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 for 6 months. Reauthorization will be for one year.

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 100 MG CAPSULE, CAPRELSA, COMETRIQ, COPIKTRA, COTELLIC, DAURISMO, ERIVEDGE, ERLEADA, ERLOTINIB HCL, EVEROLIMUS, EXKIVITY, FARYDAK, FOTIVDA, GAVRETO, GILOTRIF, IBRANCE, ICLUSIG, IDHIFA, IMATINIB MESYLATE, IMBRUVICA 140 MG CAPSULE, IMBRUVICA 140 MG TABLET, IMBRUVICA 280 MG TABLET, IMBRUVICA 420 MG TABLET, IMBRUVICA 560 MG TABLET, IMBRUVICA 70 MG CAPSULE, INLYTA, INQOVI, INREBIC, IRESSA, JAKAFI, KISQALI, KISQALI FEMARA CO-PACK, KOSELUGO, LAPATINIB, LENALIDOMIDE 10 MG CAPSULE, LENALIDOMIDE 15 MG CAPSULE, LENALIDOMIDE 25 MG CAPSULE, LENALIDOMIDE 5 MG CAPSULE, LENVIMA, LONSURF, LORBRENA, LUMAKRAS, LYNPARZA, MEKINIST, MEKTOVI, NERLYNX, NINLARO, NUBEQA, ODOMZO, ONUREG, ORGOVYX, PEMAZYRE, PIQRAY, POMALYST, QINLOCK, RETEVMO, REVLIMID 2.5 MG CAPSULE, REVLIMID 20 MG CAPSULE, 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, ZORTRESS 0.25 MG TABLET, ZORTRESS 0.5 MG TABLET, ZORTRESS 0.75 MG TABLET, 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 everolmius tablets for suspension (generic for Afinitor Disperz): documentation of medical rationale for the use of this formulation over the available everolimus tablet formulation. 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, neurologist or, for abiraterone, a urologist. 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

ANTIDEPRESSANTS

MEDICATION(S)
FETZIMA, TRINTELLIX, VIIBRYD 10-20 MG STARTER PACK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documented trial, failure, intolerance or contraindication to two formulary, generic SSRIs or SNRIs (e.g., citalopram, sertraline, paroxetine, venlafaxine, duloxetine)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
N/A

ANTIEPILEPTIC AGENTS

MEDICATION(S)
BANZEL 40 MG/ML SUSPENSION, BRIVIACT, RUFINAMIDE, SYMPAZAN, VIGABATRIN 500 MG TABLET, VIGADRONE, XCOPRI 100 MG TABLET, XCOPRI 12.5-25 MG TITRATION PK, XCOPRI 150 MG TABLET, XCOPRI 150-200 MG TITRATION PK, XCOPRI 200 MG TABLET, XCOPRI 350 MG DAILY DOSE PACK, XCOPRI 50 MG TABLET, XCOPRI 50-100 MG TITRATION PAK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of trial and failure of at least one formulary generic antiepileptic medication (divalproex sodium, valproic acid, felbamate, lamotrigine, topiramate, carbamazepine, phenytoin, levetiracetam or clobazam)

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

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, transplant specialist, 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)
ARISTADA ER 441 MG/1.6 ML SYRN, ARISTADA ER 662 MG/2.4 ML SYRN, ARISTADA ER 882 MG/3.2 ML SYRN, ASENAPINE MALEATE, CAPLYTA 42 MG CAPSULE, 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 auto-inflammatory 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). Reauthorization requires documentation of improvement of symptoms, such as fever, urticaria-like rash, arthralgia, myalgia, fatigue, and conjunctivitis. 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. Reauthorization requires documentation of improvement of symptoms.

AGE RESTRICTION
For Cryopyrin-Associated Periodic Syndrome (CAPS): patients 12 years of age and older
For Deficiency of Interleukin-1 Receptor Antagonist (DIRA): N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial auth will be approved for 6 months. Reauth will be approved for 1 yr.

OTHER CRITERIA
N/A

BARBITURATES

MEDICATION(S)
PHENOBARBITAL 16.2 MG TABLET, PHENOBARBITAL 20 MG/5 ML CUP, PHENOBARBITAL 20 MG/5 ML ELIX, PHENOBARBITAL 20 MG/5 ML SOLN, PHENOBARBITAL 30 MG TABLET, PHENOBARBITAL 30 MG/7.5 ML CUP, PHENOBARBITAL 32.4 MG TABLET, PHENOBARBITAL 60 MG/15 ML CUP, PHENOBARBITAL 64.8 MG TABLET, PHENOBARBITAL 97.2 MG TABLET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. Member is less than 65 years of age OR 2. For use for in epilepsy: documented trial, failure, contraindication or intolerance to at least two formulary anticonvulsant agents or medical rationale is provided why formulary anticonvulsants are not indicated. AND for all FDA-approved indications, prescribing provider indicates that medical benefits exceed the risks associated with these medications.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and 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 of 30-day duration (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
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),all of the following must be met: 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 one (1) of the following prophylactic medications: divalproex, valproate, topiramate, metoprolol, propranolol, timolol, amitriptyline, venlafaxine, OR b. Documented intolerance or contraindication to the above medications. Initial authorization for episodic cluster headaches (galcanezumab [Emgality] only), all of the following must be met: 1. A history of at least five cluster headache attacks, with at least two of the cluster periods lasting at least seven days, AND 2. Cluster periods are separated by at least three months of pain-free remission, AND 3. One of the following: a. Trial and inadequate response to at least one (1) of the following: verapamil or lithium, OR b. Documented intolerance or contraindication to the above medications. Reauthorization for all indications: Documented reduction in the severity or frequency of headaches.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by a headache specialist, pain specialist or neurologist if receiving concomitant botulinum toxin prophylactic therapy

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 100 MG-125 MG TABLET, ORKAMBI 100-125 MG GRANULE PKT, ORKAMBI 150-188 MG GRANULE PKT, ORKAMBI 200 MG-125 MG TABLET, SYMDEKO, TRIKAFTA 100-50-75 MG/150 MG

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 homozygous F508del mutation in the CFTR gene or 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). 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).

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
Authorization will be approved until no longer eligible with the plan

OTHER CRITERIA
N/A

CGRPS FOR ACUTE MIGRAINE TREATMENT

MEDICATION(S)
NURTEC ODT, UBRELVY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with a triptan, 5HT-1F, ergotamine, or another calcitonin gene-related peptide (CGRP) agent for the same indication

REQUIRED MEDICAL INFORMATION
For initial authorization for the acute treatment of migraines, the following criteria must be met:
1. Patient has a diagnosis of migraine, AND 2. ONE of the following: a. Patient has tried and had an inadequate response to a triptan (e.g., sumatriptan, rizatriptan) agent OR b. Patient has an intolerance or FDA labeled contraindication to triptan therapy.
For initial authorization for episodic migraine prophylaxis, Nurtec ODT may be covered if all the following criteria are met: 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 one (1) of the following prophylactic medications: divalproex, valproate, topiramate, metoprolol, propranolol, timolol, amitriptyline, venlafaxine, OR b. Documented intolerance or contraindication to the above medications. 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

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. For inappropriate sinus tachycardia (IST): 1. Documentation of sinus rhythm and resting heart rate (HR) greater than 100 bpm (with a mean HR greater than 90 bpm over 24 hours) or a rapid stable symptomatic increase in resting HR greater than 25 bpm when moving from a supine to a standing position or in response to physiological stress, 2. Documentation that other causes of sinus tachycardia have been ruled out (e.g. thyroid disease, drug-induced), 3. Documentation that inappropriate sinus tachycardia is causing significant functional impairment or distress, such as presyncope, headache, dyspnea.

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

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 (of 30-day duration) 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), 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
N/A

PRESCRIBER RESTRICTION
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

DRONABINOL

MEDICATION(S)
DRONABINOL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For nausea and vomiting associated with cancer chemotherapy: 1. Documentation of trial and failure, contraindication or intolerance to a 5HT-3 receptor antagonist (e.g., ondansetron). AND 2. Documentation of trial and failure, contraindication or intolerance to one of the following formulary medications unless contraindicated: promethazine, prochlorperazine, chlorpromazine, or metoclopramide. For anorexia with weight loss in patients with AIDS: 1. Documentation that patient is currently taking anti-retroviral therapy AND 2. If patient is less than 65 years of age: Documentation of trial and failure, contraindication, or intolerance to megestrol (Megace)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

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 must be met: 1. Diagnosis of moderate to severe atopic dermatitis despite use of therapies outlined in criterion number 2 below, 2. Documented inadequate response to one of the following: a. Moderate to high potency topical corticosteroids (e.g., clobetasol 0.05%, betamethasone dipropionate 0.05%, triamcinolone 0.5%) or b. Topical calcineurin inhibitor (e.g., tacrolimus ointment). For reauthorization in AD: Documentation of reduction or stabilization from baseline of flares, pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, lichenification, or affected BSA. For Adjunct Therapy for Chronic Rhinosinusitis with Nasal Polyp (CRSwNP), all the following must be met: 1. Patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND 2. Documentation that the patient had an inadequate response to, or has an intolerance or contraindication to, oral systemic corticosteroids, AND 3. Patient had an inadequate response to intranasal corticosteroids (such as fluticasone nasal spray) or has a documented intolerance or contraindication to ALL intranasal corticosteroids, AND 4. Documentation that patient will continue standard maintenance therapy (e.g., intranasal corticosteroids) in combination with dupilumab. For reauthorization in CRSwNP: Documentation of positive clinical response to therapy such as symptom improvement.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Moderate-to-severe atopic dermatitis: Must be prescribed by, or in consultation with, a dermatologist, allergist or immunologist. Eosinophilic and corticosteroid dependent 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.

COVERAGE DURATION

Asthma: until no longer eligible with the plan. All other indications: initial/reauth 1 yr

OTHER CRITERIA

For moderate-to-severe asthma, all of the following must be met: 1. Confirmed diagnosis of one of the following: a. Eosinophilic asthma, b. Past history of eosinophilic asthma if currently on daily maintenance treatment with oral glucocorticoids, or c. Corticosteroid dependent asthma, 2. Documentation of treatment with maximally tolerated doses of the following medications, unless intolerance or contraindication to all therapies: a. Inhaled corticosteroid AND b. one of the following: a long-acting inhaled beta 2-agonist (LABA), a leukotriene receptor antagonist (LTRA), or a long-acting muscarinic, 3. Documentation inadequate asthma control despite above therapy, defined as one of the following: a. At least two asthma exacerbations requiring oral systemic corticosteroids in the last 12 months or b. At least one asthma exacerbation requiring hospitalization, emergency room or urgent care visit in the last 12 months. For continuation of therapy in asthma: Documentation of response to therapy, such as attainment and maintenance of remission or decrease in number of relapses. For eosinophilic esophagitis (EoE), all of the following must be met: 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.

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, and valproate/ valproic acid 3. Baseline liver function tests must be documented, 4. Dose will not exceed: a. 20 mg/kg/day in Lennox-Gastaut syndrome or Dravet Syndrome b. 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 AGENS

MEDICATION(S)

ARANESP 10 MCG/0.4 ML SYRINGE, ARANESP 100 MCG/0.5 ML SYRINGE, ARANESP 100 MCG/ML VIAL, ARANESP 150 MCG/0.3 ML SYRINGE, ARANESP 200 MCG/0.4 ML SYRINGE, ARANESP 200 MCG/ML VIAL, ARANESP 25 MCG/0.42 ML SYRING, ARANESP 25 MCG/ML VIAL, ARANESP 300 MCG/0.6 ML SYRINGE, ARANESP 40 MCG/0.4 ML SYRINGE, ARANESP 40 MCG/ML VIAL, ARANESP 500 MCG/1 ML SYRINGE, ARANESP 60 MCG/0.3 ML SYRINGE, ARANESP 60 MCG/ML VIAL, EPOGEN 2,000 UNITS/ML VIAL, EPOGEN 20,000 UNITS/2 ML VIAL, EPOGEN 20,000 UNITS/ML VIAL, EPOGEN 3,000 UNITS/ML VIAL, EPOGEN 4,000 UNITS/ML VIAL, 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 of cancer not related to cancer treatment, Prophylactic use to prevent chemotherapy-induced anemia, Prophylactic use to reduce tumor hypoxia

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 10 g/dl or hematocrit (HCT) levels of less than or equal to 30% within 30 days prior to initiation of therapy, AND 2. Must meet the following indication-specific critera: a. For anemia in Chronic Kidney Disease (not on dialysis): Documentation of adequate iron stores as indicated by current (within the last three months) serum ferritin level greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20%, b. For anemia due to chemotherapy in cancer and related neoplastic conditions (see exclusion criteria for non-covered indications): i. Adequate iron stores as indicated by current (within the last three months) serum ferritin level more than or equal to 100 mcg/L or serum transferrin saturation more than or equal to 20%, AND, ii. Documentation that anemia is secondary to myelosuppressive chemotherapy in solid tumors, multiple myeloma, lymphoma, or lymphocytic leukemia, c. Anemia associated with zidovudine-treated HIV-infection patients: 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: i. Documentation of preoperative anemia with pretreatment HGB between 10 and 13 g/dL., ii. The procedure has a high risk of perioperative blood loss (e.g., expected to lose more than 2 units of blood), AND iii. Patient is unwilling or unable to donate autologous blood pre-operatively. e. For anemia secondary to myelodysplastic syndrome (MDS) or myelofibrosis, both of the following criteria must be met: i. Documentation of adequate iron stores as indicated by current (within the last three months) serum ferritin level more than or equal to 100 mcg/L or serum transferrin saturation more than or equal to 20% and ii. Documented current (within last three months) endogenous serum erythropoietin levels less than or equal to 500 mU/mL. 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 267 MG TABLET, PIRFENIDONE 801 MG TABLET

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) with or without confirmation of UIP by surgical 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

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) or Lennox-Gastaut syndrome (LGS) 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

FIRDAPSE

MEDICATION(S)
FIRDAPSE

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 symptomatic disease, such as dyspnea or 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

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 will be approved for 6 months, and reauthorization will be approved for 12 mon

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 auth will be approved for 6 months. Reauth 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 at least one appetite stimulant or anabolic agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or on the recommendation of 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 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 a long-acting inhaled beta2-agonist 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).

AGE RESTRICTION
Mepolizumab (Nucala): Approved for 6 years of age and older. Benralizumab (Fasenra): Approved for 12 years of age and older

PRESCRIBER RESTRICTION
For eosinophilic asthma: must be prescribed by or in consultation with an asthma specialist (such as a pulmonologist, immunologist, or allergist). For eosinophilic granulomatosis with polyangiitis: must be prescribed by or in consultation with a pulmonologist, neurologist, or rheumatologist

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

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. At least two of the following clinical findings: a. Biopsy evidence of eosinophilic vasculitis b. Motor deficit or nerve conduction abnormality c. Pulmonary infiltrates d. Sinonasal

abnormality e. Cardiomyopathy f. Glomerulonephritis g. Alveolar hemorrhage h. Palpable purpura i. Positive test for ANCA 5. 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 hyperesosinophilic 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/mcL 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). Reauthorization requires documentation of response to therapy, such as attainment and maintenance of remission or decrease in number of relapses.

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 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

LIDODERM

MEDICATION(S)
LIDOCAINE 5% PATCH, LIDODERM

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
Authorization will be approved until no longer eligible with the plan

OTHER CRITERIA
N/A

MAVENCLAD

MEDICATION(S)
MAVENCLAD

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documented trial and failure, intolerance, or contraindication to two (2) conventional therapies for multiple sclerosis.

AGE RESTRICTION
Approved for patients 18 years of age and older

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

COVERAGE DURATION
Initial authorization/reauthorization will be approved for 1 year, up to total treatment of 2 years.

OTHER CRITERIA
N/A

MULTIPLE SCLEROSIS DRUGS

MEDICATION(S)
EXTAVIA, ZEPOSIA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment cardiac evaluation, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
N/A

MUSCULOSKELETAL DRUGS

MEDICATION(S)
CYCLOBENZAPRINE 10 MG TABLET, CYCLOBENZAPRINE 5 MG TABLET, METHOCARBAMOL 500 MG TABLET, METHOCARBAMOL 750 MG TABLET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. Member is under 65 years old OR 2. If over 65 years: a. Documentation that the risks of the medications (CNS depression) have been discussed with the patient, including that these risks increase with age. AND b. Documentation that the provider feels this medications is appropriate for the patient's age despite the risks outlined above. Reauthorization requires: 1. Documentation that the patient is responding well to therapy without side effects AND 2. If over 65 years, documentation that the risks of the medication have been discussed at least annually with the patient and the provider and the patient both feel continuation of therapy is medically necessary despite risks.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial auth will be approved for 3 months. Reauth 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 11, 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 pitolisant (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 pitolisant (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 11, 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, all of the following must be met: 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 (such as 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
N/A

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

OTHER CRITERIA
N/A

NUEDEXTA

MEDICATION(S)
NUEDEXTA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Current use, or use within the past 14 days, of monoamine oxidase inhibitors (MAOIs) and patient’s diagnosed with a prolonged QT interval, congenital long QT syndrome, or a history suggesting torsades de pointes.

REQUIRED MEDICAL INFORMATION
Initial authorization: 1. Diagnosis of pseudobulbar affect (PBA) AND 2. 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 or contraindication to clozapine. 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

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, rheumatologist, or transplant specialist.

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

OTHER CRITERIA

N/A

OSMOLEX ER

MEDICATION(S)
OSMOLEX ER

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 one of the following: a. Diagnosis of Parkinson’s Disease or b. Diagnosis of drug-induced extrapyramidal symptoms, AND 2. Documented trial and failure of immediate release amantadine of a dose of at least 300 mg daily unless intolerable side effects at lower doses. Reauthorization requires documentation of successful response to the medication.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a neurologist, psychiatrist or expert in the treatment of movement disorders

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

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 (a-e): a. Patient has a history of multiple or severe vertebral fractures, or history of fragility fractures, b. Patient has a spine or hip bone mineral density (BMD) T-score less than or equal to -3.0, c. Patient has a spine or hip bone mineral density (BMD) T-score less than or equal to -2.5 to -3.0 and high risk for fracture, defined as one of the following: i. Age more than 80 years, ii. Chronic glucocorticoid use, iii. Documented increased fall risk, d. Patient has a spine or hip BMD T-score less than or equal to -2.5 to -3.0 and one of the following: 1. Documented failure to anti-resorptive therapy (e.g., denosumab, bisphosphonates). Failure is defined as a new fracture or worsening BMD while on therapy, or 2. Documented contraindication or intolerance to both denosumab and bisphosphonate therapies, OR e. Patient has a spine or hip BMD T-score between -1.0 and -2.5 and BOTH of the following (i. and ii.): i. Fracture Risk Assessment (FRAX) probability score for hip fracture of at least 3% or, for other major osteoporosis fracture, of at least 20%, ii. One of the following: 1. Documented failure to anti-resorptive therapy (e.g., denosumab, bisphosphonates). Failure is defined as a new fracture or worsening BMD while on therapy, 2. 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

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. Documentation serum 25-hydroxyvitamin D stores are sufficient per laboratory reference range (Note: 20 ng/mL [50 nmol/L] or greater is generally considered adequate). 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 auth will be approved for 6 months. Reauth will be approved for 1 year.

OTHER CRITERIA
N/A

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 Boome 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. 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

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 auth for one year. Reauth will be approved until no longer eligible with plan.

OTHER CRITERIA

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

PROLIA

MEDICATION(S)
PROLIA

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: 1. Documentation of trial and failure of bisphosphonate therapy or contraindication/intolerance to both oral and IV bisphosphonate therapy, AND 2. One of the following criteria: A. Documented clinical diagnosis of osteoporosis [defined as a non-traumatic, non-pathologic spinal fracture OR spine, femoral neck or hip bone mineral density (BMD) T-score less than or equal to -2.5]. OR B. Documented risk of osteoporosis (defined as BMD T-score between -1.0 and –2.5) AND meeting one of two risk assessments a) one of the following risk factors: i. previous fracture, ii. history of hip or spine fracture in first degree relative, iii. low body weight (less than 127 lbs. for women), iv. smoking, excess alcohol intake, v. secondary osteoporosis (e.g. rheumatoid arthritis), vi. history of falls, b) FRAX Hip fracture probability greater than or equal to 3% or other major osteoporosis fracture probability greater than or equal to 20% OR C. One of the following chronic glucocorticosteroid use: a) greater than 20 mg/day for longer than 1 month b) 5-20 mg/day for longer than 3 months in post menopausal women not on estrogen c) 5-20 mg/day for longer than 3 months AND T-score less than -1.5.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
Part B before Part D Step Therapy

PROMACTA

MEDICATION(S)
PROMACTA

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

OFF LABEL USES
Myelodysplastic syndromes

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of therapy, must meet the following indication-specific criteria: 1. For myelodysplastic syndromes (MDS): use must be for an FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher, 2. For Immune Thrombocytopenia (ITP), all the following criteria (a-c) must be met: a. Diagnosis of chronic immune thrombocytopenia (ITP), b. Platelet count of less than 30,000 cells per microliter, AND c. Treatment with at least one of the following therapies was ineffective or not tolerated, unless all are contraindicated: i. Systemic corticosteroids, ii. Immune globulin, iii. Splenectomy, iv. Rituximab, 3. For Severe Aplastic Anemia, documentation that the patient is at risk for bleeding with a platelet count of less than 30,000 cells per microliter, 4. Thrombocytopenia due to chronic Hepatitis C. For patients established on therapy, must meet indication-specific criteria below: 1. For MDS: documentation of improved platelet levels from baseline, 2. For ITP, severe aplastic anemia or Hepatitis C: a. Documentation of improved platelet levels from baseline AND b. Documentation the continued therapy is medically necessary 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, ORENITRAM ER, 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 20 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
Prescribed by or in consultation with a Pulmonologist or Cardiologist.

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

OTHER CRITERIA
N/A

RADICAVA

MEDICATION(S)
RADICAVA ORS 105 MG/5 ML SUSP

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. Patient is on chronic opioid therapy, AND 2. Documentation of less than three (3) spontaneous bowel movements per week, AND 3. Documentation of trial and failure (at least two weeks of therapy), intolerance, or contraindication to routine laxative therapy with lactulose, AND 4. 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 MEDICATIONS 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

SAPROPTERIN

MEDICATION(S)
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 for 3 months. Reauthorization for 6 months.

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 or lanreotide subcutaneous depot. 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

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
Documentation of cofnrimed diagnosis of benign prostatic hyperplasia (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)
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 written 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

TESTOSTERONE REPLACEMENT THERAPY

MEDICATION(S)
ANDRODERM, ANDROGEL 1% (50 MG/5 G) PKT, TESTOSTERONE 1.62% (2.5 G) PKT, TESTOSTERONE 1.62% GEL PUMP, TESTOSTERONE 1.62%(1.25 G) PKT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Use exclusively for improvement of sexual signs and symptoms (e.g., decreased libido, sexual dysfunction)

REQUIRED MEDICAL INFORMATION
For patients established on testosterone replacement therapy and requesting use of a different testosterone replacement product than currently established on: Documented trial and failure of generic topical testosterone 1%. Failure is defined as inability to reach therapeutic levels or fluctuations in levels resulting in symptoms. For initiation of testosterone replacement therapy, all of the following criteria must be met: 1. Diagnosis of primary or secondary (hypogonadatropic) hypogonadism, AND 2. One of the following confirmatory laboratory values, taken before 11 am (or within 3 hours of waking for shift-workers) on different days without acute illness/stress, according to the local laboratory’s lower limit of normal (if available) or levels according to the listed values below: a. At least two (2) serum total testosterone levels less than 264 ng/dL (9.2 nmol/L), b. At least two (2) free testosterone levels less than 2 ng/dL (20 pg/mL), c. At least one (1) serum total testosterone level less than 264 ng/dL (9.2 nmol/L), AND one (1) free testosterone levels less than 2 ng/ dL (20 pg/mL). Serum total testosterone level and free testosterone level must be taken on different days. AND 3. Documentation of trial and failure, contraindication or intolerance to generic topical testosterone 1% gel. Failure is defined as inability to reach therapeutic levels or fluctuations in levels resulting in symptoms.

AGE RESTRICTION
Approved for adults 18 years of age and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved until no longer eligible with the plan

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 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. For Rinvoq/Xeljanz/Xeljanz XR: Documentation of trial and failure, intolerance, or contraindication to a preferred TNF agent (see notes below), AND 3. Documentation of trial and failure, intolerance, or contraindication to conventional therapy prerequisite(s) for the requested indication (see notes below), AND 4. 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.

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

Notes: TNF requirements: Use of ONE preferred TNF (Enbrel or Humira) is required for diagnoses of psoriatic arthritis, rheumatoid arthritis, juvenile idiopathic arthritis, or ankylosing spondylitis. Use of Humira is required for diagnosis of ulcerative colitis. Conventional therapy requirements: Use of ONE conventional prerequisite agent is required for diagnoses of psoriatic arthritis, plaque psoriasis, rheumatoid arthritis, or juvenile idiopathic arthritis. Use of TWO conventional prerequisite agent is required for diagnoses of atopic dermatitis. NO prerequisites are required for diagnoses of ankylosing spondylitis, hidradenitis suppurativa, Crohn's disease, ulcerative colitis, uveitis, enthesitis related arthritis, 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. Formulary conventional agents for moderate to severe atopic dermatitis include one of each of the following: 1) topical corticosteroid AND 2) topical calcineurin inhibitor (e.g., tacrolimus)

TOLVAPTAN

MEDICATION(S)
TOLVAPTAN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Hepatic Impairment, Anuria, Hypovolemia.

REQUIRED MEDICAL INFORMATION
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
Initial authorization and reauthorization will be approved for 30 days.

OTHER CRITERIA
N/A

TRIENTINE

MEDICATION(S)
SYPRINE, TRIENTINE HCL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Cystinuria AND rheumatoid arthritis

REQUIRED MEDICAL INFORMATION
Documentation of severe or intolerable adverse effects to penicillamine (Depen).

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
N/A

VASCEPA

MEDICATION(S)
ICOSAPENT ETHYL 1 GRAM 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 diagnoses: a. Established atherosclerotic heart disease (such as myocardial infarction (MI), multivessel coronary artery disease, cerebrovascular or carotid artery disease, peripheral arterial disease) OR b. Diabetes mellitus and at least two additional risk factors for cardiovascular disease [such as age elevated age (men 55 years of age and older or women 65 years of age and older), hypertension, low high-density lipoprotein cholesterol (HDL-C), high-sensitivity C-reactive protein (hs-CRP) greater than 3.0 mg/dL, reduced kidney function/albuminuria, current cigarette smoker or recently quit smoking cigarettes), 2. Current use of a high-intensity statin therapy for at least four weeks or documented statin intolerance at any dose. 3. A triglyceride level within the past six months that is equal to or greater than 150 mg/dL.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

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. 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 (e.g. first or second generation antipsychotics, metoclopramide), 2. Documentation of moderate to severe tardive dyskinesia that is causing functional impairment, 3. For coverage of deutetrabenazine (Austedo®) and valbenazine (Ingrezza®): Documented trial (of at least 8 weeks) and failure or intolerance of tetrabenazine. Reauthorization requires documentation of positive clinical response to therapy, such as improved function.

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 approved for one 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 a stable dose of long-acting somatostatin analog therapy, such as octreotide LAR (Sandostatin LAR®) or lanreotide (Somatuline®), for at least three months, 3. Documentation of failure to the use of short-acting octreotide (Sandostatin) for breakthrough symptoms, 4. Documentation that long-acting 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

XGEVA

MEDICATION(S)
XGEVA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For prevention of skeletal-related events in patients with bone metastases from solid tumors: Documented trial and failure of, intolerance to, or contraindication to zoledronic acid or pamidronate therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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 a tricyclic antidepressant (e.g. amitriptyline) AND an opioid mu receptor agonist (e.g., loperamide, diphenoxylate). 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
Traveler’s diarrhea: 3 days, IBS-D: 14 days, HE: until no longer eligible with the plan

OTHER CRITERIA
N/A

XOLAIR

MEDICATION(S)
XOLAIR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with another therapeutic immunomodulator for the same indication (such as dupilumab or an injectable interleukin-5 inhibitor)

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. 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 and nasal polyps: initial 6 mo/reauth 1 yr. Asthma: auth approved until no longer eligible

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.