDICATION(S)
CAYSTON

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

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

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
CF (Initial, reauth): 12 months

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

CERDELGA (S)

MEDICATION(S)
CERDELGA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Gaucher disease: 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: Patient is 18 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Gaucher disease: 12 months

OTHER CRITERIA
N/A

CHOLBAM (S)

MEDICATION(S)
CHOLBAM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
All uses: 4 months (initial), 12 months (reauth).

OTHER CRITERIA
All uses (reauth): documentation of positive clinical response to therapy as evidenced by improvement in liver function (e.g., aspartate aminotransferase [AST], alanine aminotransferase [ALT]).

CIALIS (S)

MEDICATION(S)
TADALAFIL 2.5 MG TABLET, TADALAFIL 5 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use of nitrates.

REQUIRED MEDICAL INFORMATION
Diagnosis of benign prostatic hyperplasia (BPH). Trial and failure, contraindication, or intolerance to an alpha-blocker (e.g., doxazosin, prazosin, tamsulosin) or a 5-alpha reductase inhibitor (e.g., dutasteride, finasteride).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

CIBINQO (S)

MEDICATION(S)
CIBINQO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of moderate to severe atopic dermatitis. One of the following: a) Involvement of at least 10% body surface area (BSA), or b) SCORing Atopic Dermatitis (SCORAD) index value of at least 25. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least one of the following: a) Medium or higher potency topical corticosteroid, b) Pimecrolimus cream, c) Tacrolimus ointment, or d) Eucrisa (crisaborole) ointment. One of the following: 1) Trial and failure of a minimum 12-week supply of at least one systemic drug product for the treatment of atopic dermatitis (examples include, but are not limited to, Adbry [tralokinumab-ldrm], Dupixent [dupilumab], etc.), OR 2) Patient has a contraindication, intolerance, or treatment is inadvisable with both of the following FDA-approved atopic dermatitis therapies: Adbry (tralokinumab-ldrm) and Dupixent (dupilumab). Not used in combination with other Janus kinase (JAK) inhibitors, biologic immunomodulators, or other immunosuppressants (eg, azathioprine, cyclosporine).

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

PRESCRIBER RESTRICTION
Initial: Prescribed by or in consultation with a dermatologist or allergist/immunologist.

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

OTHER CRITERIA
Reauth: Documentation of a positive clinical response to therapy as evidenced by at least one of the

following: a) Reduction in BSA involvement from baseline, or b) Reduction in SCORAD index value from baseline. Not used in combination with other JAK inhibitors, biologic immunomodulators, or other immunosuppressants (eg, azathioprine, cyclosporine).

CICLOPIROX (S)

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
All of the following: 1) Patient does not have lunula (matrix) involvement, 2) one of the following: a) Diagnosis of onychomycosis of the toenails, OR b) Diagnosis of onychomycosis of the fingernails, 3) Diagnosis of onychomycosis has been confirmed by one of the following: a) positive potassium hydroxide (KOH) preparation, OR b) culture, OR c) histology, 4) If toenail onychomycosis, patient has mild to moderate disease involving at least 1 target toenail, AND 5) Trial and failure (of a minimum 12-week supply), 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 2X200 MG/ML SYRINGE KIT, CIMZIA 2X200 MG/ML(X3)START KT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Rheumatoid Arthritis (RA, initial): Diagnosis (dx) of moderately to severely active RA. One of the following: a) Either a trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), Humira (adalimumab)/Cyltezo/or Yuflyma, Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib) or attestation demonstrating a trial may be inappropriate, OR b) For continuation of prior therapy. Crohn's Disease (CD, initial): Dx of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. TF/C/I to two of the following: Humira/Cyltezo/or Yuflyma, Rinvoq, Skyrizi (risankizumab-rzaa), or Stelara (ustekinumab), OR for continuation of prior therapy. Psoriatic Arthritis (PsA, initial): Dx of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. One of the following: a) Either a TF/C/I to two of the following: Cosentyx (secukinumab), Enbrel, Humira/Cyltezo/or Yuflyma, Otezla (apremilast), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Rinvoq, or Xeljanz/XR, OR b) for continuation of prior therapy. Ankylosing Spondylitis (AS, initial): Dx of active AS. TF/C/I to two of the following: Enbrel, Humira/Cyltezo/or Yuflyma, Cosentyx, Rinvoq, Xeljanz/XR, OR for continuation of prior therapy. Plaque Psoriasis (PsO) (initial): Dx of moderate to severe PsO. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. TF/C/I to two of the following: Humira/Cyltezo/or Yuflyma, Enbrel, Otezla, Skyrizi (risankizumab), Stelara, Cosentyx, OR for continuation of prior therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

RA, PsA, AS, PsO, nr-axSpA (init): 6 mos, (reauth): 12 mos. CD (init): 16 wks. (reauth): 12 mos.

OTHER CRITERIA

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.). Minimum duration of a one-month TF/C/I to two non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, meloxicam, naproxen) at maximally tolerated doses. RA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. CD (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS, nr-axSpA (Reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline.

CINRYZE (S)

MEDICATION(S)
CINRYZE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Prophylaxis of hereditary angioedema (HAE) attacks: Diagnosis of HAE. Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by one of the following: a) C1-INH antigenic level below the lower limit of normal OR b) C1-INH functional level below the lower limit of normal. For prophylaxis against HAE attacks. Not used in combination with other approved treatments for prophylaxis against HAE attacks.

AGE RESTRICTION
HAE (prophylaxis): Patient is 6 years of age or older

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

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

COLUMVI (S)

MEDICATION(S)
COLUMVI

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) Relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS), or 2) Large B-cell lymphoma (LBCL) arising from follicular lymphoma. Patient has had two or more lines of systemic therapy (e.g., chemotherapy). Patient will receive pretreatment with Gazyva (obinutuzumab).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

COMETRIQ (S)

MEDICATION(S)
COMETRIQ

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Medullary thyroid cancer (MTC): Diagnosis of Metastatic MTC.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
All uses: 12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

COPIKTRA (S)

MEDICATION(S)
COPIKTRA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

CORLANOR (S)

MEDICATION(S)
CORLANOR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chronic heart failure (CHF) (initial): Diagnosis of CHF. Patient has NYHA Class II, III, or IV symptoms. Patient has a left ventricular ejection fraction less than or equal to 35%. Patient is in sinus rhythm. Patient has a resting heart rate of greater than or equal to 70 beats per minute. Patient has been hospitalized for worsening HF in the previous 12 months. Trial and failure, contraindication, or intolerance to two of the following at a maximally tolerated dose: A) One of the following: 1) ACE inhibitor (e.g., captopril, enalapril, lisinopril), 2) ARB (e.g., candesartan, losartan, valsartan), or 3) ARNI (e.g., Entresto [sacubitril and valsartan]), B) One of the following: 1) bisoprolol, 2) carvedilol, or 3) metoprolol succinate extended release, C) Sodium-glucose co-transporter 2 (SGLT2) inhibitor [e.g., Jardiance (empagliflozin), Farxiga (dapagliflozin), Xigduo XR (dapagliflozin and metformin)], or D) Mineralocorticoid receptor antagonist (MRA) [e.g., eplerenone, spironolactone]. Dilated Cardiomyopathy (DCM) (initial): Diagnosis of heart failure due to DCM. Patient has NYHA Class II, III, or, IV symptoms. Patient is in sinus rhythm. Patient has an elevated heart rate. Trial and failure, contraindication or intolerance to one of the following: 1) Beta blocker (e.g., bisoprolol, metoprolol succinate extended release), 2) Angiotensin-converting enzyme (ACE) inhibitor (e.g., captopril, enalapril), or 3) Diuretic Agent (e.g., spironolactone, furosemide).

AGE RESTRICTION
N/A

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

COVERAGE DURATION

CHF, DCM (initial, reauth): 12 months

OTHER CRITERIA

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

COSENTYX (S)

MEDICATION(S)
COSENTYX (2 SYRINGES), COSENTYX SENSOREADY (2 PENS), COSENTYX SENSOREADY PEN, COSENTYX SYRINGE, COSENTYX UNOREADY PEN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month trial and failure, contraindication, or intolerance to one nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses. Non-radiographic axial spondyloarthritis (nr-axSpA, initial): Dx of active nr-axSpA with objective signs of inflammation (eg, C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) Enthesitis-Related Arthritis (ERA) (Initial): Diagnosis of active ERA. nr-axSpA, ERA (Initial): Minimum duration of a one-month TF/C/I to two non-steroidal anti-inflammatory drugs (NSAIDs) (eg, ibuprofen, naproxen) at maximally tolerated doses.

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, nr-axSpA, ERA (initial): Prescribed by or in consultation with a rheumatologist.

COVERAGE DURATION

All uses (initial): 6 months. All uses (reauth): 12 months

OTHER CRITERIA

PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. AS, nr-axSpA (Reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. ERA (Reauth): Documentation of a positive clinical response to therapy as evidenced by at least one of the following: Reduction in the total active (swollen and tender) joint count from baseline, OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline.

COTELLIC (S)

MEDICATION(S)
COTELLIC

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Melanoma: Diagnosis of unresectable or metastatic melanoma. Patient has a BRAF V600E or V600K mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., cobas 4800 BRAF V600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with vemurafenib. Histiocytic Neoplasm: Diagnosis of histiocytic neoplasm. Used as monotherapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

CUVPOSA (S)

MEDICATION(S)
GLYCOPYRROLATE 1 MG/5 ML SOLN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of chronic severe drooling (sialorrhea). Diagnosis of a neurologic condition (e.g., cerebral palsy) associated with chronic severe drooling (sialorrhea).

AGE RESTRICTION
Initial: Patient is between 3 and 16 years of age.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial, Reauth: 12 months.

OTHER CRITERIA
Reauth: Documentation of a positive clinical response to therapy (e.g., reduction in drooling severity compared to baseline).

CYLTEZO (S)

MEDICATION(S)
CYLTEZO(CF) 10 MG/0.2 ML SYRNG, CYLTEZO(CF) 20 MG/0.4 ML SYRNG, CYLTEZO(CF) 40 MG/0.8 ML SYRNG, CYLTEZO(CF) PEN 40 MG/0.8 ML, CYLTEZO(CF) PEN CROHN'S-UC-HS, CYLTEZO(CF) PEN PSORIASIS-UV

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. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. PsO (Initial): Diagnosis of moderate to severe chronic PsO. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), methotrexate. Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial): 6 mo, (reauth): 12 mo.

OTHER CRITERIA

Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), aminosalicylate [eg, mesalamine, olsalazine, sulfasalazine]. Hidradenitis suppurativa (Initial): Diagnosis of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). RA, PJIA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Hidradenitis suppurativa (HS), Uveitis (Reauth): Documentation of positive clinical response to therapy. Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. AS (Reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. CD (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. UC (Reauth): For patients who initiated therapy within the past 12 weeks: Documentation of clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy OR For patients who have been maintained on therapy for longer than 12 weeks: Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet

counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state.

DALIRESP (S)

MEDICATION(S)
DALIRESP, ROFLUMILAST

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chronic Obstructive Pulmonary Disease (COPD) (initial): Diagnosis of COPD. History of COPD exacerbations which required the use of systemic corticosteroids, antibiotics, or hospital admission. Trial and failure, intolerance, or contraindication to two prior therapies for COPD (e.g., Combivent, Spiriva).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
COPD (init, reauth): 12 months

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

DANYELZA (S)

MEDICATION(S)
DANYELZA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Neuroblastoma: Diagnosis of high-risk neuroblastoma in bone or bone marrow. Disease is relapsed or refractory. Used in combination with granulocyte-macrophage colony-stimulating factor [e.g., Leukine (sargramostim)]. Patient has had prior therapy with one of the following responses: partial response, minor response, or stable disease.

AGE RESTRICTION
Neuroblastoma: Patient is 1 year of age or older.

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

DARAPRIM (S)

MEDICATION(S)
PYRIMETHAMINE 25 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Toxoplasmosis only: Approve for continuation of prior therapy.

DARZALEX FASPRO (S)

MEDICATION(S)
DARZALEX FASPRO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Relapsed/Refractory Multiple Myeloma (MM): Diagnosis of MM. One of the following: A) Both of the following: Used as monotherapy and One of the following: i) Patient has received at least three prior treatment regimens which included both a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis]) and an immunomodulatory agent (e.g., lenalidomide [Revlimid], thalidomide [Thalomid]) or ii) patient is double-refractory to a proteasome inhibitor and an immunomodulatory agent. OR B) Both of the following: used in combination with one of the following treatment regimens: lenalidomide and dexamethasone, bortezomib and dexamethasone, or carfilzomib and dexamethasone, AND patient has received at least one prior therapy (e.g., bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro], lenalidomide [Revlimid], thalidomide [Thalomid). OR C) Both of the following: used in combination with both pomalidomide and dexamethasone, AND patient has received at least one prior line of therapy including lenalidomide and a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis]). Newly Diagnosed MM: Newly diagnosed MM. One of the following: A) Both of the following: patient is ineligible for autologous stem cell transplant AND one of the following: 1) used in combination with all of the following: bortezomib, melphalan, and prednisone or 2) used in combination with both of the following: lenalidomide and dexamethasone. OR B) Both of the following: patient is eligible for autologous stem cell transplant AND used in combination with all of the following: bortezomib, thalidomide, and dexamethasone. Light Chain (AL) Amyloidosis: Newly diagnosed light chain (AL) amyloidosis. Used in combination with all of the following: bortezomib, cyclophosphamide, and dexamethasone. All of the following: patient does not have New York Association (NYHA) Class IIIB disease, patient does not have NYHA class IV disease, and patient does not have Mayo Stage IIIB disease.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

MM: Prescribed by or in consultation with an oncologist/hematologist. Light Chain (AL) Amyloidosis: Prescribed by or in consultation with a 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
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

DEFERASIROX (S)

MEDICATION(S)
DEFERASIROX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

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

PRESCRIBER RESTRICTION
N/A

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

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

DEMSER (S)

MEDICATION(S)
METYROSINE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Preoperative preparation: Diagnosis of pheochromocytoma confirmed by one of the following biochemical testing: a) plasma free metanephrines OR b) urinary fractioned metanephrines. Medication is being used for preoperative preparation. Trial and failure, contraindication, or intolerance to both of the following: a) alpha-adrenergic blocker (e.g., phenoxybenzamine, doxazosin, terazosin) AND b) beta-adrenergic blocker (e.g., propranolol, metoprolol). Treatment of pheochromocytoma (initial): Diagnosis of pheochromocytoma confirmed by one of the following biochemical testing: a) plasma free metanephrines OR b) urinary fractioned metanephrines. Patient with hormonally active (catecholamine excess) pheochromocytoma. One of the following: a) patient is not a candidate for surgery OR b) chronic treatment due to malignant pheochromocytoma. Patient has not reached normotension after treatment with a selective alpha-1-adrenergic blocker (e.g., doxazosin, terazosin) and beta-adrenergic blocker (e.g., propranolol, metoprolol). Medication will not be used to control essential hypertension.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Preop prep: Prescribed by or in consultation with an endocrinologist OR Endocrine surgeon. Pheochromocytoma (initial): Prescribed by or in consultation with endocrinologist OR provider who specializes in the management of pheochromocytoma.

COVERAGE DURATION
Preop prep: 4 wks. Treatment of pheo (initial): 6 months, (reauth): 12 months.

OTHER CRITERIA

Treatment of pheochromocytoma (reauth): Documentation of positive clinical response to therapy (e.g., decreased frequency and severity of hypertensive attacks).

DIACOMIT (S)

MEDICATION(S)
DIACOMIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of seizures associated with Dravet syndrome (DS). Used in combination with clobazam. Patient weighs 7kg or more.

AGE RESTRICTION
Patient is 6 months of age or older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

DUPIXENT (S)

MEDICATION(S)
DUPIXENT PEN, DUPIXENT SYRINGE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Atopic dermatitis (AD) (init): Diagnosis (dx) of mod to severe AD. One of the following: a) Involvement of at least 10% body surface area (BSA), or b) SCORing Atopic Dermatitis (SCORAD) index value of at least 25. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication (eg, safety concerns, not indicated for patient's age/weight), or intolerance to at least one of the following: a) Medium or higher potency topical corticosteroid, b) Pimecrolimus cream, c) Tacrolimus ointment, or d) Eucrisa (crisaborole) ointment. Eosinophilic Asthma (EA) (init): Dx of mod to severe asthma. Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells/microliter. One of the following: 1) Patient has had two or more asthma exacerbations requiring systemic corticosteroids (eg, prednisone) within the past 12 mo, 2) Prior asthma-related hospitalization within the past 12 mo. Corticosteroid Dependent Asthma (CDA) (init): Dx of mod to severe asthma. Patient is currently dependent on oral corticosteroids for the treatment of asthma. EA, CDA (init): Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) High-dose inhaled corticosteroid (ICS) [e.g., greater than 500 mcg fluticasone propionate equivalent/day] and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist (eg, montelukast), long-acting beta-2 agonist (LABA) (eg, salmeterol), tiotropium], OR b) One max-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone/vilanterol)].

AGE RESTRICTION
Asthma (initial): Patient is 6 years of age or older. AD (initial): Patient is 6 months or age or older. CRSwNP, PN: no age restriction. EoE (initial): Patient is at least 12 years of age.

PRESCRIBER RESTRICTION

AD, Prurigo Nodularis (PN) (Initial): Prescribed by or in consultation with one of the following: dermatologist, allergist/immunologist. Asthma (initial, reauth): Prescribed by or in consultation with a pulmonologist or allergist/immunologist. CRSwNP (initial, reauth): Prescribed by or in consultation with an otolaryngologist, allergist/immunologist, or pulmonologist. EoE (initial): Prescribed by or in consultation with a gastroenterologist or allergist/immunologist.

COVERAGE DURATION

CRSwNP, EoE (Init/Reauth): 12 months. Asthma, AD, PN (Init): 6 mo. Asthma, AD, PN (reauth): 12 mo.

OTHER CRITERIA

Chronic rhinosinusitis with nasal polyposis (CRSwNP) (initial): Diagnosis of CRSwNP. Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (eg, fluticasone, mometasone). Used in combination with another agent for CRSwNP. Eosinophilic esophagitis (EoE) (initial): Dx of EoE. Patient has symptoms of esophageal dysfunction (eg, dysphagia, food impaction, gastroesophageal reflux disease [GERD]/heartburn symptoms, chest pain, abdominal pain). Patient has at least 15 intraepithelial eosinophils per high power field (HPF). Other causes of esophageal eosinophilia have been excluded. Patient weighs at least 40 kg. Trial and failure, contraindication, or intolerance to at least an 8-week trial of one of the following: proton pump inhibitors (eg, pantoprazole, omeprazole) or topical (esophageal) corticosteroids (eg, budesonide, fluticasone). PN (init): Diagnosis of PN. TF/C/I to one medium or higher potency topical corticosteroid. AD (reauth): Documentation of a positive clinical response to therapy as evidenced by at least one of the following: a) Reduction in BSA involvement from baseline, or b) Reduction in SCORAD index value from baseline. EA (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications). CDA (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in exacerbations, improvement in FEV1, reduction in oral corticosteroid dose). EA, CDA (reauth): Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications. CRSwNP (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS, 0-8 scale], improvement in nasal congestion/obstruction score [NC, 0-3 scale]). Used in combination with another agent for CRSwNP. EoE (reauth): Documentation of a positive clinical response to therapy as evidenced by improvement of at least one of the following from baseline: symptoms (eg, dysphagia, food impaction, chest pain, heartburn), histologic measures (eg, esophageal intraepithelial eosinophil count), or endoscopic measures (eg, edema, furrows, exudates, rings, strictures). PN (reauth):

Documentation of a positive clinical response to therapy.

ELAPRASE (S)

MEDICATION(S)
ELAPRASE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

EMGALITY (S)

MEDICATION(S)
EMGALITY PEN, EMGALITY SYRINGE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

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

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

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

EMPAVELI (S)

MEDICATION(S)
EMPAVELI

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. Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
PNH (initial, reauth): 12 months

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

ENBREL (S)

MEDICATION(S)
ENBREL, ENBREL MINI, ENBREL SURECLICK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month trial and failure, contraindication, or intolerance to one nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses.

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): 6 months. All uses (reauth): 12 months

OTHER CRITERIA

RA, PJIA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. AS (Reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count.

ENJAYMO (S)

MEDICATION(S)
ENJAYMO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of cold agglutinin disease (CAD) based on ALL of the following: a) Presence of chronic hemolysis (e.g., bilirubin level above the normal reference range, elevated lactated dehydrogenase [LDH], decreased haptoglobin, increased reticulocyte count), b) Positive polyspecific direct antiglobulin test (DAT), c) Monospecific DAT strongly positive for C3d, d) Cold agglutinin titer greater than or equal to 64 measured at 4 degree celsius, e) Direct antiglobulin test (DAT) result for Immunoglobulin G (IgG) of 1+ or less. Patient does not have cold agglutinin syndrome secondary to other factors (e.g., overt hematologic malignancy, primary immunodeficiency, infection, rheumatologic disease, systemic lupus erythematosus or other autoimmune disorders). Baseline hemoglobin level less than or equal to 10.0 gram per deciliter (g/dL). One of the following: a) Prescribed dose will not exceed 6,500 mg on day 0, 7, and every 14 days thereafter for patients weighing between 39 kg to less than 75 kg OR b) Prescribed dose will not exceed 7,500 mg on day 0, 7, and every 14 days thereafter for patients for patients weighing 75 kg or greater.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Initial, Reauth: Prescribed by or in consultation with a hematologist.

COVERAGE DURATION
Initial: 6 months. Reauth: 12 months

OTHER CRITERIA

Reauth: Documentation of a positive clinical response to therapy as evidenced by ALL of the following: a) The patient has not required any blood transfusions after the first 5 weeks of therapy with Enjaymo AND b) Hemoglobin level greater than or equal to 12 gram per deciliter (g/dL) or increased greater than or equal to 2 g/dL from baseline. One of the following: a) Prescribed dose will not exceed 6,500 mg on day 0, 7, and every 14 days thereafter for patients weighing between 39 kg to less than 75 kg OR b) Prescribed dose will not exceed 7,500 mg on day 0, 7, and every 14 days thereafter for patients for patients weighing 75 kg or greater.

ENTYVIO (S)

MEDICATION(S)
ENTYVIO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Ulcerative Colitis (UC) (init): Diagnosis (Dx) of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. One of the following: a) Trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Humira (adalimumab), Stelara (ustekinumab), Rinvoq (upadacitinib), or Xeljanz/XR (tofacitinib/ER), OR b) for continuation of prior therapy. Crohn's Disease (CD) (init): Dx of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. TF/C/I to both two of the following: Humira, Skyrizi (risankizumab-rzaa), or and Stelara, OR for continuation of prior therapy.

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
UC, CD (reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab

values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline OR reversal of high fecal output state.

EPCLUSA PREFERRED (S)

MEDICATION(S)
SOFOSBUVIR-VELPATASVIR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria will be applied consistent with current AASLD/IDSA guideline. Diagnosis of chronic hepatitis C. Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)].

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
N/A

EPIDIOLEX (S)

MEDICATION(S)
EPIDIOLEX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
LGS, DS, TSC: Patient is 1 year of age or older.

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

EPKINLY (S)

MEDICATION(S)
EPKINLY

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) Relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, 2) Diffuse large B-cell lymphoma (DLBCL) arising from indolent lymphoma, or 3) High grade B-cell lymphoma. Patient has had two or more lines of systemic therapy (e.g., chemotherapy).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

EPOETIN ALFA (S)

MEDICATION(S)
PROCRIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

Subject to ESRD review. CKD (Reauth): Dx of CKD. One of the following: 1) Most recent or average (avg) Hct over 3 months is 33% or less (Hgb is 11 g/dL or less) for patients on dialysis, without ESRD, 2) Most recent or avg Hct over 3 mo is 30% or less (Hgb 10 g/dL or less) for patients not on dialysis, OR 3) Most recent or avg Hct over 3 mo is 36% or less (Hgb 12 g/dL or less) for pediatric patients. Documentation of a positive clinical response to therapy 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. Documentation of a positive clinical response to therapy 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. Documentation of a positive clinical response to therapy from pre-treatment level. Patient is receiving chemo. HCV (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Documentation of a positive clinical response to therapy 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. Documentation of a positive clinical response to therapy from pre-treatment level. Off-label uses (except MDS, HCV): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%. CKD (init, reauth), HIV (init), Chemo (init), Preop, MDS (init), HCV (init): Verify iron evaluation for adequate iron stores.

EPOPROSTENOL (S)

MEDICATION(S)
EPOPROSTENOL SODIUM

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.

ERIVEDGE (S)

MEDICATION(S)
ERIVEDGE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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
Castration-resistant or castration-recurrent prostate cancer (CRPC): Diagnosis of castration-resistant (chemical or surgical) or recurrent prostate cancer. Castration-sensitive prostate cancer (CSPC): Diagnosis of castration-sensitive prostate cancer.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

ESBRIET (S)

MEDICATION(S)
ESBRIET 267 MG CAPSULE, PIRFENIDONE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
initial, reauth: 12 months

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

EUCRISA (S)

MEDICATION(S)
EUCRISA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

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

EVRYSDI (S)

MEDICATION(S)
EVRYSDI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Spinal muscular atrophy (SMA) (initial): Diagnosis of spinal muscular atrophy (SMA) type I, II, or III. Both of the following: a) The mutation or deletion of genes in chromosome 5q resulting in one of the following: 1) Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13) or 2) Compound heterozygous mutation (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2]) AND b) Patient has at least 2 copies of SMN2. Patient is not dependent on both of the following: 1) Invasive ventilation or tracheostomy and 2) Use of non-invasive ventilation beyond use for naps and nighttime sleep. At least one of the following exams (based on patient age and motor ability) has been conducted to establish baseline motor ability: Hammersmith Infant Neurological Exam Part 2 (HINE-2) (infant to early childhood), Hammersmith Functional Motor Scale Expanded (HFMSE), Revised Upper Limb Module (RULM) Test (Non ambulatory), Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND), Motor Function Measure 32 (MFM-32) Scale, or Item 22 of the Bayley Scales of Infant and Toddler Development Third Edition (BSID-III). Patient is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Spinraza). One of the following: a) patient has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma) or b) patient has previously received gene therapy for the treatment of SMA (e.g., Zolgensma) AND submission of medical records (e.g., chart notes) documenting that there has been an inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

SMA (Initial, Reauth): Prescribed by or in consultation with a neurologist with expertise in the diagnosis and treatment of SMA

COVERAGE DURATION

Initial, Reauth: 12 months

OTHER CRITERIA

SMA (Reauth): Documentation of positive clinical response to therapy. Patient (Pt) continues to not be dependent on both of the following: 1) Invasive ventilation or tracheostomy AND 2) use of non-invasive ventilation beyond use for naps and nighttime sleep. Pt is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Spinraza). One of the following: a) pt has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma) or b) pt has previously received gene therapy for the treatment of SMA (e.g., Zolgensma) AND submission of medical records (e.g., chart notes) documenting that there has been an inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months).

EXKIVITY (S)

MEDICATION(S)
EXKIVITY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of non-small cell lung cancer (NSCLC). Disease is one of the following: a) locally advanced or b) metastatic. Disease is epidermal growth factor receptor (EGFR) exon 20 insertion mutation positive as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has progressed on or following prior treatment with a platinum-containing regimen (e.g., carboplatin, cisplatin).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

FABRAZYME (S)

MEDICATION(S)
FABRAZYME

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Fabry Disease: Diagnosis of Fabry disease. Fabrazyme will not be used in combination with Galafold (migalastat).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Fabry Disease: 12 months

OTHER CRITERIA
N/A

FARYDAK (S)

MEDICATION(S)
FARYDAK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

FASENRA (S)

MEDICATION(S)
FASENRA 30 MG/ML SYRINGE, FASENRA PEN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

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

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

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

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

exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications). Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications.

FENTANYL (S)

MEDICATION(S)
FENTANYL CIT OTFC 1,200 MCG, FENTANYL CIT OTFC 1,600 MCG, FENTANYL CITRATE OTFC 200 MCG, FENTANYL CITRATE OTFC 400 MCG, FENTANYL CITRATE OTFC 600 MCG, FENTANYL CITRATE OTFC 800 MCG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

FERRIPROX (S)

MEDICATION(S)
DEFERIPRONE, DEFERIPRONE (3 TIMES A DAY)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
All uses (reauth): Documentation of positive clinical response to therapy. ANC greater than 1.5 x 10^9/L.

FINTEPLA (S)

MEDICATION(S)
FINTEPLA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Dravet Syndrome: Diagnosis of seizures associated with Dravet syndrome. Lennox-Gastaut Syndrome: Diagnosis of seizures associated with Lennox-Gastaut syndrome.

AGE RESTRICTION
Lennox-Gastaut Syndrome: Patient is 2 years of age or older.

PRESCRIBER RESTRICTION
All Indications: Prescribed by or in consultation with a neurologist.

COVERAGE DURATION
All Indications: 12 months

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

FIRAZYR (S)

MEDICATION(S)
ICATIBANT, SAJAZIR

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. Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by one of the following: a) C1-INH antigenic level below the lower limit of normal OR b) C1-INH functional level below the lower limit of normal. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks.

AGE RESTRICTION
Patient is 18 years of age or older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an immunologist or an allergist

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

FIRMAGON (S)

MEDICATION(S)
FIRMAGON

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of advanced or metastatic prostate cancer.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

FOTIVDA (S)

MEDICATION(S)
FOTIVDA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

FYARRO (S)

MEDICATION(S)
FYARRO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Perivascular Epithelioid Cell Tumor (PEComa): Diagnosis of malignant PEComa. Disease is one of the following: a) unresectable locally advanced or b) metastatic.

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.

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

OTHER CRITERIA
N/A

GATTEX (S)

MEDICATION(S)
GATTEX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Short Bowel Syndrome (SBS) (Initial): Diagnosis of SBS. Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient is dependent on parenteral nutrition/intravenous (PN/IV) support for at least 12 months.

AGE RESTRICTION
SBS (initial): Patient is 1 year of age or older.

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

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

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

GAVRETO (S)

MEDICATION(S)
GAVRETO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Presence of metastatic rearranged during transfection (RET) gene fusion-positive tumor(s). Thyroid Cancer: Diagnosis of thyroid cancer. Disease is one of the following: advanced or metastatic. Disease has presence of rearranged during transfection (RET) gene fusion-positive tumor(s). Disease requires treatment with systemic therapy. One of the following: patient is radioactive iodine-refractory or radioactive iodine therapy is not appropriate.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy

GILENYA (S)

MEDICATION(S)
FINGOLIMOD, GILENYA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.

REQUIRED MEDICAL INFORMATION
MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions).

AGE RESTRICTION
N/A

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

COVERAGE DURATION
MS (initial, reauth): 12 months

OTHER CRITERIA
MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).

GILOTRIF (S)

MEDICATION(S)
GILOTRIF

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

GLATIRAMER ACETATE (S)

MEDICATION(S)
GLATIRAMER ACETATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.

REQUIRED MEDICAL INFORMATION
MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions).

AGE RESTRICTION
N/A

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

COVERAGE DURATION
MS (initial, reauth): 12 months

OTHER CRITERIA
MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).

GLEEVEC (S)

MEDICATION(S)
IMATINIB MESYLATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
One of the following: A) Diagnosis of Philadelphia chromosome positive (Ph+)/BCR ABL-positive chronic myelogenous leukemia (CML) OR B) Ph+/BCR ABL+ acute lymphoblastic leukemia (ALL) OR C) Gastrointestinal stromal tumor (GIST) 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 OR G) Aggressive systemic mastocytosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
All uses: 12 months

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

GLYCOPYRROLATE TABLET (S)

MEDICATION(S)
GLYCOPYRROLATE 1 MG TABLET, GLYCOPYRROLATE 2 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of peptic ulcer. One of the following: 1) Patient is receiving concomitant treatment therapy with a proton-pump inhibitor (PPI) (e.g., lansoprazole, omeprazole), OR 2) Both of the following: a) Patient has a contraindication or intolerance to PPIs, and b) Patient is receiving concomitant treatment therapy with an H2-receptor antagonist (e.g., famotidine, nizatidine).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Initial, Reauth: Prescribed by or in consultation with a gastroenterologist.

COVERAGE DURATION
Initial, Reauth: 3 months.

OTHER CRITERIA
Reauth: One of the following: 1) Patient's peptic ulcer has not healed, OR 2) Patient has a new peptic ulcer. One of the following: 1) Patient is receiving concomitant treatment therapy with a proton-pump inhibitor (PPI) (e.g., lansoprazole, omeprazole), OR 2) Both of the following: a) Patient has a contraindication or intolerance to PPIs, and b) Patient is receiving concomitant treatment therapy with an H2-receptor antagonist (e.g., famotidine, nizatidine). Patient experienced a reduction in peptic ulcer symptoms while on therapy.

GROWTH HORMONE, PREFERRED (S)

MEDICATION(S)
GENOTROPIN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by or in consultation with an endocrinologist. GFCRI: prescribed by or in consultation with an endocrinologist or nephrologist

COVERAGE DURATION

All uses (initial, reauth): 12 months

OTHER CRITERIA

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

HRM - MEGESTROL SUSPENSION

MEDICATION(S)
MEGESTROL 400 MG/10 ML CUP, MEGESTROL 400 MG/10ML SUSP CUP, 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
N/A

HRM - MEGESTROL TABLET

MEDICATION(S)
MEGESTROL 20 MG TABLET, MEGESTROL 40 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
Applies to New Starts only.

HUMIRA (S)

MEDICATION(S)
HUMIRA 40 MG/0.8 ML SYRINGE, HUMIRA PEN, HUMIRA PEN CROHN'S-UC-HS, HUMIRA PEN PSOR-UVEITS-ADOL HS, HUMIRA(CF), HUMIRA(CF) PEDIATRIC CROHN'S, HUMIRA(CF) PEN, HUMIRA(CF) PEN CROHN'S-UC-HS, HUMIRA(CF) PEN PEDIATRIC UC, HUMIRA(CF) PEN PSOR-UV-ADOL HS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. PsO (Initial): Diagnosis of moderate to severe chronic PsO. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), methotrexate. Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial): 6 mo, (reauth): 12 mo.

OTHER CRITERIA

Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), aminosalicylate [eg, mesalamine, olsalazine, sulfasalazine]. Hidradenitis suppurativa (Initial): Diagnosis of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). RA, PJIA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Hidradenitis suppurativa (HS), Uveitis (Reauth): Documentation of positive clinical response to therapy. Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. AS (Reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. CD (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. UC (Reauth): For patients who initiated therapy within the past 12 weeks: Documentation of clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy OR For patients who have been maintained on therapy for longer than 12 weeks: Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet

counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state.

IBRANCE (S)

MEDICATION(S)
IBRANCE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Breast cancer: Diagnosis of breast cancer.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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. Acute Lymphoblastic Leukemia: Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
All uses: 12 months

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

IDHIFA (S)

MEDICATION(S)
IDHIFA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

IGALMI (S)

MEDICATION(S)
IGALMI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
One of the following diagnoses: Schizophrenia or Bipolar I or II disorder. For the treatment of acute agitation. Trial and failure, contraindication or intolerance to at least two products used in acute agitation (e.g., olanzapine, ziprasidone). Patient is currently being managed with maintenance medication for their underlying disorder (e.g., aripiprazole, olanzapine, quetiapine, lithium, valproic acid).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
14 days

OTHER CRITERIA
Approve for continuation of prior therapy.

ILUMYA (S)

MEDICATION(S)
ILUMYA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Plaque Psoriasis (initial): Diagnosis of moderate-to-severe plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. One of the following: a) Trial and failure, contraindication, or intolerance to two of the following: Cosentyx (secukinumab), Enbrel (etanercept), Humira (adalimumab)/Cyltezo/or Yuflyma, Otezla (apremilast), Skyrizi (risankizumab), Stelara (ustekinumab), OR b) for continuation of prior therapy.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Plaque Psoriasis (initial): 6 months. Plaque Psoriasis (reauth): 12 months.

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

IMBRUVICA (S)

MEDICATION(S)
IMBRUVICA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chronic lymphocytic leukemia (CLL): Diagnosis of CLL. Waldenstrom's macroglobulinemia: Diagnosis of Waldenstroms macroglobulinemia/lymphoplasmacytic lymphoma. Small lymphocytic lymphoma (SLL): Diagnosis of SLL. Chronic graft versus host disease (cGVHD): Diagnosis of cGVHD AND trial and failure of one or more lines of systemic therapy (e.g., corticosteroids like prednisone or methylprednisolone, mycophenolate).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
All Uses: 12 months

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

INBRIJA (S)

MEDICATION(S)
INBRIJA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
PD (initial, reauth): 12 months

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

INCRELEX (S)

MEDICATION(S)
INCRELEX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial, reauth: 12 months

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

INFLECTRA (S)

MEDICATION(S)
INFLECTRA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Crohn's Disease (CD) and Fistulizing Crohn's Disease (FCD) (initial): Diagnosis (Dx) of moderately to severely active CD or FCD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroids (eg, prednisone), methotrexate. Ulcerative colitis (UC) (initial): Dx of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: corticosteroids (eg, prednisone), aminosalicylate (eg, mesalamine, olsalazine, sulfasalazine), azathioprine, 6-mercaptopurine. Rheumatoid arthritis (RA) (initial): Dx of moderately to severely active RA. Used in combination with methotrexate. Psoriatic arthritis (PsA) (initial): Dx of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (initial): Dx of chronic severe (ie, extensive and/or disabling) plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), anthralin, OR coal tar.

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. Sarcoidosis (initial): Prescribed by or in consultation with a pulmonologist, dermatologist, or ophthalmologist.

COVERAGE DURATION

All uses (initial): 6 months, (reauth): 12 months

OTHER CRITERIA

Ankylosing spondylitis (AS) (initial): Dx of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Sarcoidosis (initial): Dx of sarcoidosis. TF/C/I to one of the following: corticosteroid (eg, prednisone) OR immunosuppressant (eg, methotrexate, cyclophosphamide, azathioprine). All indications (initial): Trial and failure or intolerance to Remicade or Infliximab. Plaque psoriasis (reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. CD, UC (reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline OR reversal of high fecal output state. RA (reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS (reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. Sarcoidosis (reauth): Documentation of positive clinical response to therapy.

INGREZZA (S)

MEDICATION(S)
INGREZZA

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. Chorea Associated with Huntington's disease (initial): Diagnosis of chorea in patients with Huntington's disease.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
All Indications (initial): 3 months, (reauth): 12 months

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

INLYTA (S)

MEDICATION(S)
INLYTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Renal cell carcinoma (RCC): Diagnosis of RCC. One of the following: (1) used as first-line treatment in combination with avelumab or pembrolizumab or (2) used after failure of one prior systemic therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

INQOVI (S)

MEDICATION(S)
INQOVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Myelodysplastic syndrome (MDS): Diagnosis of myelodysplastic syndrome.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

IRESSA (S)

MEDICATION(S)
GEFITINIB, 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
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

ISTODAX (S)

MEDICATION(S)
ROMIDEPSIN 27.5 MG/5.5 ML VIAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Cutaneous T-cell lymphoma (CTCL): Diagnosis of CTCL. Trial and failure, contraindication, or intolerance to at least one systemic therapy for the treatment of CTCL [e.g., Trexall (methotrexate), Targretin (bexarotene), cyclophosphamide].

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.

ITRACONAZOLE CAPSULE (S)

MEDICATION(S)
ITRACONAZOLE 100 MG CAPSULE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Systemic Fungal Infection (SFI): Diagnosis of a systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis). Fingernail Onychomycosis: Diagnosis of fingernail onychomycosis as confirmed by one of the following: i) positive potassium hydroxide (KOH) preparation, ii) fungal culture, OR iii) nail biopsy. Trial and failure (of a minimum 6-week supply), contraindication, or intolerance to oral terbinafine. Toenail Onychomycosis: Diagnosis of toenail onychomycosis as confirmed by one of the following: i) positive potassium hydroxide (KOH) preparation, ii) fungal culture, OR iii) nail biopsy. Trial and failure (of a minimum 12-week supply), contraindication, or intolerance to oral terbinafine.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
SFI:6mo.Fingernail Onychomycosis:5wks.Toenail Onychomycosis:3mo.

OTHER CRITERIA
N/A

IVERMECTIN (S)

MEDICATION(S)
IVERMECTIN 3 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Strongyloidiasis: Diagnosis of intestinal (i.e., nondisseminated) strongyloidiasis due to the nematode parasite Strongyloides stercoralis. Onchocerciasis: Diagnosis of onchocerciasis due to the nematode parasite Onchocerca volvulus.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
N/A

IVIG (S)

MEDICATION(S)
ASCENIV, BIVIGAM, GAMMAKED 1 GRAM/10 ML VIAL, GAMMAKED 10 GRAM/100 ML VIAL, GAMMAKED 20 GRAM/200 ML VIAL, GAMMAKED 5 GRAM/50 ML VIAL, GAMUNEX-C, OCTAGAM, PANZYGA, PRIVIGEN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
All uses (initial, reauth): Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication). Privigen only: Hyperprolinemia. Octagam only: Allergy to corn.

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 combinedimmunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluationincluding IgG levels below the normal laboratory value for the patient's age at the time of diagnosisand the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoidor diphtheria toxoid and pneumovax or HiB vaccine). [B] Secondary Acquired Antibody Deficiency 1) Bcellchronic lymphocytic leukemia with an Ig level less than 500 mg/dL OR history of recurrent bacterialinfections. 2) HIV infection with an Ig level less than 400 mg/dL OR Patient has active bleeding or aplatelet count less than 10 x 109/L. 3) Multiple myloma in plateau phase and patient has hypogammaglobulinemia. [C] Hematological Autoimmune Disorders 1) Acquired (pure) red cell aplasia (PRCA) that is immunologic and patient had a trial and failure, contraindication, or intolerance (TF/C/I) to a corticosteroid and an immunosuppressant (i.e., cyclophosphamide, cyclosporine) OR patient has viral PRCA caused by parvovirus B19. 2) Fetal alloimmune thrombocytopenia. 3) Hemolytic disease of the newborn and the patient has established hyperbilirubinemia. 4) Idiopathic thrombocytopenic purpura and patient had a TF/C/I to a corticosteroid OR a platelet count less than 30,000 cells/mm3. Continued in Other Criteria Section.

AGE RESTRICTION

HIV (initial): patient is less than or equal to 12 years of age.

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

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

JAKAFI (S)

MEDICATION(S)
JAKAFI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Myelofibrosis: Diagnosis of primary myelofibrosis, OR post-polycythemia vera myelofibrosis, OR post-essential thrombocythemia myelofibrosis. Polycythemia vera: Diagnosis of polycythemia vera, AND trial and failure, contraindication, or intolerance to hydroxyurea. Acute graft versus host disease (aGVHD): Diagnosis of aGVHD. Disease is steroid-refractory. Chronic graft versus host disease (cGVHD): Diagnosis of cGVHD. Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
Approve for continuation of prior therapy.

JAYPIRCA (S)

MEDICATION(S)
JAYPIRCA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of mantle cell lymphoma (MCL). Disease is one of the following: a) relapsed, or b) refractory. Patient has received at least two prior therapies for MCL, one of which is a Bruton Tyrosine Kinase (BTK) inhibitor therapy [e.g., Imbruvica (ibrutinib), Calquence (acalabrutinib), Brukinsa (zanubrutinib)].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

JEMPERLI (S)

MEDICATION(S)
JEMPERLI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

JUXTAPID (S)

MEDICATION(S)
JUXTAPID 10 MG CAPSULE, JUXTAPID 20 MG CAPSULE, JUXTAPID 30 MG CAPSULE, JUXTAPID 5 MG CAPSULE

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/pre-treatment 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. One of the following: a) patient is receiving other lipid-lowering therapy, or b) patient has an inability to take 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 or in consultation with a cardiologist, endocrinologist, or lipid specialist.

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

OTHER CRITERIA
HoFH (reauthorization): One of the following: a) patient continues to receive other lipid-lowering

therapy, or b) patient has an inability to take other lipid-lowering therapy. Submission of medical records (eg, chart notes, laboratory values) documenting LDL-C reduction from baseline while on therapy. Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor.

KALYDECO (S)

MEDICATION(S)
KALYDECO 13.4 MG GRANULES PKT, KALYDECO 150 MG TABLET, KALYDECO 25 MG GRANULES PACKET, KALYDECO 50 MG GRANULES PACKET, KALYDECO 75 MG GRANULES PACKET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
CF (initial): Patient is 1 month of age or older.

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

COVERAGE DURATION
CF (initial, reauth): 12 months

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

KANJINTI (S)

MEDICATION(S)
KANJINTI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

KANUMA (S)

MEDICATION(S)
KANUMA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

KERENDIA (S)

MEDICATION(S)
KERENDIA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D). Urine albumin-to-creatinine ratio (UACR) greater than or equal to 30 mg/g. Estimated glomerular filtration rate (eGFR) greater than or equal to 25 mL/min/1.73 m2. One of the following: 1) Minimum 30-day supply trial of a maximally tolerated dose and will continue therapy with one of the following: a) generic angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril), or b) generic angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan), OR 2) Patient has a contraindication or intolerance to ACE inhibitors and ARBs.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial, Reauth: 12 months

OTHER CRITERIA
Reauth: Documentation of positive clinical response to therapy. One of the following: 1) Patient continues to be on a maximally tolerated dose of ACE inhibitor or ARB, OR 2) Patient has a contraindication or intolerance to ACE inhibitors and ARBs.

KESIMPTA (S)

MEDICATION(S)
KESIMPTA PEN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Multiple Sclerosis (MS) (Initial): Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: 1) Failure after a trial of at least 4 weeks, contraindication, or intolerance to one of the following: A) Aubagio (teriflunomide), B) Mavenclad (cladribine), C) Plegridy (peginterferon beta-1a), D) Any one of the interferon beta-1a injections (eg, Avonex), E) Any one of the interferon beta-1b injections (eg, Betaseron, Extavia), F) Any one of the oral fumarates (eg, brand Tecfidera, generic dimethyl fumarate), G) Any one of the glatiramer acetates (eg, Copaxone, Glatopa, generic glatiramer acetate), H) Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (eg, Gilenya [fingolimod], Mayzent [siponimod], Zeposia [ozanimod]), OR 2) For continuation of prior therapy. Not used in combination with another disease-modifying therapy for MS. Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ocrelizumab [Ocrevus]).

AGE RESTRICTION
N/A

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

COVERAGE DURATION
MS (Initial, Reauth): 12 months

OTHER CRITERIA

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

KIMMTRAK (S)

MEDICATION(S)
KIMMTRAK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of uveal melanoma. Disease is unresectable or metastatic. Patient is HLA-A*02:01 genotype positive as determined by a high-resolution genotyping test.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

KISQALI (S)

MEDICATION(S)
KISQALI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Breast cancer: Diagnosis of breast cancer.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy

KISQALI-FEMARA PACK (S)

MEDICATION(S)
KISQALI FEMARA CO-PACK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Breast cancer: Diagnosis of breast cancer.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

KORLYM (S)

MEDICATION(S)
KORLYM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial, reauth: 6 months

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

KOSELUGO (S)

MEDICATION(S)
KOSELUGO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

KRAZATI (S)

MEDICATION(S)
KRAZATI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Non-Small Cell Lung Cancer (NSCLC): Diagnosis of NSCLC. Disease is one of the following: locally advanced or metastatic. Disease is KRAS G12C-mutated as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has received at least one prior systemic therapy (e.g., chemotherapy, immunotherapy).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

KUVAN (S)

MEDICATION(S)
SAPROPTERIN DIHYDROCHLORIDE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
PKU (reauth): Documentation of a positive clinical response to therapy. Patient will continue to have blood Phe levels measured periodically during therapy.

KYNMOBI (S)

MEDICATION(S)
KYNMOBI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
PD (Initial, reauth): 12 months

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

LANREOTIDE (S)

MEDICATION(S)
LANREOTIDE 120 MG/0.5 ML SYRNG

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
Acromegaly (initial): Prescribed by or in consultation with an endocrinologist. GEP-NETs (initial): Prescribed by or in consultation with an oncologist. Carcinoid syndrome (initial): Prescribed by or in consultation with an endocrinologist or oncologist.

COVERAGE DURATION
All uses: 12 months

OTHER CRITERIA
All Indications: 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 disease, secondary progressive disease, including active disease with new brain lesions). One of the following: 1) Patient has not been previously treated with alemtuzumab, and failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS: A) Aubagio (teriflunomide), B) Mavenclad (cladribine), C) Plegridy (peginterferon beta-1a), D) Tysabri (natalizumab), E) Any one of the interferon beta-1a injections (eg, Avonex), F) Any one of the interferon beta-1b injections (eg, Betaseron, Extavia), G) Any one of the oral fumarates (eg, brand Tecfidera, generic dimethyl fumarate), H) Any one of the glatiramer acetate injections (eg, Copaxone, Glatopa, generic glatiramer acetate), I) Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (eg, Gilenya [fingolimod], Mayzent [siponimod], Zeposia [ozanimod]), J) Any one of the B-cell targeted therapies (eg, Ocrevus [ocrelizumab], Kesimpta [ofatumumab]), or 2) Patient has previously received treatment with alemtuzumab, and at least 12 months have or will have elapsed since the most recent treatment course with alemtuzumab. Not used in combination with another disease-modifying therapy for MS.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
MS: 12 months.

OTHER CRITERIA

N/A

LENVIMA (S)

MEDICATION(S)
LENVIMA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Differentiated thyroid cancer (DTC): Diagnosis of DTC. Renal Cell Carcinoma (RCC): Diagnosis of RCC. One of the following: 1) Both of the following: a) Used as first-line treatment and b) Used in combination with Keytruda (pembrolizumab), or 2) Both of the following: a) Treatment follows one prior anti-angiogenic therapy and b) Used in combination with everolimus. Hepatocellular Carcinoma (HCC): Diagnosis of HCC. Endometrial Carcinoma (EC): Diagnosis of advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR). Patient has disease progression following systemic therapy. Used in combination with Keytruda (pembrolizumab) therapy. Patient is not a candidate for curative surgery or radiation.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

LETAIRIS (S)

MEDICATION(S)
AMBRISENTAN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

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

LIDOCAINE TOPICAL (S)

MEDICATION(S)
GLYDO, LIDOCAINE 5% OINTMENT, LIDOCAINE HCL 2% JEL UROJET AC, LIDOCAINE HCL 2% JELLY URO-JET, LIDOCAINE-PRILOCAINE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 months

OTHER CRITERIA
N/A

LIDODERM (S)

MEDICATION(S)
LIDOCAINE 5% PATCH

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Post-herpetic neuralgia: Diagnosis of post-herpetic neuralgia.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

LIVMARLI (S)

MEDICATION(S)
LIVMARLI 9.5 MG/ML ORAL SOLN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Alagille syndrome (ALGS) (initial): Both of the following: a) Diagnosis of ALGS, and b) Molecular genetic testing confirms mutations in the JAG1 or NOTCH2 gene. Documentation of ONE of the following: a) Total serum bile acid greater than 3 times the upper limit of normal (ULN), b) Conjugated bilirubin greater than 1 mg/dL, c) Fat soluble vitamin deficiency otherwise unexplainable, or d) Gammaglutamyl transpeptidase (GGT) greater than 3 times the ULN. Patient is experiencing moderate to severe cholestatic pruritus. Patient has had an inadequate response to at least two of the following treatments used for the relief of pruritus: a) Ursodeoxycholic acid (e.g., Ursodiol), b) Antihistamines (e.g., diphenhydramine, hydroxyzine), c) Rifampin, or d) Bile acid sequestrants (e.g., Questran, Colestid, Welchol).

AGE RESTRICTION
ALGS (initial): Patient is 3 months of age or older.

PRESCRIBER RESTRICTION
ALGS (initial): Prescribed by or in consultation with a hepatologist.

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

OTHER CRITERIA
ALGS (reauth): Documentation of positive clinical response to therapy (e.g., reduced bile acids, reduced pruritus severity score).

LONSURF (S)

MEDICATION(S)
LONSURF

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Colorectal Cancer: Diagnosis of metastatic colorectal cancer AND One of the following: Used as a single agent or Used in combination with bevacizumab AND trial and failure, contraindication, or intolerance to at least one component in the following: fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI) AND trial and failure, contraindication, or intolerance to at least one anti-VEGF therapy (e.g., bevacizumab)) AND One of the following: A) patient has RAS wild-type tumors and trial and failure, contraindication, or intolerance to at least one anti-EGFR therapy (e.g., Vectibix, Erbitux) OR B) Patient has RAS mutant tumors.
Gastric/Gastroesophageal Junction Adenocarcinoma: Diagnosis of metastatic gastric cancer or diagnosis of metastatic gastroesophageal junction adenocarcinoma. Trial and failure, contraindication or intolerance to at least two of the following: fluropyrimidine-based chemotherapy (e.g. fluorouracil), Platinum-based chemotherapy (e.g., carboplatin, cisplatin, oxaliplatin), Taxane (e.g., docetaxel, paclitaxel) or irinotecan-based chemotherapy, HER2/neu-targeted therapy (e.g., trastuzumab) (if HER2 overexpression).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA

Approve for continuation of prior therapy.

LORBRENA (S)

MEDICATION(S)
LORBRENA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

LOTRONEX (S)

MEDICATION(S)
ALOSETRON HCL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
Initial: 18 years of age or older

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
IBS (reauth): Symptoms of IBS continue to persist. Documentation of positive clinical response to therapy (e.g., relief of IBS abdominal pain and discomfort, improvement in stool consistency and frequency, improvement as measured by the Global Improvement Scale).

LUMAKRAS (S)

MEDICATION(S)
LUMAKRAS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is one of the following: a) locally advanced or b) metastatic. Tumor is KRAS G12C-mutated as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has received at least one prior systemic therapy (e.g., chemotherapy, immunotherapy).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

LUMIZYME (S)

MEDICATION(S)
LUMIZYME

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Infantile Onset Pompe Disease (IOPD) (initial): Diagnosis of IOPD (lysosomal acid alpha-glucosidase [GAA] deficiency) as confirmed by one of the following: 1) Absence or deficiency (less than 1% of the lab specific normal mean) of GAA enzyme activity in lymphocytes, fibroblasts, or muscle tissues as confirmed by an enzymatic assay, OR 2) Molecular genetic testing confirms mutations in the GAA gene. Presence of clinical signs and symptoms of the disease (e.g., cardiomegaly, hypotonia, etc.). Late Onset Pompe Disease (LOPD) (initial): Diagnosis of LOPD (lysosomal acid alpha-glucosidase [GAA] deficiency) as confirmed by one of the following: 1) Absence or deficiency (less than 40% of the lab specific normal mean) of GAA enzyme activity in lymphocytes, fibroblasts, or muscle tissues as confirmed by an enzymatic assay, OR 2) Molecular genetic testing confirms mutations in the GAA gene. Presence of clinical signs and symptoms of the disease (e.g., respiratory distress, skeletal muscle weakness, etc.).

AGE RESTRICTION
IOPD (initial): Patient is less than or equal to 12 months of age. LOPD (initial): Patient is 1 year of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
IOPD, LOPD (initial, reauth): 12 months

OTHER CRITERIA

IOPD, LOPD (reauth): Documentation of positive clinical response to therapy.

LUPRON (S)

MEDICATION(S)
LEUPROLIDE 2WK 14 MG/2.8 ML KT, LEUPROLIDE 2WK 14 MG/2.8 ML VL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Prostate Cancer: Diagnosis of advanced or metastatic prostate cancer.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Prostate CA: 12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

LUPRON DEPOT (S)

MEDICATION(S)
LUPRON DEPOT, LUPRON DEPOT (LUPANETA)

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): Diagnosis of endometriosis. One of the following: Patient has had surgical ablation to prevent recurrence, or trial and failure, contraindication, or intolerance to one NSAID (e.g., diclofenac, ibuprofen, meloxicam, naproxen) and one oral contraceptive (e.g., norethindrone-ethinyl estradiol, estradiol and norethindrone). Uterine Leiomyomata (UL) (3.75 mg, 11.25 mg): a) For use prior to surgery to reduce size of fibroids to facilitate a surgical procedure (eg, myomectomy, hysterectomy) OR b) all of the following: treatment of anemia, anemia is caused by uterine leiomyomata (fibroids), and for use prior to surgery.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
Approve for continuation of prior therapy.

LUPRON DEPOT PED (S)

MEDICATION(S)
LUPRON DEPOT-PED

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 (initial, reauth): 12 months

OTHER CRITERIA
CPP (reauth): Patient demonstrates positive clinical response to therapy.

LYNPARZA TABLET (S)

MEDICATION(S)
LYNPARZA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. Breast cancer: Diagnosis of breast cancer.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Pancreatic adenocarcinoma: Diagnosis of pancreatic adenocarcinoma. Prostate cancer: Diagnosis of castration-resistant prostate cancer. BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC): Diagnosis of metastatic castration-resistant prostate cancer (mCRPC). Presence of a deleterious or suspected deleterious BRCA-mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with abiraterone and one of the following: a) prednisone or b) prednisolone. All indications: Approve for continuation of prior therapy.

LYTGOBI (S)

MEDICATION(S)
LYTGOBI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of intrahepatic cholangiocarcinoma. Disease is one of the following: a) unresectable, b) locally advanced, or c) metastatic. Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangements. Patient has been previously treated (e.g., chemotherapy).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

MAKENA (S)

MEDICATION(S)
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.

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 not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni, Zepatier].

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
N/A

MAYZENT (S)

MEDICATION(S)
MAYZENT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.

REQUIRED MEDICAL INFORMATION
MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions).

AGE RESTRICTION
N/A

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

COVERAGE DURATION
MS (initial, reauth): 12 months

OTHER CRITERIA
MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).

MEKINIST (S)

MEDICATION(S)
MEKINIST

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
Solid tumors, Low-grade glioma: Patient is 1 year of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

12 months

OTHER CRITERIA

Approve for continuation of prior therapy. Solid tumors: Diagnosis of solid tumors. Disease is unresectable or metastatic. Patient has progressed on or following prior treatment and have no satisfactory alternative treatment options. 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). Medication is used in combination with Tafinlar (dabrafenib). Low-grade glioma: Diagnosis of low-grade glioma. Patient requires systemic therapy. 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). Medication is used in combination with Tafinlar (dabrafenib).

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
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy

MIGRANAL (S)

MEDICATION(S)
DIHYDROERGOTAMINE 4 MG/ML SPRY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of migraine headaches with or without aura. Will be used for the acute treatment of migraine. One of the following: Trial and failure or intolerance to one triptan (e.g., eletriptan, rizatriptan, sumatriptan) or contraindication to all triptans.

AGE RESTRICTION
N/A

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

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

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

MONJUVI (S)

MEDICATION(S)
MONJUVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diffuse Large B-cell Lymphoma (DLBCL): Diagnosis of DLBCL. Disease is one of the following: relapsed or refractory. Used in combination with lenalidomide. Patient is not eligible for autologous stem cell transplant (ASCT).

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

MS INTERFERONS (NON-PREFERRED) (S)

MEDICATION(S)
REBIF, REBIF REBIDOSE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
MS (initial, reauth): 12 months

OTHER CRITERIA
MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).

MS INTERFERONS (PREFERRED) (S)

MEDICATION(S)
AVONEX 30 MCG/0.5 ML SYRINGE, AVONEX PREFILLED SYR 30 MCG KT, AVONEX PEN, BETASERON, PLEGRIDY, PLEGRIDY PEN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.

REQUIRED MEDICAL INFORMATION
MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions).

AGE RESTRICTION
N/A

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

COVERAGE DURATION
MS (initial, reauth): 12 months

OTHER CRITERIA
MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).

MVASI (S)

MEDICATION(S)
MVASI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

MYFEMBREE (S)

MEDICATION(S)
MYFEMBREE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Uterine Leiomyomas (Fibroids) (initial): Diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids). Patient is premenopausal. One of the following: 1) History of inadequate control of bleeding following a trial of 30 days, or history of intolerance or contraindication to one of the following: combination (estrogen/progestin) contraceptive, progestins, or tranexamic acid or 2) Patient has had a previous interventional therapy to reduce bleeding. Treatment duration of therapy has not exceeded a total of 24 months. Pain Associated with Endometriosis (initial): Diagnosis of moderate to severe pain associated with endometriosis. Patient is premenopausal. One of the following: 1) History of inadequate pain control response following a trial of 30 days, or history of intolerance or contraindication to one of the following: danazol, combination (estrogen/progestin) contraceptive, or progestins or 2) Patient has had surgical ablation to prevent recurrence. Treatment duration of Myfembree has not exceeded a total of 24 months.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
Uterine Leiomyomas (Fibroids) (reauth): Patient has improvement in bleeding associated with uterine

leiomyomas (fibroids) (e.g., significant/sustained reduction in menstrual blood loss per cycle, improved quality of life, etc.). Treatment duration of therapy has not exceeded a total of 24 months. Pain Associated with Endometriosis (reauth): Patient has improvement in pain associated with endometriosis (e.g., improvement in dysmenorrhea and nonmenstrual pelvic pain). Treatment duration of Myfembree has not exceeded a total of 24 months.

NAGLAZYME (S)

MEDICATION(S)
NAGLAZYME

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
MPS VI: 12 months

OTHER CRITERIA
N/A

NATPARA (S)

MEDICATION(S)
NATPARA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial: 6 months. Reauth: 12 months

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

NERLYNX (S)

MEDICATION(S)
NERLYNX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Early Stage Breast cancer: Diagnosis (dx) of early stage breast cancer. Advanced or Metastatic Breast Cancer: Dx of advanced or metastatic breast cancer.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

NEULASTA (S)

MEDICATION(S)
NEULASTA, NEULASTA ONPRO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA

N/A

NEXAVAR (S)

MEDICATION(S)
SORAFENIB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Renal cell carcinoma (RCC): Diagnosis of RCC. Hepatocellular carcinoma (HCC): Diagnosis of HCC. Differentiated thyroid carcinoma (DTC): Diagnosis of DTC (ie, follicular carcinoma, Hurthle cell carcinoma, or papillary carcinoma). One of the following: locally recurrent disease, metastatic disease, or unresectable disease. One of the following: patient has symptomatic disease or patient has progressive disease. Disease is refractory to radioactive iodine (RAI) treatment. Medullary thyroid carcinoma (MTC): Diagnosis of MTC. One of the following: 1) Disease is progressive or 2) Disease is symptomatic with distant metastases. Trial and failure, contraindication, or intolerance to Caprelsa (vandetanib) or Cometriq (cabozantinib).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

NINLARO (S)

MEDICATION(S)
NINLARO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Multiple myeloma: Diagnosis of multiple myeloma.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

NORTHERA (S)

MEDICATION(S)
DROXIDOPA

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.

NOXAFIL SUSPENSION (S)

MEDICATION(S)
NOXAFIL 40 MG/ML SUSPENSION, POSACONAZOLE 200 MG/5 ML SUSP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Prophylaxis of systemic fungal infections (SFI): Used as prophylaxis of invasive fungal infections caused by Aspergillus or Candida for one of the following conditions: 1) Patient is at high risk of infections due to severe immunosuppression from hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD) or hematologic malignancies with prolonged neutropenia from chemotherapy OR 2) patient has a prior fungal infection requiring secondary prophylaxis. Oropharyngeal Candidiasis (OPC): Diagnosis of OPC. One of the following: 1) Trial and failure, contraindication, or intolerance to fluconazole OR 2) Susceptibility results demonstrate resistance to fluconazole.

AGE RESTRICTION
Prophylaxis of SFI, OPC: Patient is 13 years or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Prophylaxis of SFI: 6 months. OPC: 1 month.

OTHER CRITERIA
N/A

NUBEQA (S)

MEDICATION(S)
NUBEQA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Castration-resistant or castration-recurrent prostate cancer (CRPC): Diagnosis of castration-resistant (chemical or surgical) or castration-recurrent prostate cancer. Hormone-sensitive prostate cancer (HSPC): Diagnosis of HSPC.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
CRPC, HSPC: 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 two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months or Patient has had a prior asthma-related hospitalization within the past 12 months. Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day) and ii) additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium), OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone/vilanterol)]. Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) (init): Diagnosis of CRSwNP. Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone). Used in combination with another agent for CRSwNP. Eosinophilic Granulomatosis with Polyangiitis (EGPA) (init): Diagnosis of EGPA. Patient's disease has relapsed or is refractory to standard of care therapy (i.e., corticosteroid treatment with or without immunosuppressive therapy). Patient is currently receiving corticosteroid therapy (e.g., prednisolone, prednisone).

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

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

Hypereosinophilic Syndrome (HES) (init): Diagnosis of HES. Patient has been diagnosed for at least 6 months. Verification that other non-hematologic secondary causes have been ruled out (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy). Patient is FIP1L1-PDGFRA-negative. Patient has uncontrolled HES defined as both of the following: a) History of 2 or more flares within the past 12 months AND b) Pre-treatment blood eosinophil count greater than or equal to 1000 cells/microliter. Trial and failure, contraindication, or intolerance to corticosteroid therapy (e.g., prednisone) or cytotoxic/immunosuppressive therapy (e.g., hydroxyurea, cyclosporine, imatinib). Asthma (reauth): Documentation of positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second (FEV1), decreased use of rescue medications). Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications. CRSwNP (reauth): Documentation of positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS, 0-8 scale], improvement in nasal obstruction symptoms via visual analog scale [VAS, 0-10 scale]). Used in combination with another agent for CRSwNP. EGPA (reauth): Documentation of positive clinical response to therapy (e.g., increase in remission time). HES (reauth): Documentation of positive clinical response to therapy (e.g., reduction in flares, decreased blood eosinophil count, reduction in corticosteroid dose).

NUEDEXTA (S)

MEDICATION(S)
NUEDEXTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
PBA (initial/reauth): 12 months

OTHER CRITERIA

N/A

NUPLAZID (S)

MEDICATION(S)
NUPLAZID 10 MG TABLET, NUPLAZID 34 MG CAPSULE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

NUVIGIL (S)

MEDICATION(S)
ARMODAFINIL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA

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

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., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesion). One of the following: 1) Failure after a trial of at least 4 weeks, contraindication, or intolerance to one of the following disease-modifying therapies for MS: A) Aubagio (teriflunomide), B) Kesimpta (ofatumumab), C) Lemtrada (alemtuzumab), D) Mavenclad (cladribine), E) Plegridy (peginterferon beta-1a), F) Tysabri (natalizumab), G) Any one of the interferon beta-1a injections (eg, Avonex), H) Any one of the interferon beta-1b injections (eg, Betaseron, Extavia), I) Any one of the oral fumarates (eg, brand Tecfidera, generic dimethyl fumarate), J) Any one of the glatiramer acetates (eg, Copaxone, Glatopa, generic glatiramer acetate), K) Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (eg, Gilenya [fingolimod], Mayzent [siponimod], Zeposia [ozanimod]), OR 2) For continuation of prior therapy. Primary progressive MS (initial): Diagnosis of primary progressive multiple sclerosis (PPMS). All indications (initial, reauth): Not used in combination with another disease-modifying therapy for MS. Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]). Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
All uses (initial, reauth): 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 therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).

ODOMZO (S)

MEDICATION(S)
ODOMZO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

OFEV (S)

MEDICATION(S)
OFEV

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

Initial, reauth: 12 months

OTHER CRITERIA

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

OJJAARA (S)

MEDICATION(S)
OJJAARA

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) Primary myelofibrosis, b) Post-polycythemia vera myelofibrosis, OR c) Post-essential thrombocythemia myelofibrosis. Disease is intermediate or high risk. Patient has anemia.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

ONUREG (S)

MEDICATION(S)
ONUREG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

OPDUALAG (S)

MEDICATION(S)
OPDUALAG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
One of the following diagnoses: unresectable melanoma or metastatic melanoma. Both of the following: patient is 12 years of age or older AND patient weighs at least 40 kg (88 lbs).

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.

OPSUMIT (S)

MEDICATION(S)
OPSUMIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

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

OPZELURA (S)

MEDICATION(S)
OPZELURA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Atopic Dermatitis (AD) Initial: Diagnosis of mild to moderate atopic dermatitis. One of the following: a) Greater than or equal to 3% body surface area (BSA) involvement, or b) Involvement of sensitive body areas (e.g., face, hands, feet, scalp, groin). Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least two of the following: a) Medium or higher potency topical corticosteroid, b) Elidel (pimecrolimus) cream, c) Tacrolimus ointment, or d) Eucrisa (crisaborole) ointment. Patient is not receiving Opzelura in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine). Opzelura will only be used for short-term and/or non-continuous chronic treatment. Nonsegmental Vitiligo (NV) Initial: Diagnosis of NV. Trial and failure, contraindication, or intolerance to at least one of the following: medium or higher potency topical corticosteroid or tacrolimus ointment. Not used in combination with therapeutic biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants (eg, azathioprine or cyclosporine).

AGE RESTRICTION
AD, NV Initial: Patient is 12 years of age or older.

PRESCRIBER RESTRICTION
AD Initial: Prescribed by or in consultation with a dermatologist or allergist/immunologist. NV Initial: Prescribed by or in consultation with a dermatologist.

COVERAGE DURATION
AD Initial: 12 weeks. AD Reauth: 6 months. NV Initial: 6 months. NV Reauth: 12 months.

OTHER CRITERIA

AD Reauth: Documentation of a positive clinical response to therapy as evidenced by at least one of the following: a) Reduction in BSA involvement from baseline, b) Reduction in pruritus severity from baseline, or c) Improvement in quality of life from baseline. Patient is not receiving Opzelura in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine). Opzelura will only be used for short-term and/or non-continuous chronic treatment. NV Reauth: Documentation of a positive clinical response to therapy. Not used in combination with therapeutic biologics, other JAK inhibitors, or potent immunosuppressants (eg, azathioprine or cyclosporine).

ORENITRAM (S)

MEDICATION(S)
ORENITRAM ER 0.25 MG TABLET, ORENITRAM ER 1 MG TABLET, ORENITRAM ER 2.5 MG TABLET, ORENITRAM ER 5 MG TABLET, ORENITRAM MONTH 1 TITRATION KT, ORENITRAM MONTH 2 TITRATION KT, ORENITRAM MONTH 3 TITRATION KT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

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

ORGOVYX (S)

MEDICATION(S)
ORGOVYX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

ORILISSA (S)

MEDICATION(S)
ORILISSA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

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

ORKAMBI (S)

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Cystic Fibrosis (CF) (Initial): Diagnosis of CF. Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by a U.S. Food and Drug Administration (FDA)-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).

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

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

COVERAGE DURATION
CF (initial, reauth): 12 months

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

ORKAMBI GRANULES (S)

MEDICATION(S)
ORKAMBI 100-125 MG GRANULE PKT, ORKAMBI 150-188 MG GRANULE PKT, ORKAMBI 75-94 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 1 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 1 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.

ORSERDU (S)

MEDICATION(S)
ORSERDU

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of breast cancer. Disease is advanced or metastatic. Disease is estrogen receptor (ER)-positive. Disease is human epidermal growth factor receptor 2 (HER2)-negative. Presence of estrogen receptor (ESR1) mutation(s) 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). Disease has progressed following at least one line of endocrine therapy [e.g., Faslodex (fulvestrant), Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

OSMOLEX ER (S)

MEDICATION(S)
OSMOLEX ER 129 MG TABLET, OSMOLEX ER 193 MG TABLET, OSMOLEX ER 322 MG DAILY DOSE

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 Parkinson's disease. Trial and failure or intolerance to both of the following: A) amantadine immediate release AND B) one of the following: carbidopa-levodopa, MAO-B inhibitor (e.g., rasagiline, selegiline), or dopamine agonist (e.g., pramipexole, ropinirole). Drug-Induced Extrapyramidal Reactions (EPS) (initial): Patient is experiencing drug-induced extrapyramidal reactions. One of the following: A) Patient has persistent extrapyramidal symptoms 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. Trial and failure or intolerance to amantadine immediate release.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
PD, EPS (initial, reauth): 12 months

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

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 10-20-30MG START 28 DAY, OTEZLA 30 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Psoriatic arthritis (PsA) (initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (initial): Diagnosis of plaque psoriasis. Oral ulcers associated with Behcets Disease (Initial): Diagnosis of Behcets Disease. Patient has active oral ulcers.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
All uses (initial): 6 months. All uses (reauth): 12 months.

OTHER CRITERIA
PsA (reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Plaque psoriasis (reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. Oral ulcers associated with Behcets Disease (reauth): Documentation of positive clinical response to therapy (eg, reduction in pain

from oral ulcers or reduction in number of oral ulcers).

OXANDRIN (S)

MEDICATION(S)
OXANDROLONE 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.

OXBRYTA (S)

MEDICATION(S)
OXBRYTA 300 MG TABLET, OXBRYTA 300 MG TABLET FOR SUSP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
Initial: Patient is 4 years of age or older.

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

COVERAGE DURATION
Initial, Reauth: 12 months.

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

OXLUMO (S)

MEDICATION(S)
OXLUMO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Primary Hyperoxaluria Type 1 (PH1) (initial): Diagnosis of PH1. Diagnosis has been confirmed by both of the following: 1) One of the following: a) Elevated urinary oxalate excretion or b) Elevated plasma oxalate concentration, AND 2) Genetic testing demonstrating a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene. Patient has not received a liver transplant.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PH1 (initial, reauth): Prescribed by or in consultation with one of the following: nephrologist, urologist, geneticist, or specialist with expertise in the treatment of PH1.

COVERAGE DURATION
PH1 (initial, reauth): 12 months.

OTHER CRITERIA
PH1 (reauth): Documentation of positive clinical response to therapy (e.g., decreased urinary oxalate excretion, decreased plasma oxalate concentration). Patient has not received a liver transplant.

PART D VS PART B

MEDICATION(S)

ABELCET, ACETYLCYSTEINE 10% VIAL, ACETYLCYSTEINE 20% VIAL, ACYCLOVIR 1,000 MG/20 ML VIAL, ACYCLOVIR 500 MG/10 ML VIAL, AKYNZEO 300-0.5 MG CAPSULE, ALBUTEROL 100 MG/20 ML SOLN, ALBUTEROL 15 MG/3 ML SOLUTION, ALBUTEROL 2.5 MG/0.5 ML SOL, ALBUTEROL 20 MG/4 ML SOLUTION, ALBUTEROL 25 MG/5 ML SOLUTION, ALBUTEROL 5 MG/ML SOLUTION, ALBUTEROL 75 MG/15 ML SOLN, 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, AMPHOTERICIN B, AMPHOTERICIN B LIPOSOME, APREPITANT, AZATHIOPRINE, BUDESONIDE 0.25 MG/2 ML SUSP, BUDESONIDE 0.5 MG/2 ML SUSP, BUDESONIDE 1 MG/2 ML INH SUSP, CROMOLYN 20 MG/2 ML NEB SOLN, CYCLOPHOSPHAMIDE 25 MG CAPSULE, CYCLOPHOSPHAMIDE 50 MG CAPSULE, CYCLOSPORINE 100 MG CAPSULE, CYCLOSPORINE 25 MG CAPSULE, CYCLOSPORINE MODIFIED, ENGERIX-B ADULT, ENGERIX-B PEDIATRIC-ADOLESCENT, ENVARSUS XR, EVEROLIMUS 0.25 MG TABLET, EVEROLIMUS 0.5 MG TABLET, EVEROLIMUS 0.75 MG TABLET, EVEROLIMUS 1 MG TABLET, FORMOTEROL FUMARATE, GANCICLOVIR SODIUM, GENGRAF, HEPAGAM B, HEPLISAV-B 20 MCG/0.5 ML SYRNG, HYPERHEP B, IMOVAX RABIES VACCINE, IPRATROPIUM BR 0.02% SOLN, IPRATROPIUM-ALBUTEROL, LEVALBUTEROL CONCENTRATE, LEVALBUTEROL HCL, MYCOPHENOLATE 200 MG/ML SUSP, MYCOPHENOLATE 250 MG CAPSULE, MYCOPHENOLATE 500 MG TABLET, MYCOPHENOLIC ACID, NABI-HB, NUTRILIPID, ONDANSETRON 4 MG/5 ML SOLN CUP, ONDANSETRON 4 MG/5 ML SOLUTION, ONDANSETRON HCL 4 MG TABLET, ONDANSETRON HCL 8 MG TABLET, ONDANSETRON ODT 4 MG TABLET, ONDANSETRON ODT 8 MG TABLET, PENTAMIDINE 300 MG INHAL POWDR, PLENAMINE, PREHEVBRIO, PROGRAF 0.2 MG GRANULE PACKET, PROGRAF 1 MG GRANULE PACKET, RABAVERT, RECOMBIVAX HB, SANDIMMUNE 100 MG/ML SOLN, SIROLIMUS 0.5 MG TABLET, SIROLIMUS 1 MG TABLET, SIROLIMUS 1 MG/ML SOLUTION, SIROLIMUS 2 MG TABLET, TACROLIMUS 0.5 MG CAPSULE (IR), TACROLIMUS 1 MG CAPSULE (IR), TACROLIMUS 5 MG CAPSULE (IR), TOBRAMYCIN 300 MG/5 ML AMPULE, TOBRAMYCIN PAK 300 MG/5 ML, 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.

PEGASYS (S)

MEDICATION(S)
PEGASYS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
N/A

PEMAZYRE (S)

MEDICATION(S)
PEMAZYRE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Cholangiocarcinoma: Diagnosis of cholangiocarcinoma. Disease is one of the following: unresectable locally advanced or metastatic. Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has been previously treated. Myeloid/lymphoid neoplasms: Diagnosis of myeloid/lymphoid neoplasms (MLNs). Disease is relapsed or refractory. Disease has presence of a fibroblast growth factor receptor 1 (FGFR1) rearrangement.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

PENNSAID (S)

MEDICATION(S)
DICLOFENAC 1.5% TOPICAL SOLN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial, reauth: 12 months

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

PHESGO (S)

MEDICATION(S)
PHESGO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

PIQRAY (S)

MEDICATION(S)
PIQRAY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

POLIVY (S)

MEDICATION(S)
POLIVY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diffuse large B-cell lymphoma (DLBCL): Diagnosis of diffuse large B-cell lymphoma (DLBCL). Disease is relapsed or refractory. Used in combination with bendamustine and a rituximab product. Patient has received at least two prior therapies for DLBCL (e.g., RCHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone], HSCT [hematopoietic stem cell transplantation], CAR T [chimeric antigen receptor T-cell] therapy, RCEPP [rituximab, cyclophosphamide, etoposide, prednisone, procarbazine], GemOx [gemcitabine, oxaliplatin] with or without rituximab).

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.

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. Kaposi sarcoma (KS): One of the following: 1) Diagnosis of AIDS-related KS, OR 2) Both of the following: a) Diagnosis of KS and b) Patient is HIV-negative.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

POSACONAZOLE TABLET (S)

MEDICATION(S)
POSACONAZOLE DR 100 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Prophylaxis of systemic fungal infections (SFI): Used as prophylaxis of invasive fungal infections caused by Aspergillus or Candida for one of the following conditions: 1) Patient is at high risk of infections due to severe immunosuppression from hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD) or hematologic malignancies with prolonged neutropenia from chemotherapy OR 2) patient has a prior fungal infection requiring secondary prophylaxis. Treatment (Tx) of SFI: Used as treatment of systemic fungal infections caused by Aspergillus.

AGE RESTRICTION
Prophylaxis of SFI: Patient is 2 years of age or older. Tx of SFI: Patient is 13 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Prophylaxis of SFI: 6 months. Tx of SFI: 3 months.

OTHER CRITERIA
N/A

PRALUENT (S)

MEDICATION(S)
PRALUENT PEN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
HeFH/ASCVD/Primary HLD (init): One of the following dx: A)HeFH as confirmed by one of the following: 1)Both of the following: a)Untreated/pre-treatment LDL greater than 190 mg/dL in an adult, AND b)One of the following: i) Family hx of tendinous xanthomas and/or arcus cornealis in 1st degree relative, or 2nd degree relative, ii)Hx of myocardial infarction (MI) in 1st-degree relative less than 60 years of age, iii)Family hx of MI in 2nd-degree relative less than 50 years of age, iv)Family hx of LDL-C greater than 190 mg/dL in 1st- or 2nd-degree relative, v)Family hx of FH in 1st- or 2nd-degree relative, or 2)Untreated/pre-treatment LDL-C greater than 190 mg/dL in an adult AND 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, B)ASCVD as confirmed by ACS, hx of MI, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA, or peripheral arterial disease presumed to be of atherosclerotic origin, OR C)Primary hyperlipidemia (HLD). HoFH (init): Dx of HoFH as confirmed by one of the following: 1)Gen confirmation of 2 mutations in LDL receptor, ApoB, PCSK9, or LDLRAP1 or ARH, or 2)either untreated LDL greater than 500 or treated LDL greater than 300, AND either xanthoma before 10 yo or evidence of HeFH in both parents. HeFH/ASCVD/Primary HLD (init): One of the following: set A)Both of the following: 1) One of the following: a) One of the following LDL values while on max tolerated lipid lowering regimen w/in the last 120 days: i)LDL greater than or equal to 100 mg/dL w/ASCVD or ii)LDL greater than or equal to 130 mg/dL w/o ASCVD, OR b) Both of the following: i) Patient has been receiving PCSK9 therapy as adjunct to maximally tolerated lipid lowering therapy and ii) LDL-C values drawn within the past 12 months while on maximally tolerated lipid lowering therapy has shown a reduction from baseline, AND Continued in Other Criteria

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 6 months. Reauth: 12 months

OTHER CRITERIA

Set A (cont, initial): 2)One of the following: a)Pt has been receiving at least 12 wks of one high-intensity (HI) statin therapy (tx) and will continue to receive a HI statin [ie, atorvastatin 40-80 mg, rosuvastatin 20-40 mg] at max tolerated dose, OR b) Both of the following: i) 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 ii) One of the following: (1) Pt has been receiving at least 12 wks of one moderate-intensity (MI) or low-intensity (LI) statin tx and will continue to receive a MI or LI statin [ie, atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 10-40 mg, pravastatin 10-80 mg, lovastatin 20-40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1-4 mg] at max tolerated dose, OR (2) 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 c) Pt has a labeled contraindication to all statins, OR d) 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: 1) One of the following LDL values while on max tolerated lipid lowering regimen w/in the last 120 days: a) LDL b/t 55 and 99 mg/dL w/ ASCVD or b) LDL b/t 100 and 129 mg/dL w/o ASCVD, AND 2) Both of the following: a) One of the following: i) Pt has been receiving at least 12 wks of one max-tolerated statin tx and will continue to receive a statin at max tolerated dose, ii) pt is unable to tolerate statin tx as evidenced by intolerable and persistent (ie, more than 2 wks) myalgia (muscle symptoms w/o CK elevations) or myositis (muscle symptoms w/ CK elevations less than 10 times ULN, iii) Patient has a labeled contraindication to all statins, or iv) Pt has experienced rhabdomyolysis or muscle symptoms w/ statin tx w/ CK elevations greater than 10 times ULN on one statin tx and b) Pt has been receiving at least 12 weeks of ezetimibe (Zetia) tx as adjunct to max tolerated statin tx OR Pt has a hx of contraindication or intolerance to ezetimibe. HoFH (init): One of the following: 1)Pt is receiving other lipid-lowering tx (eg statin, ezetimibe) or 2)Pt has a documented inability to take other lipid-lowering tx (eg statin, ezetimibe). HeFH/ASCVD/Primary HLD (reauth): Pt continues to receive other lipid-lowering tx (eg statins, ezetimibe) at max tolerated dose (unless pt has documented inability to take these medications). HoFH (reauth): One of the following: 1)Pt continues to receive other lipid-lowering tx (eg statin, ezetimibe) or 2)Pt has a documented inability to take other lipid-lowering tx (eg statin, ezetimibe). HeFH/ASCVD/Primary HLD/HoFH (reauth): Documentation of LDL reduction while on Praluent therapy.

PROMACTA (S)

MEDICATION(S)
PROMACTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Immune (idiopathic) thrombocytopenic purpura (ITP) (initial): Diagnosis of one of the following: relapsed/refractory ITP, persistent ITP, or chronic ITP. Baseline platelet count is less than 30,000/mcL. Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding. Trial and failure, intolerance, contraindication to corticosteroids (e.g., prednisone, methylprednisolone), immunoglobulins [e.g., Gammagard, immune globulin (human)], or splenectomy. Chronic hepatitis C (initial): Diagnosis of chronic hepatitis C-associated thrombocytpenia. One of the following: 1) Planning to initiate and maintain interferon-based treatment, or 2) currently receiving interferon-based treatment. First-line for severe aplastic anemia (SAA): Diagnosis of SAA. Used for first-line treatment (i.e., patient has not received prior immunosuppressive therapy). Used in combination with standard immunosuppressive therapy (e.g., horse antithymocyte globulin, cyclosporine). 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 (e.g., horse antithymocyte globulin, cyclosporine).

AGE RESTRICTION
N/A

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

COVERAGE DURATION

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

OTHER CRITERIA

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

PROVIGIL (S)

MEDICATION(S)
MODAFINIL 100 MG TABLET, MODAFINIL 200 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

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

PULMOZYME (S)

MEDICATION(S)
PULMOZYME

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
CF (initial, reauth): 12 months

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

PYRUKYND (S)

MEDICATION(S)
PYRUKYND

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of hemolytic anemia confirmed by the presence of chronic hemolysis (e.g., increased indirect bilirubin, elevated lactated dehydrogenase [LDH], decreased haptoglobin, increased reticulocyte count). Diagnosis of pyruvate kinase deficiency confirmed by molecular testing of ALL the following mutations on the PKLR gene: a) Presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least 1 was a missense variant AND b) Patients is not homozygous for the c.1436G to A (p.R479H) variant AND c) Patient does not have 2 non-missense variants (without the presence of another missense variant) in the PKLR gene. Hemoglobin is less than or equal to 10g/dL. Patient has symptomatic anemia or is transfusion dependent. Exclusion of other causes of hemolytic anemias (e. g., infections, toxins, drugs).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Initial, Reauth: Prescribed by or in consultation with a hematologist.

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

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

QINLOCK (S)

MEDICATION(S)
QINLOCK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

QUALAQUIN (S)

MEDICATION(S)
QUININE SULFATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
7 days

OTHER CRITERIA
N/A

RADICAVA ORS (S)

MEDICATION(S)
RADICAVA ORS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial, reauth: 6 months

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

RELYVRIO (S)

MEDICATION(S)
RELYVRIO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of amyotrophic lateral sclerosis (ALS). Diagnosis of ALS is further supported by neurogenic changes in electromyography (EMG). Patient has had ALS symptoms for less than or equal to 18 months. Patient has a percent (%) forced vital capacity (%FVC) or slow vital capacity (%SVC) greater than or equal to 60% at the start of treatment. Patient does not require permanent noninvasive ventilation or invasive ventilation.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial, Reauth: 6 months.

OTHER CRITERIA
Reauth: Documentation of slowed disease progression from baseline.

REMICADE (S)

MEDICATION(S)
INFLIXIMAB, 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. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), methotrexate. Ulcerative colitis (UC) (Initial): Dx of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), aminosalicylate (eg, mesalamine, olsalazine, sulfasalazine). Rheumatoid arthritis (RA) (Initial): Dx of moderately to severely active RA. Used in combination with methotrexate. Psoriatic arthritis (PsA) (Initial): Dx of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (Initial): Dx of chronic severe (ie, extensive and/or disabling) plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), anthralin, OR coal tar.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

CD, FCD, UC (initial): Prescribed by or in consultation with a gastroenterologist. RA, AS (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with rheumatologist or dermatologist. Plaque Psoriasis (initial): Prescribed by or in consultation with a dermatologist. Sarcoidosis (initial): Prescribed by or in consultation with a pulmonologist, dermatologist, or ophthalmologist.

COVERAGE DURATION

All uses (initial): 6 months, (reauth): 12 months

OTHER CRITERIA

Ankylosing spondylitis (AS) (Initial): Dx of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Sarcoidosis (Initial): Dx of sarcoidosis. TF/C/I to both of the following: one immunosuppressant (eg, methotrexate, cyclophosphamide, azathioprine) AND one corticosteroid (eg, prednisone). Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. CD, UC (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline OR reversal of high fecal output state. RA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS (Reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. Sarcoidosis (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. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroids (eg, prednisone), methotrexate. Ulcerative colitis (UC) (initial): Dx of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: corticosteroids (eg, prednisone), aminosalicylate (eg, mesalamine, olsalazine, sulfasalazine), azathioprine, 6-mercaptopurine. Rheumatoid arthritis (RA) (initial): Dx of moderately to severely active RA. Used in combination with methotrexate. Psoriatic arthritis (PsA) (initial): Dx of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (initial): Dx of chronic severe (ie, extensive and/or disabling) plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), anthralin, OR coal tar.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

Initial: RA, AS: Prescribed by or in consultation with a rheumatologist. PsA: Prescribed or in consultation with a rheumatologist or dermatologist. Crohn's Disease, Fistulizing Crohn's Disease, UC: Prescribed by or in consultation with a gastroenterologist. Plaque Psoriasis: Prescribed by or in consultation with a dermatologist. Sarcoidosis (initial): Prescribed by or in consultation with a pulmonologist, dermatologist, or ophthalmologist.

COVERAGE DURATION

All indications (initial): 6 months, (reauth): 12 months

OTHER CRITERIA

Ankylosing spondylitis (AS) (initial): Dx of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Sarcoidosis (initial): Dx of sarcoidosis. TF/C/I to one of the following: corticosteroid (eg, prednisone) OR immunosuppressant (eg, methotrexate, cyclophosphamide, azathioprine). All indications (initial): Trial and failure or intolerance to Remicade or Infliximab. Plaque psoriasis (reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. CD, UC (reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline OR reversal of high fecal output state. RA (reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS (reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. Sarcoidosis (reauth): Documentation of positive clinical response to therapy.

REPATHA (S)

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
HeFH/ASCVD/Primary HLD (init): One of the following dx: A)HeFH as confirmed by one of the following: 1)Both of the following: a)Untreated/pre-treatment LDL greater than 190 mg/dL in an adult, AND b)One of the following: i) Family hx of tendinous xanthomas and/or arcus cornealis in 1st degree relative, or 2nd degree relative, ii)Hx of myocardial infarction (MI) in 1st-degree relative less than 60 years of age, iii)Family hx of MI in 2nd-degree relative less than 50 years of age, iv)Family hx of LDL-C greater than 190 mg/dL in 1st- or 2nd-degree relative, v)Family hx of FH in 1st- or 2nd-degree relative, or 2)Untreated/pre-treatment LDL-C greater than 190 mg/dL in an adult AND 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, B)ASCVD as confirmed by ACS, hx of MI, stable or unstable angina, coronary or other arterial revascularization, stroke,TIA, or peripheral arterial disease presumed to be of atherosclerotic origin, OR C)Primary hyperlipidemia (HLD). HoFH (init): Dx of HoFH as confirmed by one of the following: 1)Gen confirmation of 2 mutations in LDL receptor, ApoB, PCSK9, or LDLRAP1 or ARH, or 2)either untreated LDL greater than 500 or treated LDL greater than 300, AND either xanthoma before 10 yo or evidence of HeFH in both parents. HeFH/ASCVD/Primary HLD (init): One of the following: set A)Both of the following: 1) One of the following: a) One of the following LDL values while on max tolerated lipid lowering regimen w/in the last 120 days: i)LDL greater than or equal to 100 mg/dL w/ASCVD or ii)LDL greater than or equal to 130 mg/dL w/o ASCVD, OR b) Both of the following: i) Patient has been receiving PCSK9 therapy as adjunct to maximally tolerated lipid lowering therapy and ii) LDL-C values drawn within the past 12 months while on maximally tolerated lipid lowering therapy has shown a reduction from baseline, AND Continued in Other Criteria

AGE RESTRICTION
(Initial) HeFH/HoFH: 10 years or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 6 months. Reauth: 12 months

OTHER CRITERIA

Set A (cont, initial): 2) One of the following: a) Pt has been receiving at least 12 wks of one high-intensity (HI) statin therapy (tx) and will continue to receive a HI statin [ie, atorvastatin 40-80 mg, rosuvastatin 20-40 mg] at max tolerated dose, OR b) Both of the following: i) 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 ii) One of the following: (1) Pt has been receiving at least 12 wks of one moderate-intensity (MI) or low-intensity (LI) statin tx and will continue to receive a MI or LI statin [ie, atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 10-40 mg, pravastatin 10-80 mg, lovastatin 20-40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1-4 mg] at max tolerated dose, OR (2) 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 c) Pt has a labeled contraindication to all statins, OR d) 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: 1) One of the following LDL values while on max tolerated lipid lowering tx w/in the last 120 days: a) LDL b/t 55 and 99 mg/dL w/ ASCVD or b) LDL b/t 100 and 129 mg/dL w/o ASCVD, AND 2) Both of the following: a) One of the following: i) Pt has been receiving at least 12 wks of one max-tolerated statin tx and will continue to receive a statin at max tolerated dose, ii) pt is unable to tolerate statin tx as evidenced by intolerable and persistent (ie, more than 2 wks) myalgia (muscle symptoms w/o CK elevations) or myositis (muscle symptoms w/ CK elevations less than 10 times ULN, iii) Patient has a labeled contraindication to all statins, or iv) Pt has experienced rhabdomyolysis or muscle symptoms w/ statin tx w/ CK elevations greater than 10 times ULN on one statin tx and b) Pt has been receiving at least 12 weeks of ezetimibe (Zetia) tx as adjunct to max tolerated statin tx OR Pt has a hx of contraindication or intolerance to ezetimibe. HoFH (init): One of the following: 1)Pt is receiving other lipid-lowering tx (eg statin, ezetimibe) or 2)Pt has a documented inability to take other lipid-lowering tx (eg statin, ezetimibe). HeFH/ASCVD/Primary HLD (reauth): Pt continues to receive other lipid-lowering tx (eg statins, ezetimibe) at max tolerated dose (unless pt has documented inability to take these medications). HoFH (reauth): One of the following: 1)Pt continues to receive other lipid-lowering tx (eg statin, ezetimibe) or 2)Pt has a documented inability to take other lipid-lowering tx (eg statin, ezetimibe). HeFH/ASCVD/Primary HLD/HoFH (reauth): Documentation of LDL reduction while on Repatha tx.

RETACRIT (S)

MEDICATION(S)
RETACRIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

Subject to ESRD review. CKD (Reauth): Dx of CKD. One of the following: 1) Most recent or average (avg) Hct over 3 months is 33% or less (Hgb is 11 g/dL or less) for patients on dialysis, without ESRD, 2) Most recent or avg Hct over 3 mo is 30% or less (Hgb 10 g/dL or less) for patients not on dialysis, OR 3) Most recent or avg Hct over 3 mo is 36% or less (Hgb 12 g/dL or less) for pediatric patients. Documentation of a positive clinical response to therapy 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. Documentation of a positive clinical response to therapy 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. Documentation of a positive clinical response to therapy from pre-treatment level. Patient is receiving chemo. HCV (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Documentation of a positive clinical response to therapy 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. Documentation of a positive clinical response to therapy from pre-treatment level. Other Off-label uses (except MDS, HCV): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%. CKD (init, reauth), HIV (init), Chemo (init), Preop, MDS (init), HCV (init): Verify iron evaluation for adequate iron stores.

RETEVMO (S)

MEDICATION(S)
RETEVMO 40 MG CAPSULE, RETEVMO 80 MG CAPSULE

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: Diagnosis of non-small cell lung cancer (NSCLC). Disease is locally advanced or metastatic. Disease has presence of RET gene fusion-positive tumor(s). Medullary Thyroid Cancer (MTC): Diagnosis of medullary thyroid cancer (MTC). Disease is advanced or metastatic. Disease has presence of RET gene mutation tumor(s). Disease requires treatment with systemic therapy. Thyroid Cancer: Diagnosis of thyroid cancer. Disease is advanced or metastatic. Disease has presence of RET gene fusion-positive tumor(s). Disease requires treatment with systemic therapy. Patient is radioactive iodine-refractory or radioactive iodine therapy is not appropriate. Solid Tumors: Diagnosis of solid tumors. Disease is locally advanced or metastatic. Disease has presence of RET gene fusion-positive tumor(s). ONE of the following: a) Disease has progressed on or following prior systemic treatment (e.g., chemotherapy), OR b) There are no satisfactory alternative treatment options.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Non-Small Cell Lung Cancer, MTC, Thyroid Cancer, Solid Tumors: 12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

REVATIO (S)

MEDICATION(S)
SILDENAFIL 20 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

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

REVCOVI (S)

MEDICATION(S)
REVCOVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

REVLIMID (S)

MEDICATION(S)
LENALIDOMIDE, 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. 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. Follicular Lymphoma (FL): Diagnosis of FL. Marginal Zone Lymphoma (MZL): Diagnosis of MZL.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

REZLIDHIA (S)

MEDICATION(S)
REZLIDHIA

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. Presence of a susceptible isocitrate dehydrogenase-1(IDH1) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

REZUROCK (S)

MEDICATION(S)
REZUROCK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
cGVHD (initial, reauth): 12 months

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

RILUTEK (S)

MEDICATION(S)
RILUZOLE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
ALS: 12 months

OTHER CRITERIA
N/A

RINVOQ (S)

MEDICATION(S)
RINVOQ

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Rheumatoid arthritis (RA) (init): Diagnosis (Dx) of moderately to severely active RA. Minimum (min) duration of a 3-mo trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Psoriatic arthritis (PsA) (init): Dx of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Ankylosing spondylitis (AS) (init): Dx of active AS. Non-radiographic axial spondyloarthritis (NRAS, init): Dx of active NRAS. Pt has signs of inflammation. Pt has had an inadequate response or intolerance to one or more TNF inhibitors (eg, certolizumab pegol). AS, NRAS (init): Min duration of a one-mo TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. RA, PsA, AS (init): Pt has had an inadequate response or intolerance to one or more TNF inhibitors (eg, adalimumab, etanercept). RA, PsA, AS, NRAS (init, reauth): Not used in combination with other JAK inhibitors (JAK-I), biologic DMARDs, or potent immunosuppressants (eg, azathioprine, cyclosporine). Atopic dermatitis (AD) (init): Dx of moderate to severe AD. One of the following: Involvement of at least 10% body surface area (BSA), or SCORing Atopic Dermatitis (SCORAD) index value of at least 25. TF of a min 30-day supply (14-day supply for topical corticosteroids), C/I to at least one of the following: Medium or higher potency topical corticosteroid, Pimecrolimus cream, Tacrolimus oint, or Eucrisa oint. One of the following: 1) TF of a min 12-week supply of at least one systemic drug product for the treatment of AD (ex include, but are not limited to, Adbry, Dupixent, etc.), OR 2) Pt has a C/I, or treatment is inadvisable with both of the following FDA-approved AD therapies: Adbry and Dupixent. Not used in combination with other JAK-I, biologic immunomodulators, or other immunosuppressants (eg, azathioprine, cyclosporine).

AGE RESTRICTION
AD (initial): Patient is 12 years of age or older

PRESCRIBER RESTRICTION

RA, AS, NRAS (init): Prescribed by or in consultation with a rheumatologist. PsA (init): Prescribed by or in consultation with a dermatologist or rheumatologist. AD (init): Prescribed by or in consultation with a dermatologist or allergist/immunologist. CD, UC (init): Prescribed by or in consultation with a gastroenterologist.

COVERAGE DURATION

RA, PsA, AS, NRAS, CD, UC, AD (init): 6 months, (reauth): 12 months.

OTHER CRITERIA

Crohn's disease (CD) (init): Dx of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. TF/C/I to one of the following conventional therapies:6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), methotrexate. Not used in combination with other JAK-I, biological therapies for CD, or potent immunosuppressants (e.g., azathioprine, cyclosporine). Ulcerative colitis (UC) (init): Dx of moderately to severely active UC. One of the following: greater than 6 stools/day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, aminosalicylate (eg, mesalamine, olsalazine, sulfasalazine), azathioprine, or corticosteroids (eg, prednisone). Not used in combination with a potent immunosuppressant (eg, azathioprine, cyclosporine). CD, UC (init): Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, adalimumab). RA (reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS, NRAS (Reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (ESR, CRP level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. AD (reauth): Documentation of a positive clinical response to therapy as evidenced by at least one of the following: a) Reduction in BSA involvement from baseline, or b) Reduction in SCORAD index value from baseline. Not used in combination with other JAK inhibitors, biologic immunomodulators, or other immunosuppressants (eg, azathioprine, cyclosporine). CD, UC (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, ESR, CRP level]) from

baseline OR reversal of high fecal output state. Not used in combination with other JAK inhibitors, biological therapies for CD/UC, or potent immunosuppressants (eg, azathioprine, cyclosporine).

ROLVEDON (S)

MEDICATION(S)
ROLVEDON

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Febrile neutropenia (FN) prophylaxis: Patient will be receiving prophylaxis for FN due to one of the following: 1) Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown, 3) patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN, 4) both of the following: a) patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN, AND b) patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia, OR 5) both of the following: a) patient is receiving myelosuppressive anticancer drugs associated with neutropenia, AND b) patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis).

AGE RESTRICTION
N/A

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

COVERAGE DURATION
FN prophylaxis: 3 mo or duration of tx.

OTHER CRITERIA
FN prophylaxis: Trial and failure or intolerance to one of the following: Neulasta/Neulasta Onpro ANDOR Udenyca.

ROZLYTREK (S)

MEDICATION(S)
ROZLYTREK 100 MG CAPSULE, ROZLYTREK 200 MG CAPSULE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

RUBRACA (S)

MEDICATION(S)
RUBRACA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Ovarian cancer: Diagnosis of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. Prostate cancer: Diagnosis of castration-resistant prostate cancer.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy

RUXIENCE (S)

MEDICATION(S)
RUXIENCE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Non-Hodgkin's Lymphoma (NHL): One of the following: 1) Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma. Used as first-line treatment in combination with chemotherapy, 2) Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma. Patient achieved a complete or partial response to a rituximab product in combination with chemotherapy. Used as monotherapy for maintenance therapy, 3) Diagnosis of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma. One of the following: a) Patient has stable disease following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy or, b) Patient achieved a partial or complete response following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy, 4) Diagnosis of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin's lymphoma, 5) Diagnosis of diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma. Used as first-line treatment in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens, OR 6) Diagnosis of one of the following previously untreated, advanced stage indications: a) CD-20-positive diffuse large B-cell lymphoma, b) Burkitt lymphoma, c) Burkitt-like lymphoma, or d) mature B-cell acute leukemia. Patient is 6 months of age or older. Used in combination with chemotherapy. Chronic Lymphocytic Leukemia (CLL): Diagnosis of chronic lymphocytic leukemia. Used in combination with fludarabine and cyclophosphamide.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
NHL, CLL: Prescribed by or in consultation with a hematologist/oncologist. RA: Prescribed by or in

consultation with a rheumatologist. WG, MPA: Prescribed by or in consultation with a nephrologist, pulmonologist, or rheumatologist.

COVERAGE DURATION

NHL, CLL: 12 months. WG, MPA: 3 months. RA: 1 month.

OTHER CRITERIA

Rheumatoid Arthritis (RA): Diagnosis of moderately to severely active RA. Used in combination with methotrexate. Trial and failure, contraindication, or intolerance (TF/C/I) to a TNF antagonist (eg, adalimumab, etanercept, infliximab). Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA): Diagnosis of WG or MPA. Patient is concurrently on glucocorticoids (eg, prednisone) OR contraindication or intolerance to glucocorticoids (eg, prednisone). All uses: Approve for continuation of prior therapy.

RYBREVANT (S)

MEDICATION(S)
RYBREVANT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of non-small cell lung cancer (NSCLC). Disease is one of the following: a) locally advanced or b) metastatic. Patient's disease has epidermal growth factor receptor (EGFR) exon 20 insertion 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). Disease has progressed on or after platinum-based chemotherapy (e.g., carboplatin, cisplatin).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

RYDAPT (S)

MEDICATION(S)
RYDAPT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

SABRIL (S)

MEDICATION(S)
VIGABATRIN, VIGADRONE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
IS: 1 month to 2 years of age. CPS: 2 years or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

SANDOSTATIN (S)

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, contraindication or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses. Carcinoid tumor (initial): Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea or flushing episodes. Vasoactive intestinal peptide tumor (initial): Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
Acromegaly (reauth): Documentation of positive clinical response to therapy (e.g., reduction or

normalization of IGF-1/GH level for same age and sex, reduction in tumor size). Carcinoid tumor (reauth): Patient has improvement in number of diarrhea or flushing episodes. Vasoactive intestinal peptide tumor (reauth): Patient has improvement in number of diarrhea episodes.

SAPHNELO (S)

MEDICATION(S)
SAPHNELO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Systemic lupus erythematosus (SLE) (initial): Diagnosis of moderate to severe SLE. Currently receiving standard of care treatment for SLE (e.g., antimalarials [e.g., Plaquenil (hydroxychloroquine)], corticosteroids [e.g., prednisone], or immunosuppressants [e.g., methotrexate, Imuran (azathioprine)]).

AGE RESTRICTION
N/A

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

COVERAGE DURATION
SLE (initial, reauth): 6 months.

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

SARCLISA (S)

MEDICATION(S)
SARCLISA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of multiple myeloma. One of the following: 1) Both of the following: a) Patient has received at least two prior treatment regimens which included lenalidomide and a proteasome inhibitor (e.g., bortezomib, carfilzomib), and b) Used in combination with pomalidomide and dexamethasone, OR 2) All of the following: a) Disease is relapsed or refractory, b) Patient has received one to three prior lines of therapy, and c) Used in combination with carfilzomib and dexamethasone.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

SCEMBLIX (S)

MEDICATION(S)
SCEMBLIX 20 MG TABLET, SCEMBLIX 40 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of chronic myelogenous/myeloid leukemia (CML). Disease is Philadelphia chromosome-positive (Ph+). Disease is in chronic phase. One of the following: 1) Patient has been previously treated with two or more alternative tyrosine kinase inhibitors (TKI) [e.g., Bosulif (bosutinib), imatinib, Sprycel (dasatinib), Tasigna (nilotinib), Iclusig (ponatinib)], OR 2) Disease is T315I mutation positive.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

SCIG (S)

MEDICATION(S)
CUTAQUIG, CUVITRU, HIZENTRA 1 GRAM/5 ML SYRINGE, HIZENTRA 1 GRAM/5 ML VIAL, HIZENTRA 10 GRAM/50 ML VIAL, HIZENTRA 2 GRAM/10 ML SYRINGE, HIZENTRA 2 GRAM/10 ML VIAL, HIZENTRA 4 GRAM/20 ML SYRINGE, HIZENTRA 4 GRAM/20 ML VIAL, HYQVIA 10 GM-800 UNIT PACK, HYQVIA 20 GM-1,600 UNIT PACK, HYQVIA 30 GM-2,400 UNIT PACK, HYQVIA 5 GM-400 UNIT PACK, XEMBIFY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION

Initial, reauth: 12 months

OTHER CRITERIA

Subject to Part B vs. Part D review. Patient does not meet criteria for Part B or patient is in a long-term care facility. 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.

SIGNIFOR (S)

MEDICATION(S)
SIGNIFOR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

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

SIGNIFOR LAR (S)

MEDICATION(S)
SIGNIFOR LAR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

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

SKYCLARYS (S)

MEDICATION(S)
SKYCLARYS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of Friedreich's ataxia confirmed via genetic testing demonstrating mutation in the FXN gene. Patient has a Modified Friedreich's Ataxia Rating Scale (mFARS) score of greater than or equal to 20 and less than or equal to 80. Patient has a B-type natriuretic peptide value less than or equal to 200 pg/mL.

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

PRESCRIBER RESTRICTION
Initial: Prescribed by or in consultation with one of the following: Neurologist, Neurogeneticist, or Physiatrist (Physical Medicine and Rehabilitation Specialist).

COVERAGE DURATION
Initial, Reauth: 12 months.

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

SKYRIZI (S)

MEDICATION(S)
SKYRIZI 150 MG/ML SYRINGE, SKYRIZI (2 SYRINGES) KIT, SKYRIZI ON-BODY, SKYRIZI PEN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Psoriatic arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Crohn's disease (CD) (Initial): Diagnosis of moderately to severely active CD. Will be used as a maintenance dose following the intravenous induction doses.

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): 6 months, (reauth): 12 months

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

(swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. CD (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state.

SKYRIZI IV (S)

MEDICATION(S)
SKYRIZI 600 MG/10 ML VIAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Crohn's disease (CD): Diagnosis of moderately to severely active CD. Trial and failure, contraindication, or intolerance to one of the following conventional therapies: 6-mercaptopurine, azathioprine, methotrexate, corticosteroid (eg, prednisone). Will be administered as an intravenous induction dose.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a gastroenterologist.

COVERAGE DURATION
3 months

OTHER CRITERIA
N/A

SKYTROFA (S)

MEDICATION(S)
SKYTROFA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Pediatric Growth Hormone Deficiency (PGHD) (initial): One of the following: A) History of neonatal hypoglycemia associated with pituitary disease, B) Diagnosis of panhypopituitarism, OR C) Both of the following: 1) Diagnosis of PGHD as confirmed by one of the following: a) Height is documented by one of the following (utilizing age and gender growth charts related to height): i) height is greater than 2.0 standard deviations (SD) below midparental height OR ii) height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender), b) Growth velocity is greater than 2 SD below mean for age and gender, or c) Delayed skeletal maturation of greater than 2 SD below mean for age and gender (eg, delayed greater than 2 years compared with chronological age), AND 2) Documentation of one of the following: a) Patient is male with bone age less than 16 years, OR b) Patient is female with bone age less than 14 years. Patient weight is 11.5 kg or greater. Trial and failure or intolerance to Genotropin.

AGE RESTRICTION
PGHD (initial): 1 year of age or older.

PRESCRIBER RESTRICTION
PGHD (initial, reauth): Prescribed by or in consultation with an endocrinologist.

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

OTHER CRITERIA
PGHD (reauth): Both of the following: 1) Expected adult height not attained AND 2) Documentation of

expected adult height goal.

SOMATULINE DEPOT (S)

MEDICATION(S)
SOMATULINE DEPOT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Acromegaly (initial): Prescribed by or in consultation with an endocrinologist. GEP-NETs (initial): Prescribed by or in consultation with an oncologist. Carcinoid syndrome (initial): Prescribed by or in consultation with an endocrinologist or oncologist.

COVERAGE DURATION
All uses: 12 months

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

SOMAVERT (S)

MEDICATION(S)
SOMAVERT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist

COVERAGE DURATION
Initial and reauth: 12 months

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

SPRAVATO (S)

MEDICATION(S)
SPRAVATO 56 MG DOSE PACK, SPRAVATO 84 MG DOSE PACK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
One of the following: A) Both of the following: 1) Diagnosis of major depressive disorder and 2) Patient has not experienced a clinical meaningful improvement after treatment with at least two antidepressants from different classes for an adequate duration (at least 4 weeks each) in the current depressive episode OR B) Both of the following: 1) Diagnosis of major depressive disorder and 2) Patient has both of the following: a) depressive symptoms and b) acute suicidal ideation or behavior. Used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a psychiatrist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

SPRYCEL (S)

MEDICATION(S)
SPRYCEL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
All Uses: 12 months

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

STELARA (IV) (S)

MEDICATION(S)
STELARA 130 MG/26 ML VIAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Crohn's Disease (CD): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine, azathioprine, methotrexate, corticosteroid (eg, prednisone). Ulcerative Colitis (UC): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), or an aminosalicylate [eg, mesalamine, olsalazine, sulfasalazine].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a gastroenterologist.

COVERAGE DURATION
One time

OTHER CRITERIA
Stelara is to be administered as an intravenous induction dose. Stelara induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for Crohn's

Disease/ulcerative colitis: 260 mg for patients weighing 55 kg or less, 390 mg for patients weighing more than 55 kg to 85 kg, or 520 mg for patients weighing more than 85 kg.

STELARA (S)

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Plaque psoriasis (Initial - 45mg/0.5mL): Diagnosis of moderate to severe plaque psoriasis. Plaque psoriasis (Initial - 90mg/1mL): Diagnosis of moderate to severe plaque psoriasis. Patient's weight is greater than 100 kg (220 lbs). Plaque psoriasis (Initial): One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Psoriatic arthritis (PsA) (Initial - 45mg/0.5mL): Diagnosis of active PsA. PsA (Initial - 90mg/1mL): Diagnosis of active PsA. Patient's weight is greater than 100 kg (220 lbs). Diagnosis of co-existent moderate to severe psoriasis. PsA (Initial): One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Crohn's disease (CD) (Initial): Diagnosis of moderately to severely active Crohns disease. Will be used as a maintenance dose following the intravenous induction dose.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
All uses (Initial): 6 months. All uses (reauth): 12 months

OTHER CRITERIA

Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. Will be used as a maintenance dose following the intravenous induction dose. PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. CD (Reauth), UC (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state.

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): Diagnosis of mCRC. Gastrointestinal stromal tumor (GIST): Diagnosis of locally advanced, unresectable or metastatic GIST. Hepatocellular Carcinoma (HCC): Diagnosis of HCC.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

STRENSIQ (S)

MEDICATION(S)
STRENSIQ

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Hypophosphatasia: 12 months

OTHER CRITERIA
N/A

SUPPRELIN LA (S)

MEDICATION(S)
SUPPRELIN LA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
CPP (init, reauth): 12 months

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

SUTENT (S)

MEDICATION(S)
SUNITINIB MALATE

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
N/A

COVERAGE DURATION
All uses: 12 months

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

SYMDEKO (S)

MEDICATION(S)
SYMDEKO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

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

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

COVERAGE DURATION
12 months

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

SYMLIN (S)

MEDICATION(S)
SYMLINPEN 120, SYMLINPEN 60

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

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

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.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

SYPRINE (S)

MEDICATION(S)
TRIENTINE HCL 250 MG CAPSULE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

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

TABRECTA (S)

MEDICATION(S)
TABRECTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

TAFAMIDIS (S)

MEDICATION(S)
VYNDAMAX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

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

TAFINLAR (S)

MEDICATION(S)
TAFINLAR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
Solid tumors, Low-grade glioma: Patient is 1 year of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

12 months

OTHER CRITERIA

Approve for continuation of prior therapy. Solid tumors: Diagnosis of solid tumors. Disease is unresectable or metastatic. Patient has progressed on or following prior treatment and have no satisfactory alternative treatment options. 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). Medication is used in combination with Mekinist (trametinib). Low-grade Glioma: Diagnosis of low-grade glioma. Patient requires systemic therapy. 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). Medication is used in combination with Mekinist (trametinib).

TAGRISSO (S)

MEDICATION(S)
TAGRISSO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA

Approve for continuation of prior therapy.

TALZENNA (S)

MEDICATION(S)
TALZENNA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Breast cancer: Diagnosis of breast cancer. Prostate cancer: Diagnosis of metastatic castration-resistant prostate cancer (mCRPC). Disease is homologous recombination repair (HRR) gene-mutated. Taken in combination with Xtandi (enzalutamide).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

TARCEVA (S)

MEDICATION(S)
ERLOTINIB HCL 100 MG TABLET, ERLOTINIB HCL 150 MG TABLET, ERLOTINIB HCL 25 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Non-small cell lung cancer (NSCLC): Diagnosis of 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
N/A

COVERAGE DURATION
All uses: 12 months

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

TARGRETIN (S)

MEDICATION(S)
BEXAROTENE

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
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

TARPEYO (S)

MEDICATION(S)
TARPEYO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of primary immunoglobulin A nephropathy (IgAN). Patient is at risk of rapid disease progression. Used to reduce proteinuria. Estimated glomerular filtration rate (eGFR) greater than or equal to 35 mL/min/1.73 m2. One of the following: 1) Patient has been on a minimum 90-day trial of a maximally tolerated dose and will continue to receive therapy with one of the following: a) an angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril), or b) an angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan), OR 2) Patient has a contraindication or intolerance to both ACE inhibitors and ARBs. Trial and failure, contraindication, or intolerance to another glucocorticoid (e.g., methylprednisolone, prednisone).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a nephrologist.

COVERAGE DURATION
9 months.

OTHER CRITERIA
N/A

TASIGNA (S)

MEDICATION(S)
TASIGNA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

TAVALISSE (S)

MEDICATION(S)
TAVALISSE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
ITP (initial, reauth): 12 months

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

TAVNEOS (S)

MEDICATION(S)
TAVNEOS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of one of the following types of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis: a) Granulomatosis with polyangiitis (GPA) OR b) Microscopic polyangiitis (MPA). Diagnosis is confirmed by one of the following: a) ANCA test positive for proteinase 3 (PR3) antigen, b) ANCA test positive for myeloperoxidase (MPO) antigen, OR c) Tissue biopsy. Patient is receiving concurrent immunosuppressant therapy with one of the following: a) cyclophosphamide OR b) rituximab. One of the following: a) Patient is concurrently on glucocorticoids (e.g., prednisone) OR b) History of contraindication or intolerance to glucocorticoids (e.g., prednisone).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Initial, Reauth: Prescribed by or in consultation with a nephrologist, pulmonologist, or rheumatologist

COVERAGE DURATION
Initial, Reauth: 12 months

OTHER CRITERIA
Reauth: Patient does not show evidence of progressive disease while on therapy. Patient is receiving concurrent immunosuppressant therapy (e.g., azathioprine, cyclophosphamide, methotrexate, rituximab).

TAZVERIK (S)

MEDICATION(S)
TAZVERIK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

TECFIDERA (S)

MEDICATION(S)
DIMETHYL FUMARATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.

REQUIRED MEDICAL INFORMATION
MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions).

AGE RESTRICTION
N/A

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

COVERAGE DURATION
MS (initial, reauth): 12 months

OTHER CRITERIA
MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).

TEGSEDI (S)

MEDICATION(S)
TEGSEDI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

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

TEPMETKO (S)

MEDICATION(S)
TEPMETKO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is metastatic. Presence of mesenchymal-epithelial transition (MET) exon 14 skipping alterations.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

TERIPARATIDE (S)

MEDICATION(S)
FORTEO, TERIPARATIDE 620 MCG/2.48 ML

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

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

OTHER CRITERIA

Glucocorticoid-Induced Osteoporosis (initial): Diagnosis of glucocorticoid-induced osteoporosis. History of prednisone or its equivalent at a dose greater than or equal to 5mg/day for greater than or equal to 3 months. One of the following: 1) BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site), or 2) One of the following FRAX 10-year probabilities: a) Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions, or b) Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions, 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, or 4) either glucocorticoid dosing of at least 30 mg per day or cumulative glucocorticoid dosing of at least 5 grams per year. TF/C/I to one bisphosphonate (e.g., alendronate). All uses (initial, reauth): One of the following: 1) Treatment duration of parathyroid hormones [e.g., teriparatide, Tymlos (abaloparatide)] has not exceeded a total of 24 months during the patient's lifetime, or 2) Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones [e.g., teriparatide, Tymlos (abaloparatide)].

TESTOSTERONE (S)

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than 300 ng/dL (10.4 nmol/L) or less than the reference range for the lab, OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome), OR 4) Both of the following: a) Patient is continuing testosterone therapy, and b) One of the following: i) Follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is within or below the normal limits of the reporting lab, or ii) follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted. Gender Dysphoria (GD)/Gender Incongruence (off-label): Dx of GD/Gender Incongruence.

AGE RESTRICTION
Testosterone cypionate only: HG (init): 12 years of age or older. All other testosterone: HG (init): Patient is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

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

TESTOSTERONE ENANTHATE (S)

MEDICATION(S)
TESTOSTERONE ENANTHATE

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), OR 4) Both of the following: a) Patient is continuing testosterone therapy, and b) One of the following: i) Follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is within or below the normal limits of the reporting lab, or ii) follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted. Delayed puberty (DP): Dx of DP AND male patient at birth. Breast cancer (BC): Dx of inoperable BC AND used for palliative treatment AND female patient at birth. Gender Dysphoria (GD)/Gender Incongruence (off-label): Dx of GD/Gender Incongruence.

AGE RESTRICTION
HG (init): Patient is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

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

OTHER CRITERIA

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

TEZSPIRE (S)

MEDICATION(S)
TEZSPIRE 210 MG/1.91 ML SYRING

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of severe asthma. Patient has a history of one of the following within the past 12 months: 1) Two or more asthma exacerbations requiring systemic corticosteroid (e.g., prednisone) treatment OR 2) Prior asthma-related hospitalization. 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) (i.e., greater than 500 mcg fluticasone propionate equivalent/day) and ii) Additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium), OR b) One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Symbicort [budesonide/formoterol], Breo Ellipta [fluticasone/vilanterol]). One of the following: 1) Medication will not be used to treat eosinophilic asthma OR 2) Both of the following: a) Medication will be used to treat eosinophilic asthma AND b) Trial and failure, contraindication, or intolerance to one of the following: Nucala (mepolizumab), Fasenra (benralizumab), Cinqair (reslizumab), Dupixent (dupilumab). One of the following: 1) Medication will not be used to treat oral corticosteroid-dependent asthma OR 2) Both of the following: a) Medication will be used to treat oral corticosteroid-dependent asthma AND b) Trial and failure, contraindication, or intolerance to Dupixent (dupilumab). One of the following: 1) Medication will not be used to treat persistent allergic asthma OR 2) Both of the following: a) Medication will be used to treat persistent allergic asthma AND b) Trial and failure, contraindication, or intolerance to Xolair (omalizumab).

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

PRESCRIBER RESTRICTION

Initial, Reauth: Prescribed by or in consultation with a pulmonologist or allergist/immunologist

COVERAGE DURATION

Initial: 6 months. Reauth: 12 months

OTHER CRITERIA

Reauth: Documentation of positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1]). Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications.

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
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

TIBSOVO (S)

MEDICATION(S)
TIBSOVO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

TIVDAK (S)

MEDICATION(S)
TIVDAK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of cervical cancer. Disease is one of the following: a) recurrent or b) metastatic. Disease has progressed on or after 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.

TOPICAL RETINOID (S)

MEDICATION(S)
TRETINOIN 0.025% CREAM, TRETINOIN 0.05% CREAM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Acne vulgaris: Diagnosis of acne vulgaris (i.e., acne).

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

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

TRACLEER (S)

MEDICATION(S)
BOSENTAN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

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

TRAZIMERA (S)

MEDICATION(S)
TRAZIMERA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

TRELSTAR (S)

MEDICATION(S)
TRELSTAR 11.25 MG VIAL, TRELSTAR 22.5 MG VIAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Prostate Cancer: Diagnosis of advanced or metastatic prostate cancer. Trial and failure, contraindication, or intolerance to any brand Lupron formulation.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

TRIKAFTA (S)

MEDICATION(S)
TRIKAFTA 100-50-75 MG/150 MG, TRIKAFTA 50-25-37.5 MG/75 MG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
CF (initial): For granule packets: patient is at least 2 to less than 6 years of age. For tablets: patient is 6 years of age or older.

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

COVERAGE DURATION
CF (initial, reauth): 12 months

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

TRIPTODUR (S)

MEDICATION(S)
TRIPTODUR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
CPP (Initial, reauth): 12 months

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

TRODELVY (S)

MEDICATION(S)
TRODELVY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Triple Negative Breast Cancer (TNBC): Diagnosis of TNBC. Disease is one of the following: a) unresectable locally advanced or b) metastatic. Patient has received at least two prior therapies for at least one of which is for metastatic disease (e.g., carboplatin, cisplatin, gemcitabine, paclitaxel, docetaxel, capecitabine, etc.). Breast Cancer (BC): Diagnosis of BC. Disease is one of the following: a) unresectable locally advanced, or b) metastatic. Disease is hormone receptor (HR)-positive. Disease is human epidermal growth factor receptor 2 (HER2)-negative. Both of the following: a) patient has received endocrine-based therapy (e.g., tamoxifen, aromatase inhibitors [e.g., Aromasin (exemestane), Femara (letrozole), Arimidex (anastrozole)], fulvestrant), and b) patient has received at least two additional systemic therapies in the metastatic setting (e.g., chemotherapy, poly-ADP ribose polymerase (PARP) inhibitor [e.g., olaparib, talazoparib], fam-trastuzumab deruxtecan-nxki). Urothelial Cancer: Diagnosis of urothelial cancer. Disease is one of the following: a) locally advanced or b) metastatic. Patient has previously received both of the following: 1) Platinum-containing chemotherapy (e.g., cisplatin, carboplatin) AND 2) One of the following: a) programmed death receptor-1 (PD-1) inhibitor [e.g., Keytruda (pembrolizumab)], or b) programmed death-ligand 1 (PD-L1) inhibitor [e.g., Bavencio (avelumab)].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist.

COVERAGE DURATION

12 months

OTHER CRITERIA

Approve for continuation of prior therapy.

TRUSELTIQ (S)

MEDICATION(S)
TRUSELTIQ

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

TUKYSA (S)

MEDICATION(S)
TUKYSA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Breast cancer: Diagnosis of breast cancer. Disease is one of the following: a) advanced unresectable or b) metastatic. Disease is human epidermal growth factor receptor 2 (HER2)-positive. Used in combination with trastuzumab and capecitabine. Patient has received one or more prior anti-HER2 based regimens (e.g., trastuzumab, pertuzumab, ado-trastuzumab emtansine). Colorectal cancer: Diagnosis of colorectal cancer. Disease is one of the following: a) unresectable or b) metastatic. Disease is HER2-positive. Patient has RAS wild-type tumors. Used in combination with trastuzumab. Patient has progressed following treatment with one of the following: a) fluoropyrimidine-based chemotherapy, b) oxaliplatin-based chemotherapy, c) irinotecan-based chemotherapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

TURALIO (S)

MEDICATION(S)
TURALIO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

TYKERB (S)

MEDICATION(S)
LAPATINIB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

TYMLOS (S)

MEDICATION(S)
TYMLOS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

24 months (max 24 months of therapy per lifetime)

OTHER CRITERIA

N/A

TYSABRI (S)

MEDICATION(S)
TYSABRI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Multiple Sclerosis (MS) (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following disease-modifying therapies for MS: A) Aubagio (teriflunomide), B) Lemtrada (alemtuzumab), C) Mavenclad (cladribine), D) Plegridy (peginterferon beta-1a), E) Any one of the inteferon beta-1a injections (eg, Avonex), F) Any one of the interferon beta-1b injections (eg, Betaseron, Extavia), G) Any one of the glatiramer acetate injections (eg, Copaxone, Glatopa, generic glatiramer acetate), H) Any one of the oral fumarates (eg, brand Tecfidera, generic dimethyl fumarate), I) Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (eg, Gilenya, Mayzent, Zeposia), J) Any one of the B-cell targeted therapies (eg, Ocrevus, Kesimpta), 2) Patient is not a candidate for any of the drugs listed as prerequisites due to the severity of their MS, or 3) for continuation of prior therapy. MS (init, reauth): Not used in combination with another disease-modifying therapy for MS. Crohn's Disease (CD) (initial): Diagnosis of moderately to severely active CD with evidence of inflammation (eg, elevated C-reactive protein [CRP], elevated erythrocyte sedimentation rate, presence of fecal leukocytes). TF/C/I to one of the following conventional therapies: corticosteroids (eg, prednisone, methylprednisolone), 6-mercaptopurine (6MP [Purinethol], azathioprine (Imuran), methotrexate (Rheumatrex, Trexall), aminosalicylates (eg, sulfasalazine, mesalamine, olsalazine). TF/C/I to a TNF-inhibitor (eg, Humira [adalimumab], infliximab). CD (initial and reauth): Not used in combination with an immunosuppressant (eg, 6-MP, azathioprine, cyclosporine, or methotrexate). Not used in combination with a TNF-inhibitor (eg, Enbrel [etanercept], Humira [adalimumab], or infliximab).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

MS (init, reauth): Prescribed by or in consultation with a neurologist. CD (initial): Prescribed by or in consultation with a gastroenterologist.

COVERAGE DURATION

MS (init, reauth): 12mo. CD (Init): 3 mo. CD (Reauth): 6 mo if not on steroids. Otherwise, 3 mo.

OTHER CRITERIA

MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression). CD (reauth): Documentation of positive clinical response (eg, improved disease activity index) to therapy.

UBRELVY (S)

MEDICATION(S)
UBRELVY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of migraine with or without aura. Will be used for the acute treatment of migraine. Trial and failure or intolerance to one triptan (e.g., eletriptan, rizatriptan, sumatriptan) or a contraindication to all triptans. Medication will not be used in combination with another oral CGRP inhibitor.

AGE RESTRICTION
Initial: 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
Reauth: Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea). Will not be used for preventive treatment of migraine. Medication will not be used in combination with another oral CGRP inhibitor.

UDENYCA (S)

MEDICATION(S)
UDENYCA, UDENYCA AUTOINJECTOR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA

N/A

VABYSMO (S)

MEDICATION(S)
VABYSMO 6 MG/0.05 ML VIAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: 1) One of the following diagnoses: A) neovascular (wet) age-related macular degeneration (nAMD) OR B) diabetic macular edema (DME). 2) Trial and failure, contraindication, or intolerance to compounded bevacizumab prepared by a 503(B) Outsourcing Facility OR Lucentis (ranibizumab).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Initial: Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases.

COVERAGE DURATION
Initial, Reauth: 12 months

OTHER CRITERIA
Reauth: Documentation of positive clinical response to therapy (e.g., Improvement in Best Corrected Visual Acuity (BCVA) compared to baseline, stable vision).

VALCHLOR (S)

MEDICATION(S)
VALCHLOR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

VANFLYTA (S)

MEDICATION(S)
VANFLYTA

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. Patient has a FMS-like tyrosine kinase 3 (FLT3) internal tandem duplication (FLT3-ITD) mutation 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). Both of the following: a) Used in combination with standard cytarabine and anthracycline (e.g., daunorubicin, idarubicin) induction and cytarabine consolidation, and b) Used as maintenance monotherapy following consolidation chemotherapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

VARIZIG (S)

MEDICATION(S)
VARIZIG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 months (approve one dose only)

OTHER CRITERIA
N/A

VENCLEXTA (S)

MEDICATION(S)
VENCLEXTA, VENCLEXTA STARTING PACK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL): Diagnosis of CLL or SLL. Acute Myeloid Leukemia (AML): Diagnosis of newly diagnosed AML. Used in combination with azacitidine, or decitabine, or low-dose cytarabine. One of the following: 1) age 75 years or older OR 2) comorbidities that preclude use of intensive induction chemotherapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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.

VERQUVO (S)

MEDICATION(S)
VERQUVO

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 an ejection fraction less than 45 percent. Patient has New York Heart Association (NYHA) Class II, III, or IV symptoms. One of the following: A) Patient was hospitalized for heart failure within the last 6 months, or B) Patient used outpatient intravenous diuretics (e.g., bumetanide, furosemide) for heart failure within the last 3 months. Trial and failure, contraindication, or intolerance to two of the following at a maximally tolerated dose: A) One of the following: 1) Angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril), 2) Angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan), or 3) Angiotensin receptor-neprilysin inhibitor (ARNI) [e.g., Entresto (sacubitril and valsartan)], B) One of the following: 1) bisoprolol, 2) carvedilol, or 3) metoprolol succinate extended release, C) Sodium-glucose co-transporter 2 (SGLT2) inhibitor [e.g., Jardiance (empagliflozin), Farxiga (dapagliflozin), Xigduo XR (dapagliflozin and metformin)], or D) Mineralocorticoid receptor antagonist (MRA) [e.g., eplerenone, spironolactone].

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 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 breast cancer.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

VIJOICE (S)

MEDICATION(S)
VIJOICE 125 MG TABLET, VIJOICE 250 MG DAILY DOSE PACK, VIJOICE 50 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of PIK3CA-related overgrowth spectrum (PROS). Documentation of mutation in the PIK3CA gene. Documentation of severe clinical manifestations (e.g., congenital lipomatous overgrowth, vascular malformations, epidermal nevi, scoliosis/skeletal and spinal [CLOVES], facial infiltrating lipomatosis [FIL], klippel-trenaunay syndrome [KTS], megalencephaly-capillary malformation polymicrogyria [MCAP]).

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

PRESCRIBER RESTRICTION
Initial, Reauth: Prescribed by or in consultation with a physician who specializes in the treatment of PROS.

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

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

VIMIZIM (S)

MEDICATION(S)
VIMIZIM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial, reauth: 12 months

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

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
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

VIZIMPRO (S)

MEDICATION(S)
VIZIMPRO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is metastatic. Disease is positive for one of the following epidermal growth factor receptor (EGFR) mutations: exon 19 deletion or exon 21 L858R substitution.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

VONJO (S)

MEDICATION(S)
VONJO

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) Primary myelofibrosis, b) Post-polycythemia vera myelofibrosis, OR c) Post-essential thrombocythemia myelofibrosis. Disease is intermediate or high risk. Pre-treatment platelet count below 50 x 10^9/L.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

VOQUEZNA (S)

MEDICATION(S)
VOQUEZNA DUAL PAK, VOQUEZNA TRIPLE PAK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of Helicobacter pylori infection. Trial and failure, contraindication, or intolerance to ONE of the following first line treatment regimens: a) Clarithromycin based therapy (e.g., clarithromycin based triple therapy, clarithromycin based concomitant therapy), or b) Bismuth quadruple therapy (e.g., bismuth and metronidazole and tetracycline and proton pump inhibitor [PPI]).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 month

OTHER CRITERIA
N/A

VORICONAZOLE INJECTION (S)

MEDICATION(S)
VORICONAZOLE 200 MG VIAL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Invasive aspergillosis: Diagnosis of invasive aspergillosis (IA). Candidemia: Diagnosis of candidemia. One of the following: (1) patient is non-neutropenic or (2) infection is located in skin, abdomen, kidney, bladder wall, or wounds. Esophageal Candidiasis: Diagnosis of esophageal candidiasis. Mycosis: Diagnosis of fungal infection caused by Scedosporium apiospermum (asexual form of Pseudallescheria boydii) or Fusarium spp. including Fusarium solani. For fusariosis: Patient is intolerant of, or refractory to, other therapy (e.g., liposomal amphotericin B, amphotericin B lipid complex).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 weeks

OTHER CRITERIA
N/A

VOSEVI (S)

MEDICATION(S)
VOSEVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria will be applied consistent with current AASLD/IDSA guideline. All patients: Diagnosis of chronic hepatitis C, patient is without decompensated liver disease (defined as Child-Pugh Class B or C), and not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni, Zepatier].

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
N/A

VOTRIENT (S)

MEDICATION(S)
VOTRIENT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Renal cell carcinoma (RCC): Diagnosis of advanced/metastatic RCC. Soft tissue sarcoma: Diagnosis of advanced soft tissue sarcoma.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

VOXZOGO (S)

MEDICATION(S)
VOXZOGO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Patient has open epiphyses. Diagnosis of achondroplasia as confirmed by one of the following: 1) Both of the following: a) Patient has clinical manifestations characteristic of achondroplasia (e.g., macrocephaly, frontal bossing, midface retrusion, disproportionate short stature with rhizomelic shortening of the arms and the legs, brachydactyly, trident configuration of the hands, thoracolumbar kyphosis, and accentuated lumbar lordosis) and b) Patient has radiographic findings characteristic of achondroplasia (e.g., large calvaria and narrowing of the foramen magnum region, undertubulated, shortened long bones with metaphyseal abnormalities, narrowing of the interpedicular distance of the caudal spine, square ilia and horizontal acetabula, small sacrosciatic notches, proximal scooping of the femoral metaphyses, and short and narrow chest), OR 2) Molecular genetic testing confirmed c.1138G to A or c.1138G to C variant (i.e., p.Gly380Arg mutation) in the fibroblast growth factor receptor-3 (FGFR3) gene. Patient did not have limb-lengthening surgery in the previous 18 months and does not plan on having limb-lengthening surgery while on Voxzogo therapy.

AGE RESTRICTION
Initial: Patient is 5 years of age or older.

PRESCRIBER RESTRICTION
Initial, Reauth: Prescribed by or in consultation with a clinical geneticist, endocrinologist, or a physician who has specialized expertise in the management of achondroplasia.

COVERAGE DURATION
Initial, Reauth: 12 months.

OTHER CRITERIA

Reauth: Patient continues to have open epiphyses. Documentation of a positive clinical response to therapy as evidenced by one of the following: 1) Improvement in annualized growth velocity (AGV) compared to baseline, OR 2) Improvement in height Z-score compared to baseline.

VUMERITY (S)

MEDICATION(S)
VUMERITY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
MS (initial, reauth): 12 months

OTHER CRITERIA
MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).

VYJUVEK (S)

MEDICATION(S)
VYJUVEK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of dystrophic epidermolysis bullosa (DEB). Patient has mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene. Medication is being used for the treatment of wounds. Medication will be applied by a healthcare professional. Wound(s) being treated meet all of the following criteria: a) adequate granulation tissue, b) excellent vascularization, c) no evidence of active wound infection in the wound being treated, and d) no evidence or history of squamous cell carcinoma in the wound being treated.

AGE RESTRICTION
Initial: Patient is 6 months of age or older.

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

COVERAGE DURATION
Initial, Reauth: 6 months

OTHER CRITERIA
Reauth: Documentation of positive clinical response to therapy. Wound(s) being treated meet all of the following criteria: a) adequate granulation tissue, b) excellent vascularization, c) no evidence of active wound infection in the wound being treated, and d) no evidence or history of squamous cell carcinoma in the wound being treated.

VYVGART (S)

MEDICATION(S)
VYVGART, VYVGART HYTRULO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of generalized myasthenia gravis (gMG). Patient is anti-acetylcholine receptor (AChR) antibody positive. Prior to administration, patient must be on a stable dose of at least ONE of the following therapies for the treatment of gMG: a) acetylcholinesterase (AChE) inhibitors (e.g., pyridostigmine), b) steroids (e.g., prednisone), or c) non-steroidal immunosuppressive therapies (NSISTs) (e.g., azathioprine, cyclosporine, cyclophosphamide). One of the following: a) Prescribed medication will be administered at 10mg/kg as an intravenous infusion over one hour once weekly for 4 weeks OR b) In patients weighing 120 kg or more, prescribed medication will be administered at 1200mg per infusion over one hour once weekly for 4 weeks.

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
Reauth: Documentation of positive clinical response to therapy. One of the following: a) Prescribed medication will be administered at 10mg/kg as an intravenous infusion over one hour once weekly for 4 weeks OR b) In patients weighing 120 kg or more, prescribed medication will be administered at 1200mg per infusion over one hour once weekly for 4 weeks.

WELIREG (S)

MEDICATION(S)
WELIREG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

XALKORI (S)

MEDICATION(S)
XALKORI 200 MG CAPSULE, XALKORI 250 MG CAPSULE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Non-small cell lung cancer (NSCLC): Diagnosis of advanced or metastatic NSCLC AND One of the following: A) Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) or B) Patient has MET amplification- or ROS1 rearrangement-positive tumor as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Anaplastic Large Cell Lymphoma (ALCL): Diagnosis of systemic ALCL. Disease is relapsed or refractory. Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Inflammatory Myofibroblastic Tumor (IMT): Diagnosis of IMT. Disease is one of the following: a) unresectable, b) recurrent, or c) refractory. Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).

AGE RESTRICTION
IMT: Patient is 1 year of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA

Approve for continuation of prior therapy.

XCOPRI (S)

MEDICATION(S)
XCOPRI 100 MG TABLET, XCOPRI 12.5-25 MG TITRATION PK, XCOPRI 150 MG TABLET, XCOPRI 150-200 MG TITRATION PK, XCOPRI 200 MG TABLET, XCOPRI 250 MG DAILY DOSE PACK, XCOPRI 350 MG DAILY DOSE PACK, XCOPRI 50 MG TABLET, XCOPRI 50-100 MG TITRATION PAK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of partial onset seizures.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

XELJANZ (S)

MEDICATION(S)
XELJANZ, XELJANZ XR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Xeljanz tab/Xeljanz XR tab: Rheumatoid arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Psoriatic arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Ankylosing spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses. RA, PsA, AS (Initial): Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, adalimumab, etanercept). Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine), azathioprine, or corticosteroids (eg, prednisone). Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, adalimumab). Not used in combination with other Janus kinase (JAK) inhibitors, biological therapies for UC, or potent immunosuppressants (e.g., azathioprine, cyclosporine).

AGE RESTRICTION
N/A

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

consultation with a gastroenterologist.

COVERAGE DURATION

RA/PJIA/PsA/AS (initial): 6 mo, (reauth): 12 months. UC (init): 4 mo. UC (reauth): 12 mo.

OTHER CRITERIA

Xeljanz: Polyarticular course juvenile idiopathic arthritis (PJIA) (Initial): Diagnosis of active polyarticular course juvenile idiopathic arthritis. Minimum duration of a 6-week TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, adalimumab, etanercept). RA, PsA, AS, PJIA (Initial): Not used in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or potent immunosuppressants (eg, azathioprine, cyclosporine). RA, PJIA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS (Reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. RA, PsA, AS, PJIA (reauth): Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (eg, azathioprine, cyclosporine). UC (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline OR reversal of high fecal output state. Not used in combination with other JAK inhibitors, biological therapies for UC, or potent immunosuppressants (e.g., azathioprine, cyclosporine).

XENAZINE (S)

MEDICATION(S)
TETRABENAZINE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

XENPOZYME (S)

MEDICATION(S)
XENPOZYME

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial: Diagnosis of acid sphingomyelinase deficiency (ASMD). Disease confirmed by ONE of the following: a) Molecular genetic testing confirms biallelic pathogenic variants in the SMPD1 (sphingomyelin phophodiesterase-1) gene OR b) Residual acid sphingomyelinase activity that is less than 10% of controls (in peripheral blood lymphocytes or cultured skin fibroblasts). Patient has non-central nervous system manifestations of ASMD.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Initial: Prescribed by or in consultation with a metabolic disease specialist or geneticist.

COVERAGE DURATION
Initial, Reauth: 12 months.

OTHER CRITERIA
Reauth: Documentation of positive clinical response to therapy (e.g., decrease in spleen size, decrease in liver size, increase in platelet count, improved lung function).

XERMELO (S)

MEDICATION(S)
XERMELO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial: 6 months. Reauth: 12 months

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

XGEVA (S)

MEDICATION(S)
XGEVA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
GCTB: Approve for continuation of prior therapy.

XIFAXAN (S)

MEDICATION(S)
XIFAXAN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Travelers' diarrhea (TD) (200 mg strength only): Diagnosis of travelers' diarrhea, AND one of the following: a) Trial and failure, contraindication, or intolerance to one of the following: Cipro (ciprofloxacin), Levaquin (levofloxacin), ofloxacin, Zithromax (azithromycin) OR b) resistance to all of the following: Cipro (ciprofloxacin), Levaquin (levofloxacin), ofloxacin, Zithromax (azithromycin). Prophylaxis of hepatic encephalopathy (HE) recurrence (550mg strength only): Used for the prophylaxis of hepatic encephalopathy recurrence, AND trial and failure, contraindication or intolerance to lactulose. Treatment of HE: Used for the treatment of HE. Trial and failure, contraindication, or intolerance to lactulose. Irritable bowel syndrome with diarrhea (IBS-D) (550mg strength only) (initial): Diagnosis of IBS-D, AND trial and failure, contraindication or intolerance to an antidiarrheal agent [eg, loperamide].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

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

XOLAIR (S)

MEDICATION(S)
XOLAIR 150 MG/1.2 ML POWDER VL, XOLAIR 150 MG/ML SYRINGE, XOLAIR 75 MG/0.5 ML SYRINGE

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 [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium), OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone/vilanterol)]. Chronic Spontaneous Urticaria (CSU) (init): Diagnosis of CSU. Persistent symptoms (itching and hives) with a second generation H1 antihistamine (e.g., cetirizine, fexofenadine), unless there is a contraindication or intolerance to H1 antihistamines. Patient has tried and had an inadequate response or intolerance or contraindication to at least one of the following additional therapies: H2 antagonist (e.g., famotidine, cimetidine), leukotriene receptor antagonist (e.g., montelukast), H1 antihistamine, hydroxyzine, doxepin. Used concurrently with an H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamines. Chronic Rhinosinusitis with Nasal polyps (CRSwNP) (init): Diagnosis of CRSwNP. Unless contraindicated, the patient has had an inadequate response to an intranasal corticosteroid (e.g., fluticasone, mometasone). Used in combination with another agent for chronic rhinosinusitis with nasal polyps.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

Asthma, init: 6 mo, reauth: 12 mo. CSU, init: 3 mo, reauth: 6 mo. CRSwNP, init/reauth: 12 mo.

OTHER CRITERIA

Asthma (reauth): Documentation of positive clinical response to therapy (e.g., Reduction in asthma exacerbations, improvement in forced expiratory volume in 1 second (FEV1), decreased use of rescue medications). Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications. CSU (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. CRSwNP (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS: 0-8 scale], improvement in nasal congestion/obstruction score [NCS: 0-3 scale]). Used in combination with another agent for chronic rhinosinusitis with nasal polyps.

XOSPATA (S)

MEDICATION(S)
XOSPATA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

XPOVIO (S)

MEDICATION(S)
XPOVIO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Multiple Myeloma (MM), Diffuse large B-cell lymphoma (DLBCL): Diagnosis of one of the following: 1) DLBCL OR 2) Multiple Myeloma.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

XTANDI (S)

MEDICATION(S)
XTANDI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

XYREM (S)

MEDICATION(S)
SODIUM OXYBATE, XYREM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Narcolepsy with cataplexy (Narcolepsy Type 1)(initial): Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), AND symptoms of cataplexy are present, AND symptoms of excessive daytime sleepiness (eg, irrepressible need to sleep or daytime lapses into sleep) are present. Narcolepsy without cataplexy (Narcolepsy Type 2)(initial): Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), AND symptoms of cataplexy are absent, AND symptoms of excessive daytime sleepiness (eg, irrepressible need to sleep or daytime lapses into sleep) are present, AND trial and failure, contraindication, or intolerance to one of the following: 1) amphetamine-based stimulant (eg, amphetamine, dextroamphetamine), OR 2) methylphenidate-based stimulant.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
All uses (initial): 6 months. All uses (reauth): 12 months

OTHER CRITERIA
Narcolepsy Type 1 (reauth): Documentation demonstrating a reduction in the frequency of cataplexy

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

YUFLYMA (S)

MEDICATION(S)
YUFLYMA(CF) 40 MG/0.4 ML SYRNG, YUFLYMA(CF) AUTOINJECT (2 PCK), YUFLYMA(CF) 40MG/0.4ML 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 moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. PsO (Initial): Diagnosis of moderate to severe chronic PsO. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), methotrexate. Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial): 6 mo, (reauth): 12 mo.

OTHER CRITERIA

Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), aminosalicylate [eg, mesalamine, olsalazine, sulfasalazine]. Hidradenitis suppurativa (Initial): Diagnosis of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). RA, PJIA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Hidradenitis suppurativa (HS), Uveitis (Reauth): Documentation of positive clinical response to therapy. Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. AS (Reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. CD (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. UC (Reauth): For patients who initiated therapy within the past 12 weeks: Documentation of clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy OR For patients who have been maintained on therapy for longer than 12 weeks: Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high

fecal output state.

ZAVESCA (S)

MEDICATION(S)
MIGLUSTAT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Gaucher disease: Diagnosis of mild to moderate type 1 Gaucher disease.

AGE RESTRICTION
Gaucher disease: Patient is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Gaucher disease: 12 months

OTHER CRITERIA
N/A

ZEJULA (S)

MEDICATION(S)
ZEJULA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

ZELBORAF (S)

MEDICATION(S)
ZELBORAF

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
All indications: Approve for continuation of therapy.

ZEPOSIA (S)

MEDICATION(S)
ZEPOSIA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Multiple Sclerosis (MS) (initial): Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: a) Failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS: 1) Aubagio (teriflunomide), 2) Gilenya (fingolimod), or 3) Brand Tecfidera/generic dimethyl fumarate, OR b) for continuation of prior therapy. Ulcerative Colitis (UC) (init): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. One of the following: a) Trial and failure, contraindication, or intolerance to two of the following: Humira (adalimumab)/Cyltezo/or Yuflyma, Stelara (ustekinumab), Rinvoq (upadacitinib), or Xeljanz IR (tofacitinib IR)/Xeljanz XR (tofacitinib XR), OR b) for continuation of prior therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
MS (initial, reauth): Prescribed by or in consultation with a neurologist. UC (init): Prescribed by or in consultation with a gastroenterologist.

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

OTHER CRITERIA

MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression). UC (reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline OR reversal of high fecal output state.

ZEPZELCA (S)

MEDICATION(S)
ZEPZELCA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

ZIRABEV (S)

MEDICATION(S)
ZIRABEV

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

ZOKINVY (S)

MEDICATION(S)
ZOKINVY

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) To reduce risk of mortality in Hutchinson-Gilford Progeria Syndrome, OR 2) For treatment of processing-deficient Progeroid Laminopathies with one of the following: i) Heterozygous LMNA mutation with progerin-like protein accumulation OR ii) Homozygous or compound heterozygous ZMPSTE24 mutations. Patient has a body surface area of 0.39 m2 and above.

AGE RESTRICTION
Patient is 12 months of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

ZOLADEX (S)

MEDICATION(S)
ZOLADEX 3.6 MG IMPLANT SYRN

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. Endometriosis [Zoladex (3.6 mg strength)]: Treatment of endometriosis. Trial and failure, contraindication, or intolerance to Lupron Depot . Advanced Breast Cancer [Zoladex (3.6 mg strength)]: For the palliative treatment of advanced breast cancer. Endometrial thinning [Zoladex (3.6 mg strength)] For the treatment of dysfunctional uterine bleeding. Used as an endometrial thinning agent prior to endometrial ablation.

AGE RESTRICTION
Endometriosis: 18 years or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

ZOLINZA (S)

MEDICATION(S)
ZOLINZA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

ZORBTIVE (S)

MEDICATION(S)
ZORBTIVE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a gastroenterologist.

COVERAGE DURATION
SBS: 4 weeks.

OTHER CRITERIA
N/A

ZTALMY (S)

MEDICATION(S)
ZTALMY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD). Patient has a mutation in the CDKL5 gene. Trial and failure, contraindication, or intolerance to two formulary anticonvulsants (e.g., valproic acid, levetiracetam, lamotrigine).

AGE RESTRICTION
Patient is 2 years of age or older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

ZYDELIG (S)

MEDICATION(S)
ZYDELIG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

ZYKADIA (S)

MEDICATION(S)
ZYKADIA 150 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Non-small cell lung cancer (NSCLC): Diagnosis of 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
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
Approve for continuation of prior therapy.

ZYNLONTA (S)

MEDICATION(S)
ZYNLONTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
One of the following diagnoses: 1) Diffuse large B-cell lymphoma (DLBCL), 2) DLBCL arising from low-grade lymphoma, or 3) High-grade B-cell lymphoma. Disease is one of the following: a) relapsed or b) refractory. Patient has received at least two prior systemic therapies (e.g., rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, dexamethasone, cisplatin, cytarabine).

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.

ZYTIGA (PREFERRED) (S)

MEDICATION(S)
ABIRATERONE ACETATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Castration-Resistant Prostate Cancer (CRPC): Diagnosis of castration-resistant (chemical or surgical) or recurrent prostate cancer. Castration-Sensitive Prostate Cancer (CSPC): Diagnosis of castration-sensitive prostate cancer.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
CRPC, CSPC: 12 months

OTHER CRITERIA
Approve for continuation of prior therapy