PROVIDENCE
Medicare Advantage Plans

A division of Providence Health Assurance

PROVIDENCE MEDICARE ADVANTAGE PLANS

2022 PRIOR AUTHORIZATION CRITERIA:

PHIP ALIGN GROUP PLAN + RX (HMO) AND FLEX GROUP PLAN + RX (HMO-POS) PLANS

Last Updated 11/22/2022

For more recent information or other questions, please contact Providence Health Assurance Customer Service at 503-574-8000 or 1-800-603-2340 or, for TTY users, 711, seven days a week, between 8 a.m. and 8 p.m. (Pacific Time), or visit ProvidenceHealthAssurance.com/PHIP.

H9047_2022GRAM08_C

ABILIFY MYCITE

MEDICATION(S)
ABILIFY MYCITE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation that the patient is able to tolerate generic oral aripiprazole

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with a mental health provider

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan.

OTHER CRITERIA
N/A

ACTINIC KERATOSIS AGENTS

MEDICATION(S)
FLUOROURACIL 0.5% CREAM, KLISYRI, PICATO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For the treatment of actinic keratosis (AK): Documentation of trial and failure, contraindication or intolerance to two (2) of the following formulary, generic topical agents: a. diclofenac 3% gel, b. 5-fluorouracil 2% solution or 5% cream/solution, c. imiquimod 5% cream. An adequate trial and failure is defined as failure to achieve clearance of AK lesion(s) after recommended treatment dosing and duration. Reauthorization requires documentation of a reduction in the number and/or size of lesions of AK and medical rationale for continuing therapy beyond recommended treatment course.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial authorization and reauthorization will be approved for 1 month.

OTHER CRITERIA
N/A

AEMCOLO

MEDICATION(S)
AEMCOLO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of traveler's diarrhea caused by noninvasive strains of Escherichia coli. Rifamycin is not covered if documentation shows diarrhea that is complicated by fever or blood in stool.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 days

OTHER CRITERIA
N/A

ALBENDAZOLE/EMVERM

MEDICATION(S)
ALBENDAZOLE 200 MG TABLET, EMVERM

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

OFF LABEL USES
Pinworm (Enterobius vermicularis) for albendazole.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization, documentation of confirmed diagnoses.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
For diagnoses other than pinworm (Enterobius vermicularis), must be prescribed by, or in consultation with, an infectious disease specialist, gastroenterologist, or neurologist.

COVERAGE DURATION
Initial authorization and reauthorization will be approved for three (3) months.

OTHER CRITERIA
N/A

ALPHA-1 PROTEINASE INHIBITORS

MEDICATION(S)
ARALAST NP, GLASSIA, PROLASTIN C, ZEMAIRA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization, all of the following must be met: 1. Documentation of one (1) of the following: a. Serum alpha-1 antitrypsin (AAT) concentrations less than 11 uM/L (approximately 57 mg/dL by nephelometry or 80mg/dL by immunodiffusion), or b. Patient has one of the high-risk phenotypes by protease inhibitor (PI) typing: PI*ZZ, PI*Z(null), PI*(null,null), or PI*SZ homozygotes, AND 2. Confirmed diagnosis of emphysema, AND 3. Documentation that dose does not exceed 60 mg/kg every 7 days. Criteria 1 and 2 are exempted in patients with concomitant necrotizing panniculitis. Reauthorization requires documentation of response to therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.

OTHER CRITERIA
N/A

AMIFAMPRIDINE

MEDICATION(S)
FIRDAPSE, RUZURGI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial authorization (all of the following must be met): 1. Confirmed diagnosis of Lambert-Eaton myasthenic syndrome (LEMS), 2. Documentation of confirmatory diagnostic test results including: a. Repetitive Nerve Stimulation (RNS) testing showing reproducible post-exercise increase in compound muscle action potential (CMAP) amplitude of at least 60 percent compared with pre-exercise baseline value or a similar increment on high-frequency repetitive nerve stimulation without exercise OR b. Positive anti-P/Q type voltage-gated calcium channel antibody test, 3. Documentation of clinical symptoms of LEMS, including dyspnea or functionally significant muscle weakness, 4. Member has been evaluated for malignancy and treated for malignancy, if present. Note: LEMS symptoms associated with malignancy may resolve after treatment directed at malignancy, 5. Documented trial (of at least 1 month) and failure or intolerance of pyridostigmine. Reauthorization requires documentation of improvement or stabilization of muscle weakness from baseline.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial approval will be approved for 3 months. Reauthorization will be approved for 12 months.

OTHER CRITERIA
N/A

ANTI-CANCER AGENTS

MEDICATION(S)

ABIRATERONE ACETATE, ACTIMMUNE, ALECENSA, ALUNBRIG, AYVAKIT, BALVERSA, BESREMI, BEXAROTENE, BOSULIF, BRAFTOVI 75 MG CAPSULE, BRUKINSA, CABOMETYX, CALQUENCE, CAPRELSA, COMETRIQ, COPIKTRA, COTELLIC, DAURISMO, ERIVEDGE, ERLEADA, ERLOTINIB HCL, EVEROLIMUS 10 MG TABLET, EVEROLIMUS 2 MG TAB FOR SUSP, EVEROLIMUS 2.5 MG TABLET, EVEROLIMUS 3 MG TAB FOR SUSP, EVEROLIMUS 5 MG TAB FOR SUSP, EVEROLIMUS 5 MG TABLET, EVEROLIMUS 7.5 MG TABLET, EXKIVITY, FARYDAK, FOTIVDA, GAVRETO, GILOTRIF, IBRANCE, ICLUSIG, IDHIFA, IMATINIB MESYLATE, IMBRUVICA, INLYTA, INQOVI, INREBIC, IRESSA, JAKAFI, KISQALI, KISQALI FEMARA CO-PACK, KOSELUGO, LAPATINIB, LENALIDOMIDE, LENVIMA, LONSURF, LORBRENA, LUMAKRAS, LYNPARZA, MEKINIST, MEKTOVI, NERLYNX, NINLARO, NUBEQA, ODOMZO, ONUREG, ORGOVYX, PEMAZYRE, PIQRAY, POMALYST, QINLOCK, RETEVMO, REVLIMID, ROZLYTREK, RUBRACA, RYDAPT, SCEMBLIX, SORAFENIB, SPRYCEL, STIVARGA, SUNITINIB MALATE, SYNRIBO, TABRECTA, TAFINLAR, TAGRISSO, TALZENNA, TASIGNA, TAZVERIK, TEPMETKO, TIBSOVO, TRETINOIN 10 MG CAPSULE, TRUSELTIQ, TUKYSA, TURALIO, UKONIQ, VENCLEXTA, VENCLEXTA STARTING PACK, VERZENIO, VITRAKVI, VIZIMPRO, VONJO, VOTRIENT, WELIREG, XALKORI, XOSPATA, XPOVIO, XTANDI, YONSA, ZEJULA, ZELBORAF, ZOLINZA, ZYDELIG, ZYKADIA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

One of the following for initiation of the requested agent: 1. For Bosulif or Tasigna: Documentation of use of imatinib or dasatinib (Sprycel) for the requested indication, unless one of the following: a. The patient has an intolerance or hypersensitivity to imatinib OR dasatinib, b. The patient has an FDA labeled contraindication to imatinib or dasatinib, c. National Comprehensive Cancer Network (NCCN) guidelines do not support the use of imatinib or dasatinib for the requested indication, or d. The prescriber has provided information in support of use of Bosulif or Tasigna over imatinib or dasatinib for the requested indication. 2. For Kisqali, Kisqali/Femara, or Verzenio: Documentation of use of Ibrance for the requested indication (if applicable), unless one of the following: a. The patient has an intolerance or hypersensitivity to Ibrance, b. The patient has an FDA labeled contraindication to Ibrance, c. NCCN guidelines do not support the use of Ibrance for the requested indication, or d. The prescriber has provided information in support of use of

Kisqali, Kisqali/Femara, or Verzenio over Ibrance for the requested indication. For all other agents: Indication is supported by NCCN guidelines with recommendation 2A or higher.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

For cancer diagnoses, must be prescribed by or in consultation with an oncologist, transplant specialist, or neurologist. For diagnosis of systemic mast cell disease, allergist or immunologist are also acceptable.

COVERAGE DURATION

Authorization will be approved until no longer eligible with the plan.

OTHER CRITERIA

N/A

ANTIFUNGAL AGENTS

MEDICATION(S)
CRESEMBA 186 MG CAPSULE, ITRACONAZOLE 10 MG/ML SOLUTION, ITRACONAZOLE 100 MG/10 ML CUP, NOXAFIL 40 MG/ML SUSPENSION, POSACONAZOLE, VORICONAZOLE 200 MG TABLET, VORICONAZOLE 200 MG VIAL, VORICONAZOLE 40 MG/ML SUSP, VORICONAZOLE 50 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. For oropharyngeal or esophageal candidiasis (itraconazole solution, posaconazole oral suspension (Noxafil), and voriconazole only): a. For itraconazole solution: Documented failure, intolerance, or contraindication to fluconazole b. For voriconazole or posaconazole oral suspension (Noxafil): Documented failure, intolerance, or contraindication to fluconazole and itraconazole solution. 2. For the treatment of invasive aspergillosis or invasive candidiasis: a. Confirmed diagnosis (Fungal culture and other relevant laboratory studies [including histopathology] must be documented),
b. voriconazole will be covered, c. for posaconazole or isavuconazonium: Documented failure, intolerance, or contraindication to voriconazole. 3. For the treatment of blastomycosis or histoplasmosis: itraconazole will be covered, a. For voriconazole or posaconazole: Documented failure, intolerance, or contraindication to itraconazole 4. For prophylaxis of invasive aspergillosis or invasive candidiasis: posaconazole or voriconazole will be covered in severely immunocompromised patients.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an infectious disease specialist, hematologist, oncologist, or pulmonologist for all indication except dermatomycosis

COVERAGE DURATION
Aspergillus/Candida infection prophylaxis: initial/reauth 1 yr. Other uses: initial 3 mo/reauth 1 yr

OTHER CRITERIA

5. For dermatomycosis (itraconazole only): Documentation of trial and failure, intolerance, or contraindication to one topical therapy to treat the condition, or medical rationale for not using a topical agent (e.g., treatment area is large enough or in multiple locations such that it is not practically treated with topical agents). 6. For treatment of mucormycosis: isavuconazonium or posaconazole will be covered. 7. For empiric antifungal therapy in patients with febrile neutropenia: itraconazole, voriconazole or posaconazole will be covered. For reauthorization: Documentation supporting continued use of the requested agent for the intended diagnosis (such as continued active disease, length of therapy is supported by literature or guidelines, for prophylaxis patient continues to be severely immunocompromised).

ANTIPSYCHOTICS

MEDICATION(S)
ASENAPINE MALEATE, CAPLYTA, LATUDA, LYBALVI, REXULTI, SECUADO, VRAYLAR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For adjunctive treatment of major depressive disorder (brexipiprazole only): 1. Documentation of current use of an antidepressant (e.g., citalopram, sertraline, paroxetine, duloxetine, mirtazapine, venlafaxine) AND 2. Documented trial, failure, intolerance or contraindication to quetiapine and aripiprazole. For schizophrenia:
Documented trial, failure, intolerance or contraindication to two formulary, generic antipsychotics (e.g., quetiapine, olanzapine, ziprasidone, risperidone, aripiprazole).
For bipolar disorder: Documented trial, failure, intolerance or contraindication to two formulary, generic medications for bipolar disorder (e.g., lithium, quetiapine, lamotrigine, divalproex, aripiprazole, risperidone, olanzapine).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan.

OTHER CRITERIA
N/A

ARCALYST

MEDICATION(S)
ARCALYST

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Cryopyrin-Associated Periodic Syndrome (CAPS) including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS): Diagnosis confirmed by: 1. Laboratory evidence of genetic mutation NLRP-3 (Nucleotide-binding domain, leucine rich family pyrin domain containing 3) or CIAS1 (Cold-induced autoinflammatory syndrome-1), AND 2. Classic symptoms associated with FCAS or MWS (e.g., recurrent intermittent fever and rash typically associated with natural or artificial cold). For Deficiency of Interleukin-1 Receptor Antagonist (DIRA): 1. Confirmed by laboratory evidence of genetic mutation in IL1RN (encodes for interleukin-1 receptor antagonist) 2. Current inflammatory remission of DIRA 3. Weight of at least 10 kg. For recurrent pericarditis: 1. Diagnosis of recurrent pericarditis (RP) confirmed by an acute episode of pericarditis followed by a 4-6 week symptom free period prior to the next episode without an identified cause 2. Documentation trial and failure, contraindication or intolerance to NSAIDs or glucocorticoids. Reauthorization: Documentation submitted of improvement of symptoms (such as fever, urticaria-like rash, arthralgia, myalgia, fatigue, and conjunctivitis for CAPS)

AGE RESTRICTION
For CAPS (which includes FCAS, MWS) and RP: Approved for patients 12 years of age and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization will be approved for six months. Reauthorization will be approved for one year

OTHER CRITERIA
N/A

BENLYSTA

MEDICATION(S)
BENLYSTA 200 MG/ML AUTOINJECT, BENLYSTA 200 MG/ML SYRINGE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
1. Severe active central nervous system lupus 2. Current use of other biologic immunomodulator

REQUIRED MEDICAL INFORMATION
For Systemic Lupus Erythematosus (SLE) or active lupus nephritis: All of the following must be met: 1. Documented diagnosis of Systemic Lupus Erythematosus (SLE) or active lupus nephritis by a rheumatologist or nephrologist AND 2. Documentation of laboratory test results indicating that patient has presence of auto-antibodies, defined as one (1) of the following: a. Positive Antinuclear antibody (ANA) b. Positive antidouble-stranded DNA (anti-dsDNA) on two (2) or more occasions, OR if tested by ELISA, an antibody level above laboratory reference range c. Positive anti-Smith (Anti-Sm) d. Positive anti-Ro/SSA and anti-La/SSB antibodies AND 3. Documented failure of an adequate trial (such as inadequate control with ongoing disease activity and/or frequent flares), contraindication, or intolerance to at least one (1) of the following: a. For SLE without active lupus nephritis: oral corticosteroid(s), azathioprine, methotrexate, mycophenolate mofetil, hydroxychloroquine, chloroquine, or cyclophosphamide, b. For SLE with active lupus nephritis: mycophenolate for induction followed by mycophenolate for maintenance, OR cyclophosphamide for induction followed by azathioprine for maintenance. AND 4. Documentation that patient will continue to receive standard therapy (e.g., corticosteroids, hydroxychloroquine, mycophenolate, azathioprine, methotrexate). Reauthorization: 1. Documentation of positive clinical response to belimumab (e.g. improvement in functional impairment, decrease of corticosteroid dose, decrease in pain medications, decrease in the number of exacerbations since prior to start of belimumab, reduction in renal related events) AND 2. Patient currently receiving standard therapy for SLE or active lupus nephritis.

AGE RESTRICTION
N/A

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

COVERAGE DURATION

Initial authorization and reauthorization will be approved for 6 months.

OTHER CRITERIA

N/A

BUDESONIDE ER

MEDICATION(S)
BUDESONIDE ER

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

OFF LABEL USES
MICROSCOPIC COLITIS

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For mild to moderate, active ulcerative colitis: 1. Confirmed diagnosis of mild to moderate, active ulcerative colitis AND 2. Documented trial, failure, intolerance or contraindication to treatment with an aminosalicylate (e.g., sulfasalazine, mesalamine)
AND 3. Documented trial, failure, intolerance or contraindication to one of the following oral corticosteroids: dexamethasone, hydrocortisone, methylprednisolone, prednisone or budesonide extended release capsule.
For microscopic colitis: 1. Confirmed diagnosis of active, microscopic colitis. Further approval requires medical rationale why additional treatment is warranted for ulcerative colitis and microscopic colitis and if patient is not on maintenance therapy for ulcerative colitis why it is not appropriate.

AGE RESTRICTION
Approved for patients 18 years of age and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for 8 weeks.

OTHER CRITERIA
N/A

CABLIVI

MEDICATION(S)
CABLIVI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial Criteria: 1. Diagnosis of acquired thrombotic thrombocytopenic purpura 2. Documentation that therapy will be given in combination with plasma exchange therapy 3. Documentation that therapy will be given in combination with immunosuppressive therapy (i.e., glucocorticoids, rituximab) Reauthorization criteria: If the request is for a new treatment cycle: 1. Documentation of previous positive response to therapy (such as an improvement in platelet counts, reduction in neurological symptoms, or improvements in organ-damage markers) 2. Documentation that therapy will be given in combination with plasma exchange therapy and immunosuppressive therapy (i.e., glucocorticoids, rituximab) 3. Documentation that length of therapy post plasma exchange will not exceed 58 days 4. Documentation that patient has not had more than two recurrences of acquired thrombotic thrombocytopenic purpura while on therapy with caplacizumab. Recurrence is defined as initial platelet normalization followed by a reduction in platelet count that necessitates re-initiation of plasma exchange. If request is for treatment extension: 1. Documentation of positive response to therapy (such as an improvement in platelet counts, reduction in neurological symptoms, or improvements in organ-damage markers) 2. Documentation that patient has signs of persistent underlying disease such as persistent severe ADAMTS13 deficiency 3. Documentation that length of therapy post plasma exchange will not exceed 58 days.

AGE RESTRICTION
Approved for patients 18 years of age and older

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

COVERAGE DURATION
Initial authorization and reauthorization will be approved for 90 days.

OTHER CRITERIA

N/A

CALCITONIN GENE-RELATED PEPTIDE (CGRP) RECEPTOR ANTAGONISTS FOR MIGRAINE PROPHYLAXIS

MEDICATION(S)
AIMOVIG AUTOINJECTOR, EMGALITY PEN, EMGALITY SYRINGE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with another calcitonin gene-related peptide (CGRP) agent

REQUIRED MEDICAL INFORMATION
Initial authorization for migraine prophylaxis (chronic and episodic): 1. Diagnosis of migraine headaches with at least four (4) headache days per month AND 2. One of the following: a. Trial and inadequate response to at least 6 weeks of at least one (1) prophylactic medication from one (1) of the following categories: i. Anticonvulsants (i.e., divalproex, valproate, topiramate), ii. Beta-blockers (i.e., metoprolol, propranolol, timolol), iii. Antidepressants (i.e., amitriptyline, venlafaxine), b. Documented intolerance or contraindication to an anticonvulsant, a beta blocker, AND an antidepressant listed above, AND 3. Documentation that if the patient is currently receiving botulinum toxin, treatment with botulinum toxin will be discontinued. 4. The patient has been evaluated for, and does not have, medication overuse headache. Initial authorization for cluster headaches (galcanezumab [Emgality] only): 1. Confirmed diagnosis of episodic cluster headaches with a history of at least five (5) cluster headache attacks AND 2. One of the following: a. Trial and inadequate response to at least 6 weeks of at least one (1) of the following: i. Verapamil or ii. Lithium, or b. Documented intolerance or contraindication to the therapies listed above AND 3. The patient has been evaluated for, and does not have, medication overuse headache. Reauthorization for all indications: Documented reduction in the severity or frequency of headaches.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial approval will be for 1 year. Reauth will be approved until no longer eligible with the plan

OTHER CRITERIA

N/A

CAMZYOS

MEDICATION(S)
CAMZYOS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial authorization requires documentation of all the following: 1. Clinical diagnosis of obstructive hypertrophic cardiomyopathy (HCM), defined as left ventricular hypertrophy (LVH) in the absence of another cardiac, systemic, or metabolic disease, capable of producing the magnitude of hypertrophy evident, and evidence of one of the following as measured by any imaging technique: a. Left ventricle wall thickness of 15 mm or greater OR b. Left ventricle wall thickness of 13 mm or greater with family history of HCM or in conjunction with a positive genetic test, 2. New York Heart Association (NYHA) class II, or III, 3. Left ventricular ejection fraction (LVEF) 55% or greater, 4. Left ventricular outflow tract (LVOT) peak gradient 50 mmHg or greater at rest or with provocation, and 5. Documented trial and failure, intolerance, or contraindication to all the following: a. A formulary generic non vasodilating beta blocker (such as propranolol, metoprolol, atenolol, bisoprolol) or formulary generic calcium channel blocker (verapamil or diltiazem), AND b. disopyramide. Reauthorization requires documentation of a positive clinical response, as evidenced by at least one of the following: 1. Improvement in symptoms (such as dyspnea, fatigue, chest pain, palpitations, dizziness, fainting) OR 2. NYHA class reduction

AGE RESTRICTION
18 years of age or older

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

COVERAGE DURATION
Initial auth will be approved for six months. Reauth will be approved for one year.

OTHER CRITERIA
N/A

CFTR MODULATORS

MEDICATION(S)
KALYDECO, ORKAMBI, SYMDEKO, TRIKAFTA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For ivacaftor (Kalydeco): Diagnosis of cystic fibrosis with documentation of at least one copy of a cystic fibrosis transmembrane regulator (CFTR) gene mutation that is responsive to ivacaftor (refer to package insert). For lumacaftor-ivacaftor (Orkambi): Diagnosis of cystic fibrosis with documentation of homozygous F508del mutation in the CFTR gene. For tezacaftor-ivacaftor (Symdeko): Diagnosis of cystic fibrosis with documentation of one (1) of the following: 1. Homozygous F508del mutation in the CFTR gene OR 2. A copy of a mutation in the CFTR gene that is responsive to tezacaftor-ivacaftor based on clinical evidence and/or in vitro data (refer to package insert), excluding F508del mutation. For elexacaftor- tezacaftor-ivacaftor (Trikafta): Diagnosis of cystic fibrosis with documentation of at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive to elexacaftor- tezacaftor-ivacaftor based on in vitro data (refer to package insert). Reauthorization: Documented response to therapy as defined as one (1) of the following: a. A lack of decline in lung function as measured by the FEV1 when the patient is clinically stable b. A reduction in the incidence of pulmonary exacerbations c. Reduced respiratory symptoms (e.g., persistent productive cough, wheezing, shortness of breath) d. An improvement in BMI from baseline

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a pulmonologist or provider at a Cystic Fibrosis Center.

COVERAGE DURATION
Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.

OTHER CRITERIA

N/A

CHENODAL

MEDICATION(S)
CHENODAL

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

OFF LABEL USES
Cerebrotendinous xanthomatosis.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For use in gallstone dissolution: 1. Documentation that the patient is not a candidate for surgery AND 2. Documentation of failure of an adequate trial of 30-day duration, contraindication, or intolerance to ursodiol. For cerebrotendinous xanthomatosis: documentation of confirmed diagnosis (e.g. clinical presentation and/or genetic testing). Reauthorization will require documentation of positive response to therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
For cerebrotendinous xanthomatosis, must be prescribed by, or in consultation with, a genetics or metabolism specialist. For gallstone dissolution, must be prescribed by a gastroenterologist.

COVERAGE DURATION
Initial auth for 6 months. Reauth for 1 year. Max 2 years for treatment of gallstones

OTHER CRITERIA
N/A

CHOLBAM

MEDICATION(S)
CHOLBAM

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization: 1. Documentation of baseline liver function tests (LFTs) AND 2. One of the following: A. For bile acid synthesis disorder: documentation of a single enzyme defect OR B. For peroxisomal disorder, including Zellweger spectrum disorders, both of the following criteria must be met: a. Documentation of manifestations of at least one of the following: i. Liver disease (e.g., jaundice, elevated serum transaminases) ii. Steatorrhea iii. Complications from decreased fat-soluble vitamin absorption (e.g., poor growth) AND b. The medication will be used as adjunctive therapy. For reauthorization: Documentation of positive clinical response (e.g. improvement in LFTs).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a medical geneticist, pediatric gastroenterologist, hepatologist or other specialist experienced in treating inborn errors of metabolism.

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA
N/A

CORLANOR

MEDICATION(S)
CORLANOR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For chronic heart failure in adults, all of the following must be met: 1. Symptoms consistent with New York Heart Association (NYHA) Class II, III, or IV, 2. Left ventricular ejection fraction (LVEF) of 35% or less, 3. Documentation that patient is currently in normal sinus rhythm with resting heart rate of at least 70 bpm, 4. On a maximally tolerated dose of an ACE inhibitor (e.g., lisinopril, enalapril) or ARB (e.g., losartan, valsartan), unless contraindicated or did not tolerate, 5. On a maximally tolerated dose of 1 of the 3 beta-blockers proven to reduce mortality in all stable patients of heart failure with reduced left ventricular ejection fraction (carvedilol, metoprolol succinate, bisoprolol), unless contraindicated or did not tolerate, 6. Documentation that the patient has been hospitalized for worsening heart failure in the previous 12 months. For pediatric patients at least 6 month of age: 1. Diagnosis of stable symptomatic heart failure due to dilated cardiomyopathy (DCM), 2. Documentation that patient is currently in normal sinus rhythm with resting heart rate as follows: age 6-12 months: at least 105 bpm, age 1-3 years: at least 95 bpm, age 3-5 years: at least 75 bpm, age over 5 years: at least 70 bpm.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan.

OTHER CRITERIA
N/A

DALIRESP

MEDICATION(S)
DALIRESP, ROFLUMILAST 500 MCG TABLET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
All of the following criteria must be met: 1. A confirmed diagnosis of severe chronic obstructive pulmonary disease (COPD) associated with chronic bronchitis and a history of exacerbations AND 2. An adequate trial and failure, contraindication or intolerance to one of the following maintenance therapy: a. combination long-acting beta-2 agonist (LABA)/long-acting antimuscarinic agonist (LAMA)/inhaled corticosteroid (ICS) (i.e. Trelegy), b. combination LABA/LAMA (i.e. Stiolto, Anoro) with ICS, c. LABA/ICS (i.e. Breo, Symbicort, Advair, salmeterol/fluticasone propionate) with LAMA (i.e. Spiriva, Incruse)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a pulmonologist

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan.

OTHER CRITERIA
N/A

DIACOMIT

MEDICATION(S)
DIACOMIT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization all of the following criteria must be met: 1. Documentation of seizures associated with Dravet Syndrome (DS) 2. Documentation of inadequate control on clobazam or valproate (unless contraindicated), despite optimized therapy 3. Documentation that stiripentol will be used in combination with clobazam 4. Dose will not exceed 50mg/kg (up to maximum 3,000mg) per day

AGE RESTRICTION
Approved for 2 years of age and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an epilepsy specialist or a neurologist.

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan.

OTHER CRITERIA
N/A

DISPOSABLE INSULIN PUMPS

MEDICATION(S)
OMNIPOD 5 G6 INTRO KIT (GEN 5), OMNIPOD 5 G6 PODS (GEN 5), OMNIPOD DASH INTRO KIT (GEN 4), OMNIPOD DASH PODS (GEN 4)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
One of the following:
1. Patient has Type 1 diabetes, or
2. Documentation that the patient requires multiple daily doses of rapid- or short-acting insulin (Humalog®, Humulin R®, Humulin® mix) therapy and has any of the following while on their current therapy for diabetes
a. Documented need for more than five daily injections of insulin.
b. Inadequate glycemic control, defined as glycosylated hemoglobin level (HbA1C) greater than 7%,
c. Recurring episodes of significant hyperglycemia,
d. Severe glycemic fluctuations
e. Documented hypoglycemia unawareness or recurring, symptomatic hypoglycemia episodes

Requests for additional pods may be covered when the patients' total daily dose of insulin is more than 65 units per day. The quantity will be limited to the appropriate number of pods per month based on insulin utilization (each pod can hold 200 units of insulin and must be changed every 72 hours)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan

OTHER CRITERIA

N/A

DOPTELET

MEDICATION(S)
DOPTELET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Treatment of Thrombocytopenia in Patients with Chronic Liver Disease (CLD): 1. Diagnosis of chronic liver disease 2. Platelet count of less than 50,000 platelets/uL 3. Documentation that patient will have a scheduled medical or dental procedure within the next 30 days and therapy will be started 10-13 days prior to the procedure. For chronic immune thrombocytopenia (ITP): 1. Platelet count of less than 30,000 platelets/uL 2. Inadequate response to at least TWO of the following therapies: a. Corticosteroids b. Immunoglobulins c. Splenectomy d. rituximab e. Eltrombopag (Promacta). Reauthorization: Documentation of a positive response to therapy, such as an increase in platelet count.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an oncologist hematologist, gastroenterologist, liver specialist, or surgeon.

COVERAGE DURATION
For CLD for 1 month (15 tabs). For ITP initial auth for 3 months, reauth for 1 year

OTHER CRITERIA
N/A

DPP-4 INHIBITORS

MEDICATION(S)
ALOGLIPTIN, ALOGLIPTIN-METFORMIN, ALOGLIPTIN-PIOGLITAZONE, GLYXAMBI, JENTADUETO, JENTADUETO XR, KOMBIGLYZE XR, ONGLYZA, STEGLUJAN, TRADJENTA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Type 1 diabetes

REQUIRED MEDICAL INFORMATION
For Type 2 diabetes: 1. Documentation of an intolerance or adverse effect with a trial of sitagliptin (Januvia®/Janumet®) and 2. Documented HbA1c, obtained within the last six months, that is greater than or equal to 7% and less than or equal to 10%. Reauthorization requires documentation that HbA1c remains less than or equal to 9% (taken within previous 6 months). Empagliflozin/linagliptin (Glyxambi®) is covered for patients with type 2 diabetes mellitus and established cardiovascular disease.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial auth approved for 1 yr. Reauth will be approved until no longer eligible with the plan

OTHER CRITERIA
N/A

DROXIDOPA

MEDICATION(S)
DROXIDOPA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
All of the following criteria must be met: 1. Diagnosis of symptomatic neurogenic orthostatic hypotension (nOH) 2. Documentation that neurogenic orthostatic hypotension is caused by one of the following: a. Primary autonomic failure (e.g., Parkinson's disease, multiple system atrophy, or pure autonomic failure) b. Dopamine beta-hydroxylase deficiency c. Non-diabetic autonomic neuropathy 3. Documentation of a screen for treatable causes of orthostatic hypotension and currently being treated for the identified treatable cause of orthostatic hypotension 4. Documented trial, failure, intolerance or contraindication to both midodrine and fludrocortisone. Reauthorization: 1. Documented response to initial therapy (improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out) 2. Documentation that periodic evaluations are being done to assess continued efficacy and medical rationale for continuing therapy, as none of the clinical trials demonstrated continued efficacy beyond 2 weeks of treatment.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial authorization will be for three months. Reauthorization will be approved for 1 year.

OTHER CRITERIA
N/A

DUPIXENT

MEDICATION(S)
DUPIXENT PEN, DUPIXENT SYRINGE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with another therapeutic immunomodulator agent utilized for the same indication.

REQUIRED MEDICAL INFORMATION
For atopic dermatitis, all of the following: 1. Moderate to severe atopic dermatitis despite use of topical therapies outlined in criterion number 2. Moderate to severe disease may be defined as a chronic condition affecting more than 10% body surface area (BSA), or hand, foot or mucous membrane involvement, with severe symptoms (such as pruritis, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification), 2. Documented trial and failure, contraindication, or hypersensitivity to both of the following treatment modalities: a. Topical corticosteroids (e.g., clobetasol, triamcinolone) AND b. Topical calcineurin inhibitor (e.g., tacrolimus). Reauthorization requires documentation of stabilization or reduction from baseline of one of the following: 1. Flares, 2. Affected BSA, or 3. Symptoms outlined above (e.g., pruritus, erythema, edema, xerosis, erosions/excoriations). For Chronic Rhinosinusitis with Nasal Polyp (CRSwNP), all of the following: 1. Evidence of nasal polyposis by direct examination, endoscopy or sinus CT scan, 2. Documentation that patient has had an inadequate response to (within the past 90 days), or has an intolerance, FDA labeled contraindication, or hypersensitivity to, oral systemic corticosteroids 3. Patient has had an inadequate response to a 3-month trial of intranasal corticosteroids (e.g., fluticasone) or has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an intranasal corticosteroid 4. Documentation that patient will continue standard maintenance therapy (e.g., intranasal corticosteroids) in combination with the requested agent. Reauthorization for CRSwNP: 1. Documentation of positive clinical response to therapy, 2. Documentation that patient will continue standard maintenance therapy (e.g., intranasal corticosteroids) in combination with the requested agent, unless documented intolerance, FDA labeled contraindication, or hypersensitivity to such therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

Atopic dermatitis: Must be prescribed by, or in consultation with, a dermatologist, allergist or immunologist. Asthma: Must be prescribed by, or in consultation with an asthma specialist (such as a pulmonologist, immunologist, or allergist). Chronic rhinosinusitis with nasal polyposis: Must be prescribed by, or in consultation with, an otolaryngologist, allergist, or pulmonologist. Eosinophilic esophagitis: Must be prescribed by, or in consultation with, an allergist or a gastroenterologist.

COVERAGE DURATION

Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.

OTHER CRITERIA

For moderate-to-severe asthma, all of the following: 1. Confirmed diagnosis of one of the following: a. Eosinophilic asthma, defined by one of the following: i. Blood eosinophil count greater than 150 cells/microliter while on high-dose inhaled corticosteroids (ICS) or daily oral glucocorticoids, ii. FeNO of at least 20 parts per billion while on high-dose ICS or daily oral corticosteroids, iii. Sputum eosinophils of at least 2% while on high-dose ICS or daily oral corticosteroids, or b. Oral corticosteroid dependent type asthma, 2. Documentation of moderate to severe asthma, defined as one (1) of the following: a. Frequent severe asthma exacerbations requiring two (2) or more courses of systemic corticosteroids within the past 12 months, b. Serious asthma exacerbation requiring hospitalization, mechanical ventilation, or visit to the emergency room/urgent care within the past 12 months, c. Controlled asthma that worsens when doses of inhaled or systemic corticosteroids are tapered, or d. Baseline FEV1 less than 80% of predicted and BOTH the following: i. Treatment with maximally tolerated dose of medium to high-dose ICS in the past 3 months, or documented intolerance, FDA labeled contraindication, or hypersensitivity to an ICS AND, ii. Documentation of treatment within the past 90 days, intolerance, FDA labeled contraindication, or hypersensitivity to one of the following: a. Long-acting beta-2 agonist (LABA), b. Leukotriene receptor antagonist (LRTA), c. Long-acting muscarinic antagonist (LAMA), or d. Theophylline, AND 3. Patient will continue asthma control therapy (e.g., ICS, LABA, LRTA, LAMA, theophylline) in combination with requested agent. Reauthorization: 1. Documentation of response to therapy or disease stabilization, 2. Documentation that patient has continued (unless intolerance, FDA labeled contraindication, or hypersensitivity), and will continue, standard asthma control therapy (e.g., ICS, LABA, LRTA, LAMA, theophylline) in combination with requested agent. For eosinophilic esophagitis (EoE), all of the following: 1. Eosinophil-predominant inflammation on esophageal biopsy with greater than or equal to 15 eosinophils per high power field (HPF). 2. Symptoms of esophageal dysfunction including dysphagia, chest pain, stomach pain, heartburn, regurgitation, and vomiting. 3. Documented trial and failure, contraindication, or hypersensitivity to both of the following treatment modalities: a. Proton pump inhibitors (e.g. omeprazole, pantoprazole) AND b. Topical glucocorticoids (e.g. fluticasone, budesonide). Reauthorization for EoE: Documentation of response to therapy or disease stabilization.

For all indications (initial and re-authorization): Dose must be within FDA labeled dosing for the requested indication.

EGRIFTA

MEDICATION(S)
EGRIFTA SV

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization, all of the following criteria must be met: 1. Diagnosis of HIV-associated lipodystrophy AND 2. Documentation of patient's waist circumference
a. Waist circumference greater than or equal to 37.4 inches (95 cm) for males b. Waist circumference greater than or equal to 37 inches (94 cm) for females AND 3. Documentation of waist-to-hip ratio a. Waist-to-hip ratio greater than or equal to 0.94 for males b. Waist-to-hip ratio greater than or equal to 0.88 for females AND 4. Documentation of a body mass index (BMI) greater than 20 kilograms per meter squared AND 5. Documentation of fasting blood glucose (FBG) of less than or equal to 150 mg/dL (8.33 mmol/L) AND 6. Documentation that patient has been on a stable regimen of antiretrovirals for at least eight (8) weeks. Reauthorization will require documentation of clinical improvement (e.g., decrease in waist circumference, improvement in visceral adipose tissue).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for 6 months.

OTHER CRITERIA
N/A

EMFLAZA

MEDICATION(S)
EMFLAZA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization for Duchenne Muscular Dystrophy, all of the following criteria must be met: 1. Confirmed diagnosis by genetic testing, AND 2. Documentation of trial and failure, contraindication to prednisone therapy, or clinically significant adverse events with a trial of prednisone for at least 30 days. Clinically significant adverse events may include cushingoid appearance, central (truncal) obesity, weight gain of at least 10% body weight, diabetes and/or hypertension that is difficult to manage, or psychiatric/behavioral issues (e.g., abnormal behavior, aggression, irritability AND 3. The dose requested is within FDA labeled dosing based on the patients weight (patients weight must be provided), AND 4. Dose is given in most cost effective manner (e.g., rounding to appropriate tablet strength or use of suspension). Re-authorization: 1. Documentation of clinical benefit from therapy, such as improvement or stabilization of muscle strength or pulmonary function AND 2. The dose requested is within FDA labeled dosing based on the patients weight (updated weight must be provided) AND dose is given in most cost effective manner (e.g., rounding to appropriate tablet strength or use of suspension)

AGE RESTRICTION
Approved for patients 2 years of age and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a provider that specializes in the treatment of Duchenne muscular dystrophy (DMD) and/or neuromuscular disorders.

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one (1) year.

OTHER CRITERIA
N/A

ENSPRYNG

MEDICATION(S)
ENSPRYNG

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Neuromyelitis Optica Spectrum Disorder (NMOSD), all of the following must be met:
1. Diagnosis of neuromyelitis optica spectrum disorder as defined as the following: a. Presence of at least one core clinical characteristic (optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, symptomatic cerebral syndrome with NMOSD-typical brain lesions) AND b. Anti-AQP4 antibody positive 2. Documentation that other alternative diagnoses have been excluded (i.e. Multiple Sclerosis)
3. Medication will not be used in combination with complement-inhibitor, anti-CD20-directed, anti-CD19 directed, or IL-6 inhibition pathway therapies
4. Dose and frequency is in accordance with FDA-approved labeling Reauthorization for Neuromyelitis Optica Spectrums Disorder (NMOSD):
1. Documentation of positive clinical response to therapy 2. Medication will not be used in combination with complement-inhibitor, anti-CD20-directed, anti-CD19 directed, or IL-6 inhibition pathway therapies 3. Dose and frequency is in accordance with FDA-approved labeling

AGE RESTRICTION
Approved for ages 18 and older

PRESCRIBER RESTRICTION
Must be prescribed by a neurologist or ophthalmologist

COVERAGE DURATION
Initial authorization for 6 months and reauthorization will be approved for one year

OTHER CRITERIA

N/A

EPIDIOLEX

MEDICATION(S)
EPIDIOLEX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial Authorization: 1. Documentation that patient has one of the following: a. Seizures associated with Lennox-Gastaut syndrome (LGS) b. Seizures associated with Dravet syndrome (DS) c. Tuberous sclerosis complex (TSC) 2. Documented trial, failure, intolerance or contraindication to two of the following for the seizure type: a. For DS: clobazam, valproate/ valproic acid or topiramate, b. For LGS: clobazam, lamotrigine, valproate/ valproic acid, topiramate or rufinamide, c. For TSC: clobazam, topiramate or valproate/ valproic acid
4. Baseline liver function tests must be documented, 5. Dose will not exceed: a. 20 mg/kg/day in Lennox-Gastaut syndrome or Dravet Syndrome b. 25mg/kg/day in tuberous sclerosis complex. Reauthorization: 1. Documentation of recent liver function test 2. Documentation of positive response to therapy such as a decrease in seizure frequency or intensity since beginning therapy 3. Dose continues to not exceed 20 mg/kg/day in Lennox-Gastaut syndrome or Dravet Syndrome or 25mg/kg/day in tuberous sclerosis complex.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an epilepsy specialist or neurologist.

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan.

OTHER CRITERIA
N/A

ERYTHROPOIESIS STIMULATING AGENTS

MEDICATION(S)
ARANESP, EPOGEN, PROCRIT, RETACRIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Patients with uncontrolled hypertension, Anemia induced from hepatitis C therapy, Anemia in cancer treatment patients due to folate deficiency, iron deficiency, hemolysis, or active bleeding, Anemia associated with the treatment of acute and chronic myelogenous leukemias, Anemia associated with the treatment of erythroid cancers, Anemia in cancer or cancer treatment patients due to bone marrow fibrosis, Anemia of cancer not related to cancer treatment, Prophylactic use to prevent chemotherapy-induced anemia, Prophylactic use to reduce tumor hypoxia, Patients with erythropoietin-type resistance due to neutralizing antibodies.

REQUIRED MEDICAL INFORMATION
1. All diagnoses with the exception of 2d (preoperative use in anemic patients scheduled for elective noncardiac, nonvascular surgery) must have documented Hemoglobin (HGB) levels of less than or equal to 10g/dl or hematocrit (HCT) levels of less than or equal to 30% within 30 days prior to initiation of therapy, AND 2. Must meet listed criteria below for each specific diagnosis: a. Treatment of Anemia in Chronic Kidney Disease (not on dialysis): epoetin or darbepoetin will be covered, b. Treatment of anemia due to chemotherapy in cancer and related neoplastic conditions (see exclusion criteria for non-covered indications): epoetin or darbepoetin will be covered with documentation that anemia is secondary to myelosuppressive chemotherapy in solid tumors, multiple myeloma, lymphoma, or lymphocytic leukemia. Note: May only be used up to 8 weeks following the final dose of myelosuppressive chemotherapy (subject to audit), c. Anemia associated with zidovudine-treated HIV-infection patients: only epoetin will be covered with documented endogenous serum erythropoietin level less than or equal to 500 mU/ml and zidovudine dose less than or equal to 4200 mg/week

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA

d. Preoperative use in anemic patients scheduled for elective hip or knee surgery: epoetin will be covered when all of the following criteria are met: i. Documentation that anemia is due to chronic disease, ii. Documentation of preoperative anemia with pretreatment HGB between 10 and 13 g/dL., iii. The procedure has a high risk of perioperative blood loss (e.g., expected to lose more than 2 units of blood), AND iv. Patient is unwilling or unable to donate autologous blood pre-operatively. Reauthorization requires: 1. Documentation of continued medical necessity AND 2. Documented HGB levels of less than or equal to 12 g/dl within previous 30 days.

ESBRIET/OFEV

MEDICATION(S)
ESBRIET 267 MG CAPSULE, OFEV, PIRFENIDONE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial authorization: For Idiopathic Pulmonary Fibrosis (IPF) 1. Diagnosis of Idiopathic Pulmonary Fibrosis a. Note: Confirmed by exclusion of other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, drug toxicity, or connective tissue disease AND 2. Presence of a histological pattern associated with usual interstitial pneumonia (UIP) on high-resolution computed tomography (HRCT) or histological pattern of probable or indeterminate UIP and diagnosis is supported by lung biopsy. For Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) (nintedanib only): 1. Confirmed diagnosis of systemic sclerosis AND 2. Presence of ILD confirmed by evidence of pulmonary fibrosis on HRCT tomography. For other chronic fibrosing interstitial lung diseases with a progressive phenotype (nintedanib only): 1. Presence of ILD confirmed by evidence of pulmonary fibrosis on HRCT tomography AND 2. One (1) of the following criteria: a. Relative decline in FVC of at least 10% of predicted value (as reported by spirometry performed on two different dates within the last two years) b. Relative decline in FVC of at least 5% of predicted value combined with worsening of respiratory symptoms c. Relative decline in FVC of at least 5% of predicted value combined with increased extent of fibrotic changes on chest imaging d. Increased extent of fibrotic changes on chest imaging combined with worsening of respiratory symptoms e. Increased fibrotic changes on HRCT. Reauthorization: Documentation of positive clinical response to therapy, such as slowed rate or lack of declining lung function (e.g., FVC, DLCO) and improved or stable respiratory symptoms (e.g., cough, dyspnea).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
For SSc-ILD only: Must be prescribed by or in consultation with a pulmonologist or rheumatologist. For all other indications: Must be prescribed by or in consultation with a pulmonologist

COVERAGE DURATION

Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.

OTHER CRITERIA

N/A

EVRYSDI

MEDICATION(S)
EVRYSDI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
1. Use in combination with Spinraza (nusinersen) therapy 2. Concomitant use with, or following, gene therapy for SMA (e.g., onasemnogene abeparvovec)

REQUIRED MEDICAL INFORMATION
Initial authorization 1. The patient has a diagnosis, confirmed by genetic testing, of Spinal Muscular Atrophy (SMA) 2. Baseline assessment with an age appropriate tool that establishes baseline motor ability must be submitted (i.e. HINE-2, HFSME, CHOP-INTEND, MFM-32) 3. Requested dose is within FDA labeling. Reauthorization: 1. Documentation of response to therapy, such as a clinically meaningful improvement in motor function, disease stabilization or a reduction in normal motor decline (e.g., stabilization or improvement in motor function test scores performed at baseline) 2. Requested dose is within FDA labeling

AGE RESTRICTION
Approved for patients aged 2 months or older

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

COVERAGE DURATION
Initial authorization and reauthorization will be approved for 12 months.

OTHER CRITERIA
N/A

FENTANYL CITRATE

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
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of all the following: 1. Treatment of breakthrough cancer pain (prescriber MUST submit chart notes or other documentation supporting a diagnosis of cancer related pain AND list type of cancer), 2. Failure of or intolerance to ONE short-acting opioid formulary agent used for breakthrough pain (e.g. morphine sulfate, oxycodone, oxymorphone, hydromorphone), AND 3. Pain is not controlled with ONE long-acting opioid formulary agent (e.g. morphine sulfate ER, Xtampza ER, hydrocodone ER). Reauthorization: 1. Documentation that patient continues to have breakthrough cancer pain (prescriber MUST submit recent chart notes or other documentation supporting a diagnosis of cancer related pain AND list type of cancer) AND 2. Documentation of successful response to the medication.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.

OTHER CRITERIA
N/A

FINTEPLA

MEDICATION(S)
FINTEPLA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use of, or within 14 days of administration of monoamine oxidase inhibitors because of an increased risk of serotonin syndrome

REQUIRED MEDICAL INFORMATION
Initial authorization: 1. Documentation that patient has seizures associated with Dravet syndrome (DS) AND 2. Documented trial, failure, intolerance or contraindication to one of the following: valproate/valproic acid, clobazam, or topiramate.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an epilepsy specialist or neurologist.

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan

OTHER CRITERIA
N/A

GALAFOLD

MEDICATION(S)
GALAFOLD

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
1. Given concurrently with enzyme replacement therapy [e.g. agalsidase beta (Fabrazyme®)]. 2. Severe renal impairment or end-stage renal disease.

REQUIRED MEDICAL INFORMATION
1. Diagnosis of Fabry Disease AND 2. Documentation that patient has an amenable galactosidase alpha gene (GLA) variant based on an in vitro assay.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a metabolic disorder specialist, geneticist, nephrologist or prescriber with experience in treating lysosomal storage disorders.

COVERAGE DURATION
Initial authorization and reauthorization will be approved for 1 year.

OTHER CRITERIA
N/A

GAMMA GLOBULIN - IGG

MEDICATION(S)
BIVIGAM, FLEBOGAMMA DIF, GAMMAGARD LIQUID, GAMMAGARD S-D, GAMMAKED, GAMMAPLEX, GAMUNEX-C, OCTAGAM, PANZYGA, PRIVIGEN

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

OFF LABEL USES
Hematopoietic stem cell transplant recipients, acute Guillain-Barre syndrome, dermatomyositis, relapsing-remitting type multiple sclerosis, myasthenia gravis, autoimmune hemolytic anemia, autoimmune mucocutaneous blistering disease.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Primary immune deficiency disorders (e.g., agammaglobulinemia, hypogammaglobulinemia, common variable immunodeficiency, hyperIgM, or Wiskott-Aldrich syndrome) are covered by Medicare Part B only. For secondary immunodeficiency due to drugs/biologics agents, underlying disease or other causes: 1. Documentation of significant recurrent infections AND 2. One of the following: a. Laboratory evidence of immunoglobulin deficiency defined as either i. Agammaglobulinemia (total pre-treatment IgG less than 200 mg/dL) or ii. Persistent hypogammaglobulinemia (total IgG less than 400 mg/dl, or at least two standard deviations below normal, on at least two occasions), OR b. Deficiency in producing antibodies in response to vaccination. For Kawasaki syndrome: documentation that use is for acute treatment given in conjunction with aspirin and within ten days of the onset of symptoms. For children with Idiopathic or Immune Thrombocytopenic Purpura (ITP): Documentation of one of the following: a. Platelet count less than 20,000 and significant mucous membrane bleeding b. Platelet count less than 10,000 and minor purpura c. Rapid increase in platelets required due to planned surgery, dental extractions, or other procedures likely to cause blood loss. For pregnant women with ITP: Documentation of one of the following: a. Platelet count is less than 100,000 b. History of splenectomy c. History of delivered infant with autoimmune thrombocytopenia. For adult patients with ITP: 1. Documentation of one of the following: a. Platelet count of less than 30,000 b. Platelet count less than 50,000 with acute bleeding or high-risk of bleeding c. To defer or avoid splenectomy d. Rapid increase in platelets required due to planned surgery, dental extractions, or other procedures likely to cause blood loss AND 2. Documentation that IGG product will be used in combination with corticosteroid therapy or corticosteroid therapy is contraindicated.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, an appropriate specialist (e.g., a neurologist for multiple sclerosis or a hematologist for autoimmune hemolytic anemia)

COVERAGE DURATION

Initial authorization for 6 months. Reauthorization for 12 months.

OTHER CRITERIA

For prevention of infections in patients with chronic B-cell CLL: 1. Documented pre-treatment endogenous IgG less than 700 mg/dL OR more than 2 standard deviations below mean for the patient's age OR 2. History of recurrent, severe bacterial infections requiring antibiotics and/or hospitalization. For dermatomyositis and polymyositis: 1. Documented trial, failure, intolerance or contraindication to systemic corticosteroids with concurrent immunosuppressive treatment, 2. Documentation of severe symptoms/disability despite therapy with above agents. For multifocal motor neuropathy: 1. Motor involvement of at least two nerves (for more than one month) without symptoms of sensory abnormalities AND 2. Documentation of severe disease/disability. For MS: 1. Documentation of relapsing/remitting disease AND 2. Documented trial, failure, intolerance or contraindication to at least 2 conventional therapies. For Allogenic Bone Marrow Transplantation or Hematopoietic Stem Cell Transplant (HSCT) Recipients: 1. Therapy is requested for use within 100 days of transplantation (transplantation date must be documented) OR 2. Documentation of that member has hypogammaglobulinemia (see criteria for Secondary Immunodeficiency). For chronic inflammatory demyelinating polyneuropathy (CIDP): 1. Documentation of severe disability and 2. One of the following: a. Documented trial, failure, intolerance or contraindication to systemic corticosteroids, b. Documentation of pure motor CIDP. For autoimmune hemolytic anemia: 1. Documented trial, failure, intolerance or contraindication to systemic corticosteroids AND 2. Documented trial, failure, intolerance or contraindication to another conventional therapy (e.g., cyclophosphamide, azathioprine, cyclosporine). For Guillain-Barre Syndrome: Documentation that symptom onset is within 2 weeks or symptoms are severe (e.g. unable to ambulate independently). For myasthenia gravis exacerbation: 1. Evidence of myasthenic exacerbation, defined by at least one of the following symptoms in the last month: difficulty swallowing, acute respiratory failure, major functional disability responsible for the discontinuation of physical activity. For myasthenia gravis refractory disease: 1. Documentation that patient has severely impaired function due to myasthenia gravis AND 2. Documented trial, failure, intolerance or contraindication to at least 2 of the following conventional therapies: acetylcholinesterase inhibitors (e.g., pyridostigmine), corticosteroids or immunosuppressive agents. For autoimmune mucocutaneous blistering disease [pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatricial) pemphigoid, epidermolysis bullosa acquisita, pemphigoid gestationis, linear IgA bullous dermatosis]: 1. Biopsy proven disease AND 2. Documented trial, failure, intolerance or contraindication to systemic corticosteroids with concurrent immunosuppressive treatment.

GATTEX

MEDICATION(S)
GATTEX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For short bowel syndrome (SBS) all of the following criteria must be met: 1. An initial nutritional assessment has been completed by a registered dietitian who has determined that oral/enteral nutrition is not sufficient to meet nutritional goals, 2. Patient is stable and dependent on parenteral support (fluids, electrolytes and/or nutrients) delivered at least three times per week, AND 3. The medication has been made part of a treatment plan established by a gastroenterologist or a hospital Metabolic Support Team that includes: a. Member evaluation indicates the possibility of success with treatment b. Defined parameters to measure response to therapy

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial authorization and reauthorization will be approved for six months.

OTHER CRITERIA
N/A

GNRH ANTAGONISTS

MEDICATION(S)
ORIAHNN, ORILISSA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Patient has osteoporosis or severe hepatic impairment.

REQUIRED MEDICAL INFORMATION
Initial authorization in endometriosis (Orilissa only): 1. Documentation that patient has moderate to severe pain associated with endometriosis AND 2. Documentation that patient has trial and failure of, intolerance to, or contraindication to at least one hormonal contraceptive agent. Reauthorization: 1. Request is for the 150 mg daily dose and total duration will not exceed 24 months AND 2. Documentation of a positive response to therapy (e.g., reduction in pain). Initial authorization in management of heavy menstrual bleeding associated with uterine leiomyomas/fibroids (Oriahnn only): 1. Documentation of confirmed diagnosis of uterine fibroids (e.g. ultrasound), AND 2. Documentation of heavy menstrual bleeding, AND 3. Documentation that patient has trial and failure of, intolerance to, or contraindication to hormonal contraceptives. Reauthorization: 1. Total treatment duration will not exceed 24 months, AND 2. Documentation of a positive response to therapy (e.g., reduction in bleeding).

AGE RESTRICTION
Approved for patients 18 years of age and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an obstetrician-gynecologist (OB-GYN)

COVERAGE DURATION
Initial x 6 months. Reauth approved for 12 mo up to 24 mo. Orilissa 200mg is not elig for reauth.

OTHER CRITERIA
N/A

HEPATITIS C

MEDICATION(S)
LEDIPASVIR-SOFOSBUVIR, SOFOSBUVIR-VELPATASVIR, VOSEVI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria will be applied consistent with current American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a gastroenterologist, hepatologist, infectious disease specialist, or providers experienced in Hepatitis C management.

COVERAGE DURATION
8 to 24 weeks based on medication, indication and established treatment guidelines

OTHER CRITERIA
N/A

HEREDITARY ANGIOEDEMA THERAPY

MEDICATION(S)
CINRYZE, HAEGARDA, ICATIBANT, ORLADEYO, SAJAZIR, TAKHZYRO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use of more than one agent used for prophylaxis

REQUIRED MEDICAL INFORMATION
All of the following must be met: 1. Diagnosis of Hereditary Angioedema (HAE) Type I, II or III, 2. One of the following: a. For HAE Type I and Type II, documentation of a complement study that shows: i. C4 less than normal AND ii. One of the following: C1-Inhibitor (C1-INH) protein or C1-INH function less than normal. b. For HAE with normal C1-INH or HAE Type III, one of the following: i. Confirmed Factor 12 (FXII) ANGPT1, PLG, KNG1 gene mutation OR ii. Positive family history for HAE and attacks that lack response to high dose antihistamines or corticosteroids, and 3. Dosing regimens are within FDA labeled dosing outlined in package insert or sufficient evidence-based rationale is provided for increased dosing and/or frequency. 4. For coverage of Cinryze: Documentation of trial and failure or contraindication to Haegarda. Reauthorization requires documentation of positive clinical response to therapy.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial prior authorization will be approved for 3 months. Reauthorization may be approved for 1 yr.

OTHER CRITERIA
N/A

HETLIOZ

MEDICATION(S)
HETLIOZ, HETLIOZ LQ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Sleep disorders other than Non-24 and nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)

REQUIRED MEDICAL INFORMATION
For Non-24-Hour Sleep-Wake Disorder (Non-24): All of the following criteria must be met: 1. Member is totally blind (i.e. no light perception), 2. Documented diagnosis of Non-24-Hour Sleep-Wake Disorder (Non-24), as characterized by all of the following: a. Distinct pattern of sleeping and waking that drifts by a consistent time period every night AND b. History of periods of insomnia, excessive sleepiness, or both, which alternate with short asymptomatic periods, 3. Documented sleep study to exclude other sleep disorders. Reauthorization requires documentation of entrainment to the 24-hour circadian period. For nighttime sleep disturbances in Smith-Magenis Syndrome (SMS): All of the following criteria must be met: 1. Documented diagnosis of SMS, as characterized by: a. Confirmation of the deletion or mutations of retinoic acid-induced 1 (RAI1) gene, 2. Documented sleep study to exclude other sleep disorders, 3. Documentation of at least one of the following: a. difficulties falling asleep, b. shortened sleep cycles, c. frequent and prolonged nocturnal awakenings, d. excessive daytime sleepiness or e. daytime napping. Reauthorization requires documentation of improvement in sleep quality or total sleep time.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a sleep specialist or neurologist

COVERAGE DURATION
Initial authorization will be approved for 6 months. Reauthorization will be approved for 1 year.

OTHER CRITERIA
N/A

HUMAN GROWTH HORMONES

MEDICATION(S)
OMNITROPE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Treatment of adults: 1. For GHD in adults that had GHD as a child, the following criteria must be met: a. Patient has congenital defects, genetic defects, organic hypothalamic-pituitary disease (e.g., suprasellar mass with irreversible damage from previous surgery and irradiation) or other history of destructive lesions of the hypothalamic region (such as traumatic brain injury) and b. One of the following: i. At least 3 pituitary hormone deficiencies (other than GH) AND IGF-1 level less than or equal to 2 Standard Deviations (SDS) below normal, ii. IGF-1 level below normal and one of the following stimulation tests: 1. Insulin Tolerance Test with peak GH less than or equal to 5 mcg/L, 2. Glucagon Stimulation Test based on BMI: a. BMI less than 25: Peak GH less than or equal to 3 mcg/L b. BMI 25-30: Peak GH less than/equal to 1 mcg/L. For patients with high clinical suspicion of GHD, peak GH less than 3 mcg/L may be considered c. BMI 30 and above: Peak GH less than/equal to 1 mcg/L 3. If ITT/GST are contraindicated, macimorelin with peak GH less than or equal to 2.8 mcg/L, 2. For GHD diagnosed as adult, one of the following: a. For patients with history of destructive lesions of the hypothalamic region (e.g., hypothalamic-pituitary tumors, surgery, or cranial irradiation, empty sella, pituitary apoplexy, traumatic brain injury), all of the following: i. IGF-1 level below normal and ii. One stimulation test from criterion 1.a.ii., or b. For organic disease of the hypothalamic region from congenital or genetic defects: same as 1.b. above. Reauthorization for GHD in adults requires evidence of improved quality of life and annual documentation of IGF-1 levels with appropriate dose adjustments, 3. For HIV associated wasting, all of the following: a. Involuntary loss of at least 10% body weight, b. Absence of other related illnesses contributing to weight loss, and c. Documented failure, intolerance, or contraindication to appetite stimulants and/or anabolic agents.

AGE RESTRICTION
N/A

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

COVERAGE DURATION

GHD: Initial/reauth for 12 months. SBS: 4 weeks. AIDS wasting: 12 months.

OTHER CRITERIA

Treatment of children: 1. For GHD, must meet criteria for one of the following: a. Newborn with hypoglycemia and both of the following: i. Serum GH level less than or equal to 5 mcg/L and ii. One of the following: 1. An additional pituitary hormone deficiency (other than GH), or 2. Classical imaging triad (ectopic posterior pituitary and pituitary hypoplasia with abnormal stalk), b. Patient with extreme short stature (height more than 3 SDS below the mean for chronological age/sex) and all of the following: i. IGF-1 level at least 2 SDS below normal, ii. Insulin-like growth factor binding protein-3 (IGFBP-3) at least 2 SDS below normal, or iii. Delayed bone age, defined as bone age that is 2 SDS below the mean for chronological age, c. Patient has pituitary abnormality (secondary to a congenital anomaly, tumor, or irradiation) and meets both of the following criteria: i. An additional pituitary hormone deficiency (other than GH), and ii. Evidence of short stature/growth failure (GF) by one of the following: 1. Height more than 3 SDS below the mean for chronological age/sex, 2. Height below 3rd percentile (or greater than 2 SD below the mean) AND untreated growth velocity (GV) is below the 25th percentile, 3. Severe growth rate deceleration (GV over one year of more than 2 SD below the mean for age/sex), d. Patient with suspected GHD must meet all of the following: i. Evidence of short stature/GF using criteria 1.c.ii. above, ii. Biochemical GHD by one of the following: 1. Two GH stimulation tests (using arginine, clonidine, glucagon, insulin or levodopa) with peak GH concentrations less than 10 ng/ml or 2. One GH stim test with peak GH less than 15ng/ml and IGF-1 and IGFBP-3 levels below normal, 2. For Prader-Willi Syndrome: confirmed diagnosis by genetic testing, 3. For Turner’s Syndrome: a. Confirmed diagnosis by genetic testing AND b. Evidence of short stature/GF using criteria 1.c.ii. above, 4. For Noonan Syndrome: confirmed diagnosis by genetic testing or made by pediatric endocrinologist based on clinical features, AND b. Evidence of short stature/GF using criteria 1.c.ii. above, 5. For Chronic Renal Insufficiency: a. Other causes of growth failure have been ruled out, b. Nutritional status has been optimized, AND c. Evidence of short stature/GF using criteria 1.c.ii. above, 6. For Small for Gestational Age: a. Birth weight or length at least two SDS below the mean AND b. Current height at least two SDS below the mean for age/sex. For Reauthorization for children: 1. Evidence of GV more than 2.5 cm/year AND 2. Evidence of open epiphyses

IL-5 INHIBITORS

MEDICATION(S)
FASENRA PEN, NUCALA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with another therapeutic immunomodulator agent utilized for the same indication.

REQUIRED MEDICAL INFORMATION
For initial authorization, must meet all of the following criteria: For eosinophilic asthma: 1. Documentation of eosinophilic asthma by one of the following: a. A blood eosinophil count of greater than 150 cells/microliter in the past 12 months, or b. Past history of eosinophilic asthma if currently on daily maintenance treatment with oral glucocorticoids, 2. Documentation of treatment with maximally tolerated dose of medium to high dose inhaled corticosteroid plus an additional asthma controller (e.g., long-acting inhaled beta2-agonist, leukotriene receptor antagonist), 3. Documentation of severe asthma with inadequate control such as frequent exacerbations requiring oral corticosteroids or hospitalizations or a poor asthma control scores (An ACT score less than 20 or an ACQ greater than or equal to 1.5). For hypereosinophilic syndrome (HES): 1. Request is for mepolizumab (Nucala) 2. Document of primary HES without an identifiable nonhematologic secondary cause such as parasitic infections, solid tumors, or T cell lymphoma 3. Blood eosinophil count of 1,000 cells/microliter or higher for at least 6 months 4. Documentation of use of HES therapy including one of the following in the past for the past 12 months: a. chronic or episodic oral corticosteroids, b. immunosuppressive therapy, c. cytotoxic therapy 5. Documentation of at least two HES flares within the past 12 months (defined as HES-related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Medications must be prescribed by, or in consultation with the following specialists based on the diagnosis. 1. Asthma: asthma specialist (such as a pulmonologist, immunologist, or allergist), 2. EGPA: pulmonologist, neurologist, or rheumatologist, 3. HES: hematologist, immunologist, pulmonologist, cardiologist, or neurologist, 4. CRSwNP: otolaryngologist, allergist, or pulmonologist.

COVERAGE DURATION

EGPA/HES/CRSwNP:Initial 6 mo/reauth 1 yr. Asthma:Initial 1 yr/reauth until no longer elig with plan

OTHER CRITERIA

For eosinophilic granulomatosis with polyangiitis (EGPA): 1. Request is for mepolizumab (Nucala) 2. History or presence of asthma 3. Blood eosinophil level of at least 10% or an absolute eosinophil count of more than 1000 cells/microliter 4. Documentation of one of the following a. History of relapse requiring an increase in glucocorticoid dose, initiation or increase in other immunosuppressive therapy, or hospitalization in the previous 2 years while receiving at least 7.5 mg/day prednisone (or equivalent) OR b. Failure to achieve remission following a standard induction regimen administered for at least 3 months OR recurrence of symptoms of EGPA while tapering of glucocorticoids. Standard treatment regimens include: prednisone (or equivalent) dosed at least 7.5 mg/day in combination with an immunosuppressant such as cyclophosphamide, azathioprine, methotrexate, or mycophenolate mofetil. For Chronic Rhinosinusitis with Nasal Polyp (CRSwNP): 1. Request is for mepolizumab (Nucala) 2. Evidence of nasal polyposis by direct examination, endoscopy or sinus CT scan, 3. Documentation that patient has had an inadequate response to (within the past 90 days), or has an intolerance, FDA labeled contraindication, or hypersensitivity to, oral systemic corticosteroids 4. Patient has had an inadequate response to a three month trial of intranasal corticosteroids (e.g., fluticasone) or has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an intranasal corticosteroid 5. Documentation that patient will continue standard maintenance therapy (e.g., intranasal corticosteroids) in combination with the requested agent. Reauthorization for asthma, HES, and EGPA requires documentation of positive clinical response to therapy, such as attainment and maintenance of remission or decrease in number of relapses. Reauthorization for CRSwNP: 1. Documentation of positive clinical response to therapy, 2. Documentation that patient will continue standard maintenance therapy (e.g., intranasal corticosteroids) in combination with the requested agent, unless documented intolerance, FDA labeled contraindication, or hypersensitivity to such therapy.

INCRELEX

MEDICATION(S)
INCRELEX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Subjects with secondary forms of IGF-1 deficiency (e.g., GH deficiency, malnutrition, hypothyroidism, chronic treatment with pharmacologic doses of anti-inflammatory steroids). Concurrent use of growth hormone therapy. Malignant neoplasia

REQUIRED MEDICAL INFORMATION
For severe primary IGF-1 deficiency all of the following criteria must be met: 1. Height standard deviation score of less than or equal to -3.0, 2. Basal IGF-1 standard deviation score of less than or equal to -3.0, 3. Normal or elevated growth hormone (GH) levels, AND 4. Documentation of open epiphyses by bone radiograph. For GH gene deletion: 1. Documentation of open epiphyses by bone radiograph AND 2. Patient has developed neutralizing antibodies to growth hormone. Reauthorization will require evidence that the medication remains effective, growth velocity is above 2.0 cm/year, evidence of open epiphyses, and documentation of expected adult height goal that is not yet obtained.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA
N/A

ISTURISA/SIGNIFOR

MEDICATION(S)
ISTURISA, SIGNIFOR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization all of the following criteria must be met: 1. Diagnosis of endogenous Cushing’s Disease AND 2. Documentation of one of the following: a. Patient has failed pituitary surgery OR b. Patient is not a candidate for surgery. Reauthorization requires 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).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an endocrinologist

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA
N/A

JUXTAPID

MEDICATION(S)
JUXTAPID

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
All of the following must be met: 1. Diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) as evidenced by either genetic or clinical confirmation, as outlined below: a. Genetic confirmation: biallelic functional mutations in the low density lipoprotein receptor (LDLR), apolipoprotein B (apo B), or proprotein convertase subtilisin/kexin type 9 (PCSK9) genes, b. Clinical confirmation defined as untreated total cholesterol greater than 500 mg/dL and one of the following: i. Presence of xanthomas before the age of 10 years, or ii. Untreated total cholesterol level greater than 250 mg/dL in both parents AND 2. Current use of both of the following therapies: a. High-intensity statin therapy, defined as atorvastatin 80mg daily or rosuvastatin 40mg daily, unless contraindicated or documented statin intolerance and b. PCSK-9 inhibitor (e.g., evolocumab), unless contraindicated or prior intolerance, 3. Documentation of LDL cholesterol levels greater than 100 mg/dL despite at least six (6) months of use of the therapies outlined above. Initial reauthorization requires documentation of at least a 30% reduction in LDL cholesterol levels from pre-treatment levels.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a cardiologist, endocrinologist, or board certified lipidologist

COVERAGE DURATION
Initial auth approved for 1 year. Reauth will be approved until no longer eligible with the plan

OTHER CRITERIA
N/A

KERENDIA

MEDICATION(S)
KERENDIA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of therapy:
1. Patient has a diagnosis of type 2 diabetes
2. Patient has evidence of diabetic nephropathy, defined as one of the following:
a. Estimated glomerular filtration rate (eGFR) of 60 mL/min/1.73m2 or less for at least three months
b. Persistent moderate to severe albuminuria [urine albumin-to-creatinine ratio (UACR) 30 mg/g or greater, or 0.113 mg/mmol or greater] for at least three months
c. Moderate to severe proteinuria [urine protein-to-creatinine ratio (UPCR) 200 mg/g or greater] for at least three months
3. Documentation that patient is on a maximally tolerated Angiotensin Converting Enzyme inhibitor (such as lisinopril) or an Angiotensin Receptor Blocker (such as losartan), unless all agents in these classes are contraindicated
4. Documentation of trial, contraindication, or intolerance to a Sodium Glucose Co-transporter-2 inhibitor (such as empagliflozin or dapagliflozin)

AGE RESTRICTION
Approved for patients 18 years of age and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan.

OTHER CRITERIA
N/A

KORLYM

MEDICATION(S)
KORLYM

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Current pregnancy

REQUIRED MEDICAL INFORMATION
Initial authorization: 1. Documentation that the patient has hyperglycemia secondary to endogenous Cushing’s Syndrome (defined as hypercortisolism that is not a result of chronic administration of high dose glucocorticoids), AND 2. Documentation that the patient has type 2 diabetes mellitus or glucose intolerance, AND 3. Documentation that the patient has failed surgery or is not a candidate for surgery. Reauthorization: Documentation that the patient has improved or stable glucose tolerance.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.

OTHER CRITERIA
N/A

KUVAN

MEDICATION(S)
JAVYGTOR 100 MG POWDER PACKET, JAVYGTOR 100 MG TABLET, SAPROPTERIN DIHYDROCHLORIDE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Doses greater than 20mg/kg/day will not be approved. Use in combination with pegvalise-pqpz (Palynziq).

REQUIRED MEDICAL INFORMATION
Initial authorization: 1. Diagnosis of phenylketonuria (PKU) AND 2. Documentation that the patients pre-treatment phenylalanine blood levels measured within 90 days prior to starting therapy is above 6 mg/dL (360 micromol/L) in children less than 12 years of age, or above 10 mg/dL (600 micromol/L) for ages 12 and older. Reauthorization requires improvement in average blood Phe level from pretreatment baseline.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a specialist in metabolic disorders

COVERAGE DURATION
Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.

OTHER CRITERIA
N/A

LIDOCAINE PATCH

MEDICATION(S)
LIDOCAINE 5% PATCH

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

OFF LABEL USES
Diabetic peripheral neuropathy and cancer-related neuropathic pain.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Confirmed diagnosis of post-herpetic neuralgia, cancer-related neuropathic pain, or diabetic peripheral neuropathy

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization for 3 months. Reauthorization for 6 months.

OTHER CRITERIA
N/A

LONG-ACTING OPIOIDS

MEDICATION(S)

BELBUCA, BUPRENORPHINE, BUPRENORPHINE 150 MCG FILM, BUPRENORPHINE 300 MCG FILM, BUPRENORPHINE 450 MCG FILM, BUPRENORPHINE 600 MCG FILM, BUPRENORPHINE 75 MCG FILM, BUPRENORPHINE 750 MCG FILM, BUPRENORPHINE 900 MCG FILM, FENTANYL 100 MCG/HR PATCH, FENTANYL 12 MCG/HR PATCH, FENTANYL 25 MCG/HR PATCH, FENTANYL 50 MCG/HR PATCH, FENTANYL 75 MCG/HR PATCH, HYDROCODONE ER 10 MG CAPSULE, HYDROCODONE ER 15 MG CAPSULE, HYDROCODONE ER 20 MG CAPSULE, HYDROCODONE ER 30 MG CAPSULE, HYDROCODONE ER 40 MG CAPSULE, HYDROCODONE ER 50 MG CAPSULE, LEVORPHANOL 2 MG TABLET, METHADONE 10 MG/5 ML SOLUTION, METHADONE 5 MG/5 ML SOLUTION, METHADONE HCL 10 MG TABLET, METHADONE HCL 5 MG TABLET, XTAMPZA ER

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

As needed (prn) use. For treatment of acute pain such as recent injury, sprain, strain or surgery.

REQUIRED MEDICAL INFORMATION

For ALL requests, chart notes must be provided documenting the following: 1. Outline of current treatment regimen including all opioids with daily dose and frequency, all non-opioid therapy, and/or non-pharmacological therapy AND 2. Comprehensive documentation including an appropriate patient medical history, physical examination, and treatment plan. In addition, patient must meet all of the criteria under one of the patient-specific conditions listed below: A. For patients initiating long-acting opioid therapy for cancer pain, palliative care with a terminal diagnosis, sickle cell disease, or severe burns: 1. Documentation of active pain directly related to the condition(s) mentioned above, AND 2. Documentation that with in the past 30 days patient has failed at least a two-week trial of short-acting opioids and is requiring at least four doses daily consistently to manage pain AND 3. Documentation of trial and failure, contraindication, or intolerance to long-acting morphine sulfate therapy. B. For patients established on long-acting opioid therapy for cancer pain, palliative care with a terminal diagnosis, sickle cell disease, or severe burns: 1. Documentation of positive response to therapy AND 2. Documentation of continued active pain directly related to the condition(s) mentioned above.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA

C. For patients initiating long-acting opioid therapy for chronic pain (other than cancer pain, palliative care, sickle cell disease, or severe burns): 1. Documentation of chronic pain (lasting longer than 3 months) that is severe enough to require around-the-clock analgesic therapy, 2. Documentation that within the past 30 days patient has failed at least a two-week trial of short-acting opioids and is requiring at least four doses daily consistently to manage pain, 3. Documentation that the pain is not caused by a condition for which opioids are not recommended, including: migraine headaches, fibromyalgia, abdominal pain, diabetic neuropathy, 4. No contraindications to opioids, including but not limited to: untreated substance use disorder, significant respiratory depression, hypercapnia, or central apnea GI obstruction or paralytic ileus, 5. Documentation of trial and failure, contraindication, or intolerance to long-acting morphine sulfate therapy, 6. Documentation of a pain management agreement between the prescriber and patient including monitoring plan and functional goals, 7. Documentation that Prescription Drug Monitoring Program (PDMP) has been checked, AND 8. For fentanyl patch: Patient must be opioid-tolerant, defined as using at least 60 morphine milligram equivalents (MME) per day. D. For patients established on long-acting opioid therapy for chronic pain (other than cancer pain, palliative care, sickle cell disease, or severe burns) all of the following criteria must be met: 1. Documentation of positive response to therapy, 2. Documentation of appropriate monitoring with no findings of concern for adverse events (e.g. no unmonitored dose escalation, no excess sedation, no signs of developing substance use disorder), 3. Documentation of a pain management agreement between the prescriber and patient including monitoring plan and functional goals. AND 4. Documentation that PDMP has been checked.

LUPKYNIS

MEDICATION(S)
LUPKYNIS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
1. Estimated glomerular filtration rate (eGFR) less than 45. 2. Use in combination with benlimumab (Benlysta®), anifrolumab (Saphnelo®) or cyclophosphamide

REQUIRED MEDICAL INFORMATION
For active lupus nephritis, all of the following must be met: 1. Confirmed diagnosis of systemic lupus erythematosus (SLE) 2. Kidney biopsy with a histologic diagnosis of lupus nephritis classes III, IV, or V 3. Documentation of laboratory test results indicating that patient has presence of auto-antibodies for SLE, defined as one (1) of the following: a. Positive Antinuclear antibody (ANA) b. Positive anti-double-stranded DNA (anti-dsDNA) on two or more occasions, OR if tested by ELISA, an antibody level above laboratory reference range c. Positive anti-Smith (Anti-Sm) d. Positive anti-Ro/SSA and anti-La/SSB antibodies 4. Documented failure of an adequate trial of 30-day duration (such as inadequate control with ongoing disease activity and/or frequent flares), contraindication, or intolerance to at least one of the following: a. Mycophenolate-based regimen OR b. Cyclophosphamide-based regimen 5. Documentation that patient will continue to receive standard therapy (e.g., corticosteroids, mycophenolate, azathioprine). Reauthorization criteria: 1. Documentation currently receiving standard therapy active lupus nephritis 2. Documentation of a positive response to therapy based on one of the following: a. Improvement in urine protein/creatinine ratio (UPCR) (i.e. less than or equal to 0.5 mg/mg) and eGFR of at least 60 b. Decrease from baseline in eGFR of less than 20%

AGE RESTRICTION
Approved for adults 18 years of age and older

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

COVERAGE DURATION
Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.

OTHER CRITERIA

N/A

MEDICATIONS FOR RARE INDICATIONS

MEDICATION(S)
CARGLUMIC ACID, CERDELGA, MIGLUSTAT, RAVICTI, SODIUM PHENYLBUTYRATE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial authorization: 1. Confirmation of FDA-labeled indication AND 2. Dosing is within FDA-labeled guidelines OR documentation has been submitted in support of therapy with a higher dose for the intended diagnosis (e.g., high-quality peer reviewed literature, guidelines, other clinical information). Reauthorization: 1. Documentation of successful response to therapy AND 2. Dosing is within FDA-labeled guidelines OR documentation has been submitted in support of therapy with a higher dose for the intended diagnosis (e.g., high-quality peer reviewed literature, guidelines, other clinical information).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an endocrinologist, geneticist, hematologist, or metabolic disorder specialist.

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA
N/A

MYALEPT

MEDICATION(S)
MYALEPT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. Diagnosis of congenital or acquired generalized lipodystrophy (i.e., not related to HIV, nor obesity not related to leptin deficiency) AND 2. Documentation of at least one of the following metabolic complications of leptin deficiency: a. Diabetes mellitus b. Triglyceride levels greater than or equal to 200 mg/dL c. Increased fasting insulin levels greater than or equal to 30 microU/mL AND 3. Documentation that the patient has not had a response to current standards of care for lipid and diabetic management. Reauthorization requires documentation of response to therapy as indicated by one of the following: a. Sustained reduction in hemoglobin A1c level from baseline or b. Sustained reduction in triglyceride levels from baseline.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA
N/A

NARCOLEPSY AGENTS

MEDICATION(S)
SUNOSI, WAKIX, XYREM, XYWAV

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For cataplexy with narcolepsy, all of the following criteria must be met: 1. Diagnosis of narcolepsy as confirmed by sleep study or low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (less than 110 pg/mL or less than one-third of the normative values with the same standardized assay), 2. Documentation of excessive daytime sleepiness defined as an Epworth Sleepiness Scale (ESS) score greater than or equal to 12, or documentation of daily periods of irrepressible need to sleep/daytime lapses into sleep occurring for at least three (3) months, 3. Documentation of at least three (3) weekly cataplexy attacks, 4. For adult patients requesting sodium oxybate (Xyrem/Xywav): documentation of a 30-day trial and failure, intolerance, or contraindication to pilotisant (Wakix). For excessive daytime sleepiness with narcolepsy, the following criteria must be met: 1. Diagnosis of narcolepsy as confirmed by sleep study or low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (less than 110 pg/mL or less than one third of the normative values with the same standardized assay), 2. Documentation of daily periods of irrepressible need to sleep/daytime lapses into sleep occurring for at least three (3) months, 3. Other causes of sleepiness have been ruled out or treated (such as obstructive sleep apnea, shift work, effects of substances or medications or their withdrawal, other sleep disorders), 4. For adult patients: documentation of a 30-day trial and failure, intolerance, or contraindication to both of the following: a. modafinil or armodafinil and b. For patients requesting sodium oxybate (Xyrem/Xywav): documentation of a 30-day trial and failure, intolerance, or contraindication to pilotisant (Wakix).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a sleep specialist, neurologist, pulmonologist, or psychiatrist

COVERAGE DURATION

Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.

OTHER CRITERIA

For excessive sleepiness due to Obstructive Sleep Apnea (OSA), solriamfetol (Sunosi) will be covered if the following criteria are met: 1. Diagnosis of OSA as confirmed by sleep study and 2. Documented trial and failure, intolerance or contraindication of armodafinil or modafinil. For idiopathic hypersomnia, sodium oxybate salt (Xywav) will be covered if all of the following criteria are met: 1. Diagnosis of idiopathic hypersomnia confirmed by sleep study 2. Documentation that sleepiness is not due to another medical, behavioral, or psychiatric disorder condition, including but not limited to: insufficient sleep (less than seven hours per night), depression, sedating medications, and sleep-related breathing disorders. 3. Documentation of excessive daytime sleepiness defined as an Epworth Sleepiness Scale (ESS) score greater than or equal to 12, or documentation of daily periods of irrepressible need to sleep/daytime lapses into sleep occurring for at least three months. Reauthorization requires documentation of successful response to the medication, such as a reduction in symptoms of excessive daytime sleepiness or reduction in frequency of cataplexy attacks.

NEXLETOL/NEXLIZET

MEDICATION(S)
NEXLETOL, NEXLIZET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Initial Authorization: 1. Confirmed diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) or familial hypercholesterolemia, 2. Fasting LDL-C greater than or equal to 70 mg/dL despite treatment with therapies below, 3. One of the following: a. Current use of high-intensity statin therapy for at least 3 months, defined as atorvastatin 80 mg daily or rosuvastatin 40 mg daily or b. Documented intolerance, FDA labeled contraindication or hypersensitivity to a statin, 4. Current use of a formulary PCSK-9 inhibitor (i.e., Repatha®) for at least three (3) months, or documented intolerance/contraindication to its use. Reauthorization requires documented response to therapy, as defined by a reduction in fasting LDL-C.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial auth approved for 6 months. Reauth will be approved until no longer eligible with the plan.

OTHER CRITERIA
N/A

NOURIANZ

MEDICATION(S)
NOURIANZ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Patients with a major psychotic disorder

REQUIRED MEDICAL INFORMATION
Initial authorization: 1. Confirmed diagnosis of Parkinson’s Disease 2. Documentation the patient is experiencing OFF episodes with current use of oral carbidopa/levodopa therapy 3. Documentation of attempts to adjust dosing and formulation of carbidopa/levodopa to manage OFF symptoms 4. Documentation that at least one other agent has been used as adjunctive therapy with carbidopa/levodopa to reduce number and frequency of OFF episodes (e.g. dopamine agonist, COMT inhibitor, or MAO-B inhibitor). Reauthorization: Documentation that patient had a positive response to therapy, such as decrease in number, duration or severity of OFF episodes

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial authorization will be approved for 6 months, reauthorization will be approved for 1 year

OTHER CRITERIA
N/A

NUEDEXTA

MEDICATION(S)
NUEDEXTA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial authorization: Documentation of a neurologic disease or brain injury (such as traumatic brain injury, stroke, dementia, multiple sclerosis, amyotrophic lateral sclerosis [ALS], or Parkinson’s disease).
Reauthorization: Documentation of response to therapy, defined as a reduction in episodes of laughing, crying, and/or emotional lability.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA
N/A

NUPLAZID

MEDICATION(S)
NUPLAZID

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial authorization requires 1. Diagnosis of Parkinson’s disease with hallucinations and/or delusions causing clinically significant distress, with delirium ruled out AND 2. Mini-mental status exam (MMSE) score greater than or equal to 21 or Saint Louis University Mental Status (SLUMS) exam score greater than or equal to 16, to indicate that patients can self-report symptoms AND 3. Documented trial, failure, intolerance to clozapine or quetiapine OR contraindication to both clozapine and quetiapine. Reauthorization requires documentation of reduction in frequency and/or severity of hallucinations and/or delusions.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan.

OTHER CRITERIA
N/A

OCALIVA

MEDICATION(S)
OCALIVA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For the diagnosis of primary biliary cholangitis: 1. Confirmed diagnosis of primary biliary cholangitis as evidenced by two (2) of the following criteria: a. Elevated alkaline phosphatase (ALP) [above the upper limit of normal (ULN) as defined by laboratory reference values] b. Presence of antimitochondrial antibody (AMA) c. Histologic evidence of primary biliary cirrhosis from liver biopsy AND 2. Both of the following: a. Use of ursodiol for a minimum of six (6) months and has had an inadequate response according to prescribing physician AND b. Documentation that the medication will be used in combination with ursodiol, unless patient is unable to tolerate ursodiol. Reauthorization Criteria: 1. Maintenance of biochemical response (e.g. improvement or stabilization of ALP or total bilirubin levels) 2. Documentation that ursodiol will be continued, if tolerated 3. Hepatic function is assessed at least annually.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a gastroenterologist or hepatologist.

COVERAGE DURATION
Initial authorization will be approved for 4 months. Reauthorization will be approved for one year.

OTHER CRITERIA
N/A

OPZELURA (PENDING CMS APPROVAL)

MEDICATION(S)
OPZELURA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants

REQUIRED MEDICAL INFORMATION
For initial authorization for atopic dermatitis, all the following criteria must be met: 1. Diagnosis of mild to moderate atopic dermatitis despite therapies outlined in criterion number 2. Mild to moderate atopic dermatitis may be defined by all of the following: a. Patient has a body surface area (BSA) involvement of 3% to 20% b. Chronic condition, affecting patient for at least two years 2. Documented trial and failure, contraindication, or hypersensitivity to both of the following: a. A topical corticosteroids applied at least once daily for at least two weeks and b. A topical calcineurin inhibitor (such as tacrolimus ointment) applied twice daily for at least one month. For reauthorization for atopic dermatitis: Documentation of reduction or stabilization from baseline of flares, pruritis, erythema, edema, xerosis, erosions/excoriation, oozing/crusting, lichenification or affected BSA. For initial authorization for nonsegmental vitiligo, all the following criteria must be met: 1. Diagnosis of nonsegmental vitiligo with depigmented areas affecting less than or equal to 10% total BSA, which has both facial and non-facial involvement 2. Inadequate response to both of the following: a. A topical calcineurin inhibitor (such as tacrolimus) and b. A moderate to high potency topical corticosteroid (such as clobetasol or fluocinolone). For reauthorization for nonsegmental vitiligo: Documentation of positive clinical response to therapy

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a dermatologist, allergist, or immunologist

COVERAGE DURATION
Initial authorization will be approved for six months. Reauthorization will be approved for one year

OTHER CRITERIA

N/A

ORAL IVERMECTIN

MEDICATION(S)
IVERMECTIN 3 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Treatment or prevention of COVID-19 infection

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one month

OTHER CRITERIA
N/A

ORAL OCTREOTIDE

MEDICATION(S)
MYCAPSSA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial authorization: 1. Confirmed diagnosis of acromegaly, AND 2. Documentation of an inadequate response to surgery or pituitary irradiation or patient is not a candidate for surgical resection and pituitary irradiation, AND 3. Patient has been maintained (for at least 6 months) on octreotide injection therapy and responded to and tolerated therapy. Reauthorization requires documentation of a positive clinical response to therapy (e.g. reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization for 12 months

OTHER CRITERIA
N/A

ORENCIA

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

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For patients already established on the requested therapy: 1. Documentation of response to therapy (i.e. slowing of disease progression or decrease in symptom severity and/or frequency) and 2. One of the following: a. Patient is not currently being treated with another biologic immunomodulator OR b. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator. For patients being initiated on therapy, all of the following criteria must be met: 1. Patient must have an FDA labeled indication for the requested agent, 2. One of the following: a. Patient is not currently being treated with another biologic immunomodulator OR b. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator prior to starting the requested agent, 3. Documentation of trial and failure, intolerance, or contraindication to at least two (2) preferred biologic agents: Use of TWO preferred biologics (Enbrel, Humira, Rinvoq, Xeljanz or Xeljanz XR) is required for diagnosis of rheumatoid arthritis. Use of TWO preferred biologics (Enbrel, Humira, Xeljanz, or Xeljanz XR) is required for diagnosis of juvenile idiopathic arthritis. Use of TWO preferred biologics (Cosentyx, Tremfya, Enbrel, Humira, Otezla, Stelara, Xeljanz, or Xeljanz XR) is required for diagnosis of psoriatic arthritis.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA

N/A

OSTEOANABOLIC AGENTS

MEDICATION(S)
TERIPARATIDE, TYMLOS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For the treatment or prevention of osteoporosis, must meet ONE of the following criteria: 1. Patient has a history of multiple or severe vertebral fractures, or history of fragility fractures, OR 2. Patient has a spine or hip bone mineral density (BMD) T-score less than or equal to -2.5 and high risk for fracture, defined as one of the following: a. Age more than 80 years, b. Chronic glucocorticoid use, c. Documented increased fall risk, OR 3. Patient has a spine or hip BMD T-score less than or equal to -2.5 and one of the following: a. Documented failure to both denosumab and bisphosphonate therapies (e.g., alendronate). Failure is defined as a new fracture or worsening BMD or b. Documented contraindication or intolerance to both denosumab and bisphosphonate therapies, OR 4. Patient has a spine or hip BMD T-score between -1.0 and -2.5 and BOTH of the following: a. Fracture Risk Assessment (FRAX) probability score for hip fracture of at least 3% or, for other major osteoporosis fracture, of at least 20%, AND b. One of the following: i. Documented failure to both denosumab and bisphosphonate therapies. Failure is defined as a new fracture or worsening BMD or ii. Documented contraindication or intolerance to both denosumab and bisphosphonate therapies.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an endocrinologist or rheumatologist

COVERAGE DURATION
Initial auth x 2 yrs. Reauth will be limited based on max total duration in lifetime of 2 yrs.

OTHER CRITERIA
Part B before Part D Step Therapy. Applies only to beneficiaries in an MA-PD plan.

OXERVATE

MEDICATION(S)
OXERVATE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Retreatment of the same eye

REQUIRED MEDICAL INFORMATION
Initial authorization: 1. Confirmed diagnosis of stage 2 (recurrent/persistent epithelial defect) or stage 3 (corneal ulcer) neurotrophic keratitis in the affected eye(s) with diagnosis supported by chart notes AND 2. The request specifies the affected eye(s) intended for treatment. Reauthorization will not be renewed for retreatment of the same eye.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Authorization will be approved for 8 weeks per eye.

OTHER CRITERIA
N/A

PALYNZIQ

MEDICATION(S)
PALYNZIQ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Use in combination with sapropterin (Kuvan)

REQUIRED MEDICAL INFORMATION
For initial authorization all of the following criteria must be met: 1. Diagnosis of phenylketonuria (PKU) and 2. Blood phenylalanine concentration greater than 600 micromol/L (10 mg/dL) despite management with sapropterin (Kuvan). For reauthorization, ONE of the following criteria must be met: 1. Documentation of positive clinical response from therapy (such as an improvement in blood phenylalanine concentration levels) OR 2. For those not on maximum allowed dose of 60 mg once daily: Authorization for 6 months will be approved those who have not met blood phenylalanine control when there is a documented plan for further dose increase up to a maximum dose of 60 mg once daily. Note: Prescribing information recommends considering dose increase in those who have been on pegvaliase 20 mg daily for at least 24 weeks or 40 mg daily for at least 16 weeks and have not met blood phenylalanine control, up to a maximum dose of 60 mg once daily.

AGE RESTRICTION
Approved for patients 18 years of age and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a metabolic disease specialist or a provider who specializes in the treatment of PKU.

COVERAGE DURATION
Initial authorization for 6 months, reauthorization for 1 year

OTHER CRITERIA
N/A

PARATHYROID HORMONE

MEDICATION(S)
NATPARA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization, all of the following criteria must be met: 1. Patient must be diagnosed with permanent/chronic hypoparathyroidism (i.e. not acute post-surgical hypoparathyroidism), 2. Confirmed serum albumin corrected calcium is above 7.5 mg/dL (1.9 mmol/L), AND 3. Confirm serum 25-hydroxyvitamin D is greater than or equal to 30 ng/mL (75 nmol/L). Reauthorization requires annual documentation of regular monitoring of serum calcium levels with appropriate dosage adjustments to meet patient specific goal.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial authorization for 6 months and reauthorization will be approved for 1 year.

OTHER CRITERIA
N/A

PART D VS PART B

MEDICATION(S)

ABELCET, ACETYLCYSTEINE 10% VIAL, ACETYLCYSTEINE 20% VIAL, ACYCLOVIR SODIUM, ALBUTEROL 100 MG/20 ML SOLN, ALBUTEROL 2.5 MG/0.5 ML SOL, ALBUTEROL 5 MG/ML SOLUTION, ALBUTEROL SUL 0.63 MG/3 ML SOL, ALBUTEROL SUL 1.25 MG/3 ML SOL, ALBUTEROL SUL 2.5 MG/3 ML SOLN, AMBISOME, AMINOSYN II 15% IV SOLUTION, AMPHOTERICIN B 50 MG VIAL, AMPHOTERICIN B LIPOSOME, ASCENIV, ASTAGRAF XL, AZATHIOPRINE 50 MG TABLET, AZATHIOPRINE SODIUM, BUDESONIDE 0.25 MG/2 ML SUSP, BUDESONIDE 0.5 MG/2 ML SUSP, BUDESONIDE 1 MG/2 ML INH SUSP, CALCITONIN-SALMON 200 UNITS SP, CALCITRIOL 0.25 MCG CAPSULE, CALCITRIOL 0.5 MCG CAPSULE, CALCITRIOL 1 MCG/ML SOLUTION, CELLCEPT 200 MG/ML ORAL SUSP, CINACALCET HCL, CLINOLIPID, CROMOLYN 20 MG/2 ML NEB SOLN, CUTAQUIG, CUVITRU, CYCLOPHOSPHAMIDE 25 MG CAPSULE, CYCLOPHOSPHAMIDE 25 MG TABLET, CYCLOPHOSPHAMIDE 50 MG CAPSULE, CYCLOPHOSPHAMIDE 50 MG TABLET, CYCLOSPORINE 100 MG CAPSULE, CYCLOSPORINE 25 MG CAPSULE, CYCLOSPORINE MODIFIED, DERMACINRX EMPRICAINE, DERMACINRX PRIZOPAK, DOXERCALCIFEROL 0.5 MCG CAP, DOXERCALCIFEROL 1 MCG CAPSULE, DOXERCALCIFEROL 2.5 MCG CAP, 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, GAMASTAN, GAMASTAN S-D, GANCICLOVIR 500 MG VIAL, GENGRAF, HEPARIN 10,000 UNIT/10 ML VIAL, HEPARIN 2,000 UNIT/2 ML VIAL, HEPARIN 30,000 UNIT/30 ML VIAL, HEPARIN SOD 1,000 UNIT/ML VIAL, HIZENTRA, HYQVIA, INTRALIPID, IPRATROPIUM BR 0.02% SOLN, IPRATROPIUM-ALBUTEROL, LEVOCARNITINE 1 G/10 ML SOLN, LEVOCARNITINE 330 MG TABLET, LIDO-PRILO CAINE PACK, LIDOCAINE 5% OINTMENT, LIDOCAINE-PRILOCAINE, LIDOPRIL, LIDOPRIL XR, MYCOPHENOLATE 200 MG/ML SUSP, MYCOPHENOLATE 250 MG CAPSULE, MYCOPHENOLATE 500 MG TABLET, MYCOPHENOLIC ACID, NULOJIX, NUTRILIPID, OCTAGAM, OMEGAVEN, PANZYGA, PARICALCITOL 1 MCG CAPSULE, PARICALCITOL 2 MCG CAPSULE, PARICALCITOL 4 MCG CAPSULE, PENTAMIDINE 300 MG INHAL POWDR, PLENAMINE, PRILOLID, PRIVIGEN, PROGRAF 0.2 MG GRANULE PACKET, PROGRAF 1 MG GRANULE PACKET, PROGRAF 5 MG/ML AMPULE, PULMOZYME, RAPAMUNE 1 MG/ML ORAL SOLN, RECOMBIVAX HB, RELADOR PAK, RELADOR PAK PLUS, SIROLIMUS 0.5 MG TABLET, SIROLIMUS 1 MG TABLET, SIROLIMUS 1 MG/ML SOLUTION, SIROLIMUS 2 MG TABLET, SMOFLIPID, TACROLIMUS 0.5 MG CAPSULE (IR), TACROLIMUS 1 MG CAPSULE (IR), TACROLIMUS 5 MG CAPSULE (IR), TOBRAMYCIN 300 MG/5 ML AMPULE, XEMBIFY, ZEMPLAR 10 MCG/2 ML VIAL, ZEMPLAR 2 MCG/ML VIAL, ZEMPLAR 5 MCG/ML VIAL, ZOLEDRONIC ACID 5 MG/100 ML, ZORTRESS

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.

PCSK-9 INHIBITORS

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

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with another PCSK9 inhibitor

REQUIRED MEDICAL INFORMATION
For initial authorization, both criteria 1 and 2 must be met. 1. One of the following: a. Provider attestation of a trial and failure of at least eight (8) weeks of therapy with a high-intensity statin therapy (i.e., atorvastatin 40-80 mg or rosuvastatin 20-40 mg daily), defined as failure to achieve desired LDL-C lowering OR b. Provider attestation of statin intolerance, defined as one of the following: i. Rhabdomyolysis ii. Skeletal muscle related symptoms while on atorvastatin or rosuvastatin, and resolution of symptoms after discontinuation iii. Elevated liver enzymes OR c. The patient has an FDA labeled contraindication to a statin, AND 2. Must meet listed criteria below for each specific diagnosis: a. For primary hyperlipidemia, including Heterozygous Familial Hypercholesterolemia (HeFH) OR Homozygous Familial Hypercholesterolemia (HoFH), confirmed diagnosis by one of the following must be met: i. A “possible” diagnosis of FH via Simon Broome criteria or a “probable” diagnosis of FH via Dutch Lipid Clinic Network Criteria score of greater than or equal to 6, OR ii. Genetic mutation in one of the following genes: low-density lipoprotein receptors (LDLR), apolipoprotein B gene (APOB), or proprotein convertase subtilisin kexin type 9 (PCSK9), or ARH adaptor protein 1/LDLRAP1, OR iii. LDL-C greater than 190 mg/dL (pretreatment or highest level while on treatment) and secondary causes have been ruled out.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
For ASCVD: must be prescribed by or in consultation with a cardiologist. For FH: must be prescribed by or in consultation with a cardiologist, endocrinologist, or board certified lipidologist

COVERAGE DURATION
Initial authorization for one year. Reauth will be approved until no longer eligible with plan.

OTHER CRITERIA

Secondary causes may include hypothyroidism, nephrosis, or extreme dietary patterns, OR iv. Presence of xanthomas, b. For ASCVD, attestation of LDL-C greater than or equal to 70 mg/dL and history of clinical ASCVD, defined as one of the following: i. Acute coronary syndromes ii. History of myocardial infarction iii. Stable/unstable angina iv. Coronary or other arterial revascularization v. Stroke or transient ischemic attack vi. Peripheral artery disease presumed to be of atherosclerotic origin vii. Clinically significant multi-vessel coronary heart disease presumed to be of atherosclerotic origin. Initial Reauthorization: Provider attestation of response to therapy, defined as a decrease in LDL-C levels from pre-treatment levels.

PREVYMIS

MEDICATION(S)
PREVYMIS 240 MG TABLET, PREVYMIS 480 MG TABLET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
All of the following criteria must be met: 1. Patient is within 100 days post-allogeneic transplant AND 2. Cytomegalovirus (CMV) recipient positive

AGE RESTRICTION
Approved for patients 18 years of age and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a hematologist, oncologist, transplant specialist, or infectious disease specialist.

COVERAGE DURATION
Authorization will be approved until 100 days post-transplant.

OTHER CRITERIA
N/A

PROCYSBI

MEDICATION(S)
PROCYSBI DR 300 MG GRANULE PKT, PROCYSBI DR 75 MG GRANULE PKT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
All of the following criteria must be met: 1. Confirmed diagnosis of nephropathic cystinosis as evidenced by measuring leukocyte cystine levels (LCL) or genetic analysis of the CTNS gene AND 2. Documentation of trial and failure, intolerance, or contraindication to immediate release cysteamine capsules (Cystagon).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA
N/A

PROMACTA

MEDICATION(S)
PROMACTA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization of chronic immune thrombocytopenia (ITP): 1. Patient is at risk for bleeding with a platelet count of less than 30,000 cells per microliter. AND 2. Treatment by at least one of the following was ineffective or not tolerated: a. Systemic corticosteroids, OR b. Immune globulin, OR c. Splenectomy. For initial authorization of severe aplastic anemia: 1. Patient is at risk for bleeding with a platelet count of less than 30,000 cells per microliter. For reauthorization for ITP or severe aplastic anemia:
Platelet levels demonstrating response to therapy as well as documentation that eltrombopag continues to be required to maintain a platelet count of at least 50,000 cells per microliter.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with an oncologist, hematologist, infectious disease specialist, gastroenterologist, or hepatologist.

COVERAGE DURATION
Initial authorization will be approved for 6 months. Reauthorization will be approved for 12 months.

OTHER CRITERIA
N/A

PULMONARY ARTERIAL HYPERTENSION

MEDICATION(S)
ADEMPAS, ALYQ, AMBRISENTAN, BOSENTAN, OPSUMIT, SILDENAFIL 20 MG TABLET, TADALAFIL 20 MG TABLET, TRACLEER 32 MG TABLET FOR SUSP, UPTRAVI 1,000 MCG TABLET, UPTRAVI 1,200 MCG TABLET, UPTRAVI 1,400 MCG TABLET, UPTRAVI 1,600 MCG TABLET, UPTRAVI 200 MCG TABLET, UPTRAVI 200-800 TITRATION PACK, UPTRAVI 400 MCG TABLET, UPTRAVI 600 MCG TABLET, UPTRAVI 800 MCG TABLET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization the following criteria must be documented: 1. Diagnosis of Pulmonary Arterial Hypertension (PAH) confirmed by right heart catheterization, as defined by all of the following: a. Mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest, b. Pulmonary capillary wedge pressure (PCWP) or left ventricular end diastolic pressure (LVEDP) less than or equal to 15 mmHg, AND c. Pulmonary vascular resistance (PVR) greater than 3 Wood units (WU), 2. Patient has documented World Health Organization (WHO) Group 1 classification PAH (or WHO Group 4 classification CTEPH for Adempas® only) with WHO/New York Heart Association (NYHA) functional class II, III, or IV. Reauthorization requires documentation of response to therapy including lack of disease progression or improvement in WHO functional class

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial auth will be approved for 1 year. Reauth approved until no longer eligible with the plan.

OTHER CRITERIA
N/A

PYRUKYND

MEDICATION(S)
PYRUKYND

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization, all the following criteria must be met: 1. Diagnosis of pyruvate kinase deficiency (PKD) (ICD-10 d55.21). Must include evidence supporting diagnosis, such as: a. Documentation of markers of chronic hemolytic anemia (such as low hemoglobin, low haptoglobin, elevated bilirubin, and elevated reticulocytes) and evidence of family history of PKD), OR b. Documentation of pyruvate kinase enzyme activity below the lower limit of normal per the laboratory standard (actual laboratory results must be included), OR c. Documentation of at least two mutant alleles in the PKLR gene AND 2. Hemoglobin less than or equal to 10 mg/dL taken within the previous three months. For reauthorization: Documentation of positive clinical response (such as an increase in hemoglobin level, reduction in transfusion burden from prior to treatment).

AGE RESTRICTION
18 years or older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a hematologist

COVERAGE DURATION
Initial authorization for six months, reauthorization for one year.

OTHER CRITERIA
N/A

RADICAVA

MEDICATION(S)
RADICAVA, RADICAVA ORS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. For initiation of therapy, all of the following criteria must be met: a. Documentation of definite or probable amyotrophic lateral sclerosis (ALS) within the previous two years per the El Escorial (Airlie House) Criteria b. Documentation of baseline ALS Functional Rating Scale-Revised (ALSFRS-R) with at least 2 points in each individual item c. Forced vital capacity (FVC) of at least 80% (taken within the past three months) d. Dosing is in accordance with the FDA approved labeling 2. For patients established on therapy:
a. Documentation of a clinical benefit from therapy such as slowing of disease progression or stabilization of functional ability and maintenance of activities of daily living (ADLs) b. Documentation that patient is not dependent on invasive ventilation or tracheostomy c. Dosing is in accordance with the FDA approved labeling

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a neurologist with expertise in ALS.

COVERAGE DURATION
Initial authorization and reauthorization will be approved for six months

OTHER CRITERIA
N/A

REGRANEX

MEDICATION(S)
REGRANEX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization, documentation must be submitted showing adequate blood tissue supply to the affected area. For reauthorization, documentation must be submitted showing an adequate response defined by a 30% reduction or greater in ulcer size. There is no medical evidence to justify ongoing treatment after 180 days.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization will be approved for 90 days. One additional auth will be approved for 90 days

OTHER CRITERIA
N/A

RELISTOR

MEDICATION(S)
RELISTOR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization all of the following criteria must be met: 1. Medication will not be used concomitantly with other intestinal secretagogues, or peripherally acting mu-opioid receptor antagonists, AND 2. Patient is on chronic opioid therapy, AND 3. Documentation of less than three (3) spontaneous bowel movements per week, AND 4. Documentation of trial and failure (at least two weeks of therapy), intolerance, or contraindication to routine laxative therapy with lactulose, AND 5. One of the following: A. Opioid-induced constipation in adult patients with advanced illness, OR B. For opioid-induced constipation in patients with chronic noncancer pain, documentation of trial and failure (at least two weeks of therapy), intolerance, or contraindication to one of the following: a. naloxegol (Movantik), b. lubiprostone (Amitiza), or c. naldemedine (Symproic). Reauthorization requires documentation of response to therapy (e.g., less straining, less pain on defecation, improved stool consistency, increased number of stools per week or reduction in the number of days between stools).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for 1 year.

OTHER CRITERIA
N/A

RESCUE MEDICATION FOR EPILEPSY

MEDICATION(S)
NAYZILAM, VALTOCO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan

OTHER CRITERIA
N/A

REZUROCK

MEDICATION(S)
REZUROCK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial authorization for chronic graft-versus-host disease: indication supported by National Comprehensive Cancer Network guidelines
with recommendation 2A or higher

For coverage of twice daily dosing, all of the following must be met:

1. Patient is on an interacting drug and dosing is recommended per labeling
2. The interacting drug cannot be substituted with an alternative agent treating the same condition
3. The interacting drug is medically necessarily to continue

AGE RESTRICTION
Approved for patients 12 years of age and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an oncologist or transplant specialist

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan.

OTHER CRITERIA
N/A

SOMATOSTATIN ANALOGS

MEDICATION(S)
SANDOSTATIN LAR DEPOT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. For initiation of therapy (new starts), must meet the indication specific criteria below:
a. For Acromegaly:
i. Confirmed diagnosis of acromegaly
ii. Documentation of an inadequate response to surgery or pituitary irradiation, or patient is not a candidate for surgical resection and pituitary irradiation
iii. Documentation of good response and tolerability to short-acting octreotide
b. For Carcinoid Tumors:
i. Treatment is for symptomatic diarrhea or flushing:
ii. Documentation that patient has severe diarrhea or flushing caused by a carcinoid tumor
iii. Documentation of good response and tolerability to short-acting octreotide
c. For Vasoactive Intestinal Peptide Tumors:
i. Treatment is for symptomatic diarrhea
ii. Documentation that patient has severe diarrhea caused by vasoactive intestinal peptide tumors
iii. Documentation of good response and tolerability to short-acting octreotide
d. For Chemotherapy induced diarrhea:
i. Documentation that patient has severe diarrhea caused by chemotherapy
ii. Documentation of an inadequate response or contraindication to loperamide
iii. Documentation of good response and tolerability to short-acting octreotide
e. For AIDS-related diarrhea:
i. Documentation that patient has severe diarrhea
ii. Documentation of an inadequate response or contraindication to loperamide OR diphenoxylate
iii. Documentation of good response and tolerability to short-acting octreotide
f. For oncologic diagnoses: use must be for a FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher
2. For patients established on the requested therapy within the previous year, documentation of positive

response to therapy must be provided.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year

OTHER CRITERIA

N/A

SOMAVERT

MEDICATION(S)
SOMAVERT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization all of the following criteria must be met: 1. Diagnosis of acromegaly, 2. Documentation that the patient has persistent disease (e.g., biochemical or clinical) following surgical resection or patient is ineligible for surgery, AND 3. Documentation of trial and failure, intolerance or contraindication to octreotide injection therapy. Reauthorization requires documentation of a positive response to therapy, such as a decrease or normalization of insulin like growth factor (IGF)-1.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA
N/A

SUBLINGUAL IMMUNOTHERAPY WITH ALLERGEN-SPECIFIC POLLEN EXTRACTS (SLIT)

MEDICATION(S)
GRASTEK, ODACTRA, ORALAIR, RAGWITEK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial authorization: 1. Diagnosis of allergic rhinitis, with or without conjunctivitis AND 2. Documentation that member remains symptomatic despite treatment with both of the following: a) An intranasal steroid and b) An oral anti-histamine AND 3. Documentation that the sublingual immunotherapy will begin 12 to 16 weeks before the start of the allergy season according to the respective FDA labels. AND 4. Documentation of a positive skin test to the relevant perennial aeroallergen AND 5. Subcutaneous immunotherapy will not be used concurrently. Reauthorization requires documentation of consistent use of medication during treatment period for allergy season previously approved for coverage.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an allergist, immunologist, otolaryngologist or other physician currently providing subcutaneous immunotherapy to patients in their practice.

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA
N/A

SYNAREL

MEDICATION(S)
SYNAREL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For endometriosis all of the following criteria must be met: 1. Documentation that other causes of gynecologic pain have been ruled out (e.g., irritable bowel syndrome, interstitial cystitis, urinary tract disorders) AND 2. Documentation of trial and failure, intolerance, or contraindication to leuprolide therapy with add-back progesterone. Reauthorization is not covered, as treatment is only recommended for up to 6 months for endometriosis. For initial authorization in central precocious puberty (Note, a one-time dose may be approved for diagnostic purposes): 1. Documentation of a history of early onset of secondary sexual characteristics (age 8 years and under for females or 9 years and under for males) AND 2. Confirmation of diagnosis by one (1) of the following: a. Pubertal response to a GnRH or GnRH analog (such as leuprolide) stimulation test [e.g., stimulated peak luteinizing hormone (LH) of approximately 4.0 to 6.0 IU/L and/or elevated ratio of LH/follicle-stimulating hormone at 0.66 or greater (reference range may vary depending on assay)] b. Pubertal level of basal LH levels (0.3 IU/L or greater) c. Bone age advanced one year beyond the chronological age AND 3. Documented trial and failure or contraindication/intolerance to Lupron.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Endometriosis: auth approved for 6 months. CPP: initial/re-auth approved for one year

OTHER CRITERIA
N/A

TADALAFIL

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

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Use for sexual dysfunction without comorbid diagnosis of benign prostatic hypertrophy (BPH)

REQUIRED MEDICAL INFORMATION
For signs and symptoms of benign prostatic hyperplasia (BPH): Documentation of an adequate trial and failure, intolerance, or contraindication to at least one formulary drug from BOTH of the following medication categories: 1. Alpha-adrenergic blockers (e.g. tamsulosin, doxazosin, terazosin, alfuzosin) AND 2. 5-alpha reductase inhibitor (e.g. finasteride or dutasteride). An adequate trial and failure is defined as daily use for at least four (4) weeks of therapy without improvement in signs and symptoms of BPH.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan.

OTHER CRITERIA
N/A

TAFAMIDIS

MEDICATION(S)
VYNDAMAX, VYNDAQEL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial authorization: 1. Documentation of genetic testing results for mutations of the transthyretin (TTR) gene (patient may have a genetic variation or be wild type) 2. Confirmation of amyloid deposits showing cardiac involvement by ONE of the following: a. A positive 99mTechnetium-Pyrophosphate (99mTc-PYP) scan b. A positive cardiac biopsy for ATTR amyloid c. A positive non-cardiac biopsy for ATTR amyloid and evidence of cardiac involvement by end-diastolic interventricular septal wall thickness greater than 12 mm (by echocardiogram or MRI) or suggestive cardiac MRI findings 3. Documentation that patient has a NYHA functional classification of I, II or III 4. Documentation of clinical signs or symptoms of cardiomyopathy and/or heart failure (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema, elevated BNP or NT-BNP levels). Reauthorization: 1. Documentation of a positive clinical response such as evidence of slowing of clinical decline, reduced number of cardiovascular related hospitalizations, improvement or stabilization of the 6-minute walk test or improvement or stabilization in the KCCQ-OS

AGE RESTRICTION
Approved for patients 18 years of age and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a cardiologist or a physician who specializes in the treatment of amyloidosis

COVERAGE DURATION
Initial authorization will be approved for 6 months, reauthorization will be approved for 1 year

OTHER CRITERIA
N/A

TAVALISSE

MEDICATION(S)
TAVALISSE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization all of the following criteria must be met: 1. Diagnosis of chronic immune thrombocytopenia (ITP), 2. Platelet count of less than 30,000 per microliter, and 3. Inadequate response to at least TWO of the following therapies: a. Corticosteroids b. Immunoglobulins c. Splenectomy d. Thrombopoietin receptor agonists e. Rituximab. Reauthorization requires documentation of an improvement in platelet count to at least 50,000 per microliter.

AGE RESTRICTION
Approved for patients 18 years of age and older

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

COVERAGE DURATION
Initial authorization will be approved for 3 months. Reauthorization will be approved for 1 year.

OTHER CRITERIA
N/A

TEGSEDI

MEDICATION(S)
TEGSEDI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Platelet count less than 100 x 10^9 per liter

REQUIRED MEDICAL INFORMATION
Initial authorization: 1. Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy AND 2. Documentation of a pathogenic TTR mutation AND 3. Documentation of baseline polyneuropathy disability (PND) score OR baseline familial amyloid polyneuropathy (FAP) stage AND 4. Baseline neuropathy impairment score (NIS) between 5 and 130 AND 5. Demonstrate symptoms consistent with polyneuropathy of hATTR amyloidosis including at least two of the following: Peripheral sensorimotor polyneuropathy (e.g., tingling or increased pain in the hands, feet, hands and/or arms, loss of feeling in the hands and/or feet, numbness or tingling in the wrists, carpal tunnel syndrome, loss of ability to sense temperature, difficulty with fine motor skills, weakness in the legs, difficulty walking), autonomic neuropathy symptoms (e.g., orthostasis, abnormal sweating, sexual dysfunction, recurrent urinary tract infection, dysautonomia [constipation and/or diarrhea, nausea, vomiting, anorexia, early satiety]) AND 6. Not taking in combination with patisiran or tafamidis. Reauthorization: 1. Documentation that patient is tolerating applicable gene therapy AND 2. Documented improvement or stabilization in polyneuropathy symptoms, defined as improvement or stabilization from baseline in the Neuropathy impairment score (NIS) AND at least one of the following measures: a) Polyneuropathy disability (PND) score, OR b) Familial amyloid polyneuropathy (FAP) stage

AGE RESTRICTION
Approved for patients 18 years of age and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a neurologist or a provider who specializes in the treatment of amyloidosis.

COVERAGE DURATION
Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.

OTHER CRITERIA

N/A

THERAPEUTIC IMMUNOMODULATORS

MEDICATION(S)

COSENTYX (2 SYRINGES), COSENTYX PEN, COSENTYX PEN (2 PENS), COSENTYX SYRINGE, ENBREL, ENBREL MINI, ENBREL SURECLICK, HUMIRA, 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, OTEZLA 28 DAY STARTER PACK, OTEZLA 30 MG TABLET, RINVOQ, SKYRIZI 150 MG/ML SYRINGE, SKYRIZI (2 SYRINGES) KIT, SKYRIZI ON-BODY, SKYRIZI PEN, STELARA 45 MG/0.5 ML SYRINGE, STELARA 45 MG/0.5 ML VIAL, STELARA 90 MG/ML SYRINGE, TREMFYA, XELJANZ, XELJANZ XR

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Patient is currently being treated with another therapeutic immunomodulator or apremilast

REQUIRED MEDICAL INFORMATION

For patients already established on the requested therapy: 1. Documentation of response to therapy (i.e. slowing of disease progression or decrease in symptom severity and/or frequency), AND 2. One of the following: a. Patient is not currently being treated with another therapeutic immunomodulator, OR b. Patient is currently being treated with another therapeutic immunomodulator AND will discontinue the other therapeutic immunomodulator. For patients being initiated on therapy, all of the following criteria must be met: 1. Patient must have an FDA labeled indication for the requested agent, AND 2. Documentation of trial and failure, intolerance, or contraindication to one conventional therapy prerequisite for the requested indication (see notes below), AND 3. One of the following: a. Patient is not currently being treated with another therapeutic immunomodulator, OR b. Patient is currently being treated with another therapeutic immunomodulator AND will discontinue the other therapeutic immunomodulator prior to starting the requested agent. Notes: Use of ONE conventional prerequisite agent is required for diagnoses of psoriatic arthritis, plaque psoriasis, rheumatoid arthritis, or juvenile idiopathic arthritis. NO prerequisites are required for diagnoses of ankylosing spondylitis, hidradenitis suppurativa, Crohns disease, ulcerative colitis, uveitis, non-radiographic axial spondyloarthritis, or oral ulcers associated with Behcet's disease. Formulary conventional agents for rheumatoid arthritis, juvenile idiopathic arthritis, or psoriatic arthritis include methotrexate, hydroxychloroquine, sulfasalazine, cyclosporine, or leflunomide. Formulary conventional topical or systemic antipsoriatic agents include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial auth approved for 1 year. Reauth will be approved until no longer eligible with the plan

OTHER CRITERIA

N/A

THIOLA

MEDICATION(S)
THIOLA EC, TIOPRONIN 100 MG TABLET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization: Confirmation of cystinuria by at least one 24-hour urine collection with measurement of urinary cysteine levels greater than 500 mg/day. Reauthorization requires documentation of positive clinical response, such as a reduction in urine cysteine concentration or a reduction in production of cysteine stones.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a nephrologist or urologist.

COVERAGE DURATION
Initial authorization will be approved for 6 months. Reauthorization will be approved for 1 year.

OTHER CRITERIA
N/A

TOLVAPTAN

MEDICATION(S)
JYNARQUE, TOLVAPTAN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Hepatic Impairment, Anuria, Hypovolemia

REQUIRED MEDICAL INFORMATION
For autosomal dominant polycystic kidney disease (ADPKD), tolvaptan (Jynarque) can be covered when all of the following criteria are met: 1. Diagnosis of ADPKD confirmed by ultrasound, MRI or CT scan and exclusion of other cystic kidney diseases. Conditions to be excluded include: multiple simple renal cysts, renal tubular acidosis, cystic dysplasia of the kidney, multicystic kidney, multilocular cysts of the kidney, medullary cystic kidney and acquired cystic disease of the kidney, AND 2. The patient must have a confirmed diagnosis of rapidly progressing ADPKD by at least one of the following criteria: a. eGFR decline of at least 5 mL/min/1.73 meter squared per year over 1 year, b. eGFR decline of at least 2.5 mL/min/1.73 meter squared per year over a period of 5 years, c. Total kidney volume increase of at least 5% per year confirmed by at least 3 repeated ultrasound or MRI measurements taken at least 6 months apart, AND 3. Patient does not have significant renal disease other than ADPKD (e.g., renal cancer, acute kidney injury). Reauthorization requires documentation of a positive response to therapy (such as a slowing in patients decline in kidney function). For hypervolemic and euvolemic hyponatremia, tolvaptan (Samsca) can be covered when all of the following criteria are met: 1. One of the following: a. Serum sodium of less than 125 mEq/L, b. Less marked hyponatremia (less than 135 mEq/L), but symptomatic, AND 2. Evidence that initiation and re-initiation of therapy in a hospital setting where serum sodium can be monitored closely, AND 3. Patient does not have any of the following: Urgent need to raise serum sodium acutely (e.g., acute/transient hyponatremia associated with head trauma)

AGE RESTRICTION
Approved for patients 18 years of age and older

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

COVERAGE DURATION

Tolvaptan (Samsca): approved for 30 days. Tolvaptan (Jynarque): initial/reauth approved for 1 year

OTHER CRITERIA

N/A

TOPIRAMATE ER

MEDICATION(S)
TOPIRAMATE ER

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For seizure disorder: Documentation of trial and failure, intolerance, or contraindication to topiramate immediate-release and one additional formulary anti-epileptic medication (e.g., valproic acid, levetiracetam, lamotrigine). For migraine prophylaxis: Documentation of trial and failure, intolerance, or contraindication to topiramate immediate-release and one additional formulary agent used for migraine prophylaxis (e.g., divalproex, propranolol, metoprolol).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
For seizure disorder, must be prescribed by, or in consultation with, a neurologist.

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan.

OTHER CRITERIA
N/A

TRIENTINE

MEDICATION(S)
CLOVIQUE, TRIENTINE HCL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Cystinuria or rheumatoid arthritis

REQUIRED MEDICAL INFORMATION
Documentation of trial and failure, intolerance, or contraindication to penicillamine tablet (Depen®)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a gastroenterologist, medical geneticist, or hepatologist.

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA
N/A

VASCEPA

MEDICATION(S)
ICOSAPENT ETHYL, VASCEPA 0.5 GM CAPSULE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Hypertriglyceridemia all of the following must be met: 1. Trial and failure (defined as at least two (2) months of therapy), intolerance, or contraindication to one of the following formulary agents to treat very high triglycerides: fenofibrate or gemfibrozil. 2. A triglyceride level within the past 6 months that is greater than 500 mg/dL. For ASCVD Risk Prevention all of the following must be met: 1. One of the following: a. Established atherosclerotic heart disease as defined as one or more of the following: i. Documented multivessel coronary artery disease (equal or greater than 50% stenosis in at least two major epicardial coronary arteries), prior myocardial infarction (MI), or hospitalization for non-ST elevation acute coronary syndrome. ii. Documented cerebrovascular or carotid artery disease iii. Documented peripheral arterial disease OR b. Diabetes mellitus and two or more of the following additional risk factors for cardiovascular disease: i. Men equal to or greater than 55 years of age or women equal to or greater than 65 years of age ii. Hypertension iii. High-density lipoprotein cholesterol (HDL-C) equal to or less than 40 mg/dL for men or equal to or less than 50 mg/dL for women iv. High-sensitivity C-reactive protein (hs-CRP) greater than 3.0 mg/dL v. Reduced kidney function (eGFR less than 60 mL/min per 1.73 meter squared) vi. Current cigarette smoker or recently quit smoking cigarettes within the past 3 months vii. Retinopathy viii. Micro- or macro-albuminuria ix. Ankle-brachial index less than 0.9 without symptoms of intermittent claudication 2. Current use of a high-intensity statin therapy for at least 4 weeks or documented statin intolerance at any dose. 3. A triglyceride level within the past 6 months that is equal to or greater than 150 mg/dL. 4. A low-density lipoprotein cholesterol (LDL-C) level within the past 6 months that is less than or equal to 100 mg/dL.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

Authorization will be approved until no longer eligible with the plan.

OTHER CRITERIA

N/A

VERKAZIA

MEDICATION(S)
VERKAZIA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial authorization requires documentation of all the following: 1. Clinical diagnosis of vernal keratoconjunctivitis (H16.26) and 2. Documentation of inadequate response to a trial (defined as at least three weeks of consistent use) of two (2) of the following topical mast cell stabilizer eye drops: azelastine, epinastine, cromolyn, or lodoxamide (Alomide®). Reauthorization requires documentation of positive clinical response to therapy.

Reauthorization requires documentation of positive clinical response to therapy.

AGE RESTRICTION
May be covered for patients aged four (4) years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial auth will be approved for six months. Reauth will be approved for one year.

OTHER CRITERIA
N/A

VERQUVO

MEDICATION(S)
VERQUVO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For chronic heart failure, all of the following criteria must be met:
1.Documentation of symptomatic heart failure (NYHA Class II-IV) with a left ventricular ejection fraction (LVEF) less than 45%
2.On maximally tolerated guideline-directed therapy including both of the following, unless contraindicated or not tolerated:
a.Beta-blocker (specifically carvedilol, metoprolol succinate, or bisoprolol)
b.One of the following:
i.Angiotensin-converting enzyme (ACE) inhibitor (such as lisinopril, enalapril)
ii.Angiotensin II receptor blocker (ARB) (such as losartan, valsartan)
iii.Angiotensin receptor-neprilysin inhibitor (ARNI) (sacubitril/valsartan), unless not tolerated or contraindicated,
3.Documentation of clinical worsening of heart failure, defined as one of the following, despite maximal therapy as outlined above:
a.Hospitalization for heart failure within the previous six months
b.Need for outpatient intravenous diuretic therapy within the previous three months

AGE RESTRICTION
Approved for adults 18 years of age and older

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

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan

OTHER CRITERIA

N/A

VIBERZI

MEDICATION(S)
VIBERZI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Patients without a gallbladder.

REQUIRED MEDICAL INFORMATION
For initial authorization: 1. Diagnosis of Irritable Bowel Syndrome with Diarrhea (IBS-D) AND 2. Documentation of trial and failure, contraindication, or intolerance to loperamide. Reauthorization requires documentation of response to treatment, defined as improvement in stool consistency and abdominal pain.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan.

OTHER CRITERIA
N/A

VIJOICE

MEDICATION(S)
VIJOICE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial authorization requires criteria 1-3 to be met:
1. Confirmed diagnosis of PIK3CA-related overgrowth spectrum (PROS) as defined by meeting criteria A-D:

A. Presence of somatic PIK3CA mutation
B. Congenital or early childhood onset
C. Overgrowth sporadic or mosaic (other terms: patchy, irregular)
D. Clinical features as described in either a or b:
a. Spectrum (require two ore more of the following): i. Overgrowth (adipose, muscle, nerve, skeletal) ii. Vascular malformations (capillary, venous, arteriovenous malformations, lymphatic) iii. Epidermal nevus
b. Isolated features (one of the following): i. Large isolated lymphatic malformation ii. Isolated macrodactyly OR overgrown splayed feet/hands, overgrown limbs iii. Truncal adipose overgrowth iv. Hemimegalencephaly (bilateral)/dysplastic megalencephaly/focal cortical dysplasia v. Epidermal nevus vi. Seborrheic keratoses vii. Benign lichenoid keratoses large, AND
2. Patient has at least one target lesion identified on imaging, AND
3. Patient's condition is severe or life-threatening and treatment is deemed necessary as determined by the treating physician.
Reauthorization requires documentation of positive response to therapy such as reduction in the sum of measurable target lesion volume.

AGE RESTRICTION
Approved for patients 2 years of age and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a specialist in treating PROS.

COVERAGE DURATION

Initial authorization and reauthorization will be approved for six months

OTHER CRITERIA

N/A

VMAT-2 INHIBITORS

MEDICATION(S)
AUSTEDO, INGREZZA, INGREZZA INITIATION PACK, TETRABENAZINE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For chorea associated with Huntington disease, the following criteria must be met: 1. Diagnosis of Huntington disease as defined by all of the following: a. DNA testing showing CAG expansion of 36 or higher, b. Family history (if known), and c. Classic presentation (choreiform movements, psychiatric problems, and dementia), and 2. For coverage of deutetrabenazine (Austedo), documented trial (of at least 8 weeks) and failure or intolerance of tetrabenazine. Reauthorization requires documentation of response to therapy (e.g., improved function through reduction of choreiform movements). For tardive dyskinesia, all of the following criteria must be met: 1. Diagnosis of tardive dyskinesia secondary to therapy with a dopamine receptor blocking agent, 2. Documentation of the patient's baseline Abnormal Involuntary Movement Scale (AIMS) score, 3. Documentation of moderate to severe tardive dyskinesia, as defined by a total score on items 1-7 of at least 8 or a score of 3 or 4 on item 8 (severity of abnormal movement overall) on the AIMS, AND 4. Documentation of a 30-day trial and failure, contraindication, or intolerance to amantadine. Reauthorization requires documentation of positive clinical response to therapy, as demonstrated by improvement in AIMS.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial authorization will be approved for 3 months. Reauthorization will be approved for 1 year.

OTHER CRITERIA
N/A

XERMELO

MEDICATION(S)
XERMELO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
All of the following criteria must be met: 1. Diagnosis of carcinoid syndrome diarrhea, 2. Patient is experiencing four (4) or more bowel movements per day, despite use of long-acting octreotide therapy, such as octreotide LAR (Sandostatin LAR), lanreotide (Somatuline), for at least three (3) months, 3. Documentation of failure to the use of short-acting octreotide (Sandostatin) for breakthrough symptoms, 4. Documentation that somatostatin analog therapy will be used in combination with the requested medication. Reauthorization will require documentation of positive clinical response to therapy.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year

OTHER CRITERIA
N/A

XIFAXAN

MEDICATION(S)
XIFAXAN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
More than three (3) treatment courses for IBS-D.

REQUIRED MEDICAL INFORMATION
For traveler's diarrhea (200 mg tablets): Diagnosis of traveler’s diarrhea caused by noninvasive strains of Escherichia coli. Rifaximin is not covered if documentation shows diarrhea that is complicated by fever or blood in stool. For hepatic encephalopathy (HE) (550 mg tablets): Documentation of trial and failure, contraindication or intolerance to lactulose. For irritable bowel syndrome with diarrhea (IBS-D) (550 mg tablets) with or without small intestinal bacterial growth (SIBO): Documentation of trial and failure, contraindication, or intolerance to TWO (2) of the following medications: a. Anti-spasmodic agent [e.g. dicyclomine (Bentyl®)] b. Tricyclic antidepressant [e.g. amitriptyline (Elavil®)] c. Opioid mu receptor agonist [e.g., loperamide (Imodium®), diphenoxylate (Lomotil®)]. Reauthorization in IBS-D requires documentation of initial response to treatment with rifaximin and recurrence of IBS-D symptoms. Limited to three (3) total 14-day course treatments (initial treatment and two reauthorizations).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
For irritable bowel syndrome with diarrhea (IBS-D): Must be prescribed by, or in consultation with, a gastroenterologist.

COVERAGE DURATION
Hepatic encephalopathy: 1 year. Traveler’s diarrhea: 3 days. IBS-D: 14 days

OTHER CRITERIA
N/A

XOLAIR

MEDICATION(S)
XOLAIR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For asthma, must meet all of the following criteria: 1. Diagnosis of moderate or severe persistent allergic asthma, 2. IgE baseline levels greater than 30 IU/ml, 3. Positive skin test to common perennial aeroallergens, 4. Documentation of at least a 90-day trial of a combination of a medium/high-dose inhaled corticosteroid and a long-acting inhaled beta2-agonist unless there is intolerance or contraindication to the medications, 5. Documentation of inadequate asthma control defined as one of the following: a. Asthma Control Test (ACT) score less than 20 or Asthma Control Questionnaire (ACQ) score greater than or equal to 1.5, b. At least two exacerbations requiring oral systemic corticosteroids in the last 12 months, or c. At least one exacerbation requiring hospitalization, 6. Documented trial and failure, intolerance, or contraindication to therapy with benralizumab (Fasenra®). Reauthorization for asthma requires documentation of response to therapy, such as attainment and maintenance of remission or decrease in number of relapses. For chronic idiopathic urticaria, must meet all of the following criteria: 1. Documentation that the condition is idiopathic and that secondary causes of urticaria (e.g. offending allergens, physical contact, etc.) have been ruled out , 2. Trial and failure, intolerance, or contraindication to a second-generation non-sedating H1 antihistamine, such as levocetirizine, and 3. Trial and failure of one additional medication from the following classes: leukotriene receptor antagonists (e.g., montelukast), first generation H1 antihistamine , or histamine H2-receptor antagonist. Reauthorization will require documentation of response to therapy (e.g. reduction in flares or oral steroid dose).

AGE RESTRICTION
Asthma: 6 years of age and older
Urticaria: 12 years of age and older
Nasal polyps: 18 years of age and older

PRESCRIBER RESTRICTION
Urticaria: Must be prescribed by, or in consultation with, a dermatologist, allergist or immunologist.

Asthma: Must be prescribed by, or in consultation with an asthma specialist (such as a pulmonologist, immunologist, or allergist).
Nasal polyps: Must be prescribed by or in consultation with an otolaryngologist, allergist, pulmonologist or immunologist

COVERAGE DURATION
Urticaria/nasal polyps: initial 6mo/reauth 1yr. Asthma: approved until no longer elig with the plan.

OTHER CRITERIA
For Nasal Polyps, all of the following: 1. Evidence of nasal polyposis by direct examination, endoscopy or sinus CT scan, 2. Documentation that patient has had an inadequate response to (within the past 90 days), or has an intolerance, FDA labeled contraindication, or hypersensitivity to, oral systemic corticosteroids, 3. Patient has had an inadequate response to a three-month trial of intranasal corticosteroids (e.g., fluticasone) or has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an intranasal corticosteroid, 4. Documentation that patient will continue standard maintenance therapy (e.g., intranasal corticosteroids) in combination with the requested agent. Reauthorization for nasal polyps: 1. Documentation of positive clinical response to therapy, 2. Documentation that patient will continue standard maintenance therapy (e.g., intranasal corticosteroids) in combination with the requested agent, unless documented intolerance, FDA labeled contraindication, or hypersensitivity to such therapy.