



A division of Providence Health Assurance

PROVIDENCE MEDICARE ADVANTAGE PLANS

2021 PRIOR AUTHORIZATION CRITERIA

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

H9047_2021AM32_C

ABILIFY MYCITE

MEDICATION(S)

ABILIFY MYCITE 10 MG KIT, ABILIFY MYCITE 15 MG KIT, ABILIFY MYCITE 2 MG KIT, ABILIFY MYCITE 20 MG KIT, ABILIFY MYCITE 30 MG KIT, ABILIFY MYCITE 5 MG KIT

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Trial, failure, intolerance or contraindication to at least two injectable depot antipsychotics (e.g., Risperdal Consta, Abilify Maintena, Aristada, Aristada Initio, Invega Sustenna etc.)

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

ACTINIC KERATOSIS AGENTS

MEDICATION(S)

FLUOROURACIL 0.5% CREAM, PICATO

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

Initial authorization and reauthorization will be approved for 1 month.

OTHER CRITERIA

N/A

AEMCOLO

MEDICATION(S)

AEMCOLO

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

3 days

OTHER CRITERIA

N/A

ALBENDAZOLE/EMVERM

MEDICATION(S)

ALBENDAZOLE 200 MG TABLET, EMVERM

PA INDICATION INDICATOR

4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES

Pinworm (*Enterobius vermicularis*) for albendazole.

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial authorization, documentation of confirmed diagnoses.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

ALPHA-1 PROTEINASE INHIBITORS

MEDICATION(S)

ARALAST NP, GLASSIA, PROLASTIN C, ZEMAIRA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial authorization, all of the following must be met: 1. Documentation of one (1) of the following: a. Serum alpha-1 antitrypsin (AAT) concentrations less than 11 uM/L (approximately 57 mg/dL by nephelometry or 80mg/dL by immunodiffusion), or b. Patient has one of the high-risk phenotypes by protease inhibitor (PI) typing: PI*ZZ, PI*Z(null), PI*(null,null), or PI*SZ homozygotes, AND 2. Diagnosis of emphysema confirmed by one (1) of the following: a. Forced expiratory volume per one second (FEV1) of 35 to 65% of predicted volume, or b. Rapid lung function decline as evidence by reduction of FEV1 of 100 mL/year or greater, 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.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

N/A

AMIFAMPRIDINE

MEDICATION(S)

FIRDAPSE, RUZURGI

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Initial authorization (all of the following must be met): 1. Confirmed diagnosis of Lambert-Eaton myasthenic syndrome (LEMS), 2. Documentation of confirmatory diagnostic test results including: a. Repetitive Nerve Stimulation (RNS) testing showing reproducible post-exercise increase in compound muscle action potential (CMAP) amplitude of at least 60 percent compared with pre-exercise baseline value or a similar increment on high-frequency repetitive nerve stimulation without exercise OR b. Positive anti-P/Q type voltage-gated calcium channel antibody test, 3. Documentation of clinical symptoms of LEMS, including dyspnea or functionally significant muscle weakness, 4. Member has been evaluated for malignancy and treated for malignancy, if present. Note: LEMS symptoms associated with malignancy may resolve after treatment directed at malignancy, 5. Documented trial (of at least 1 month) and failure or intolerance of pyridostigmine, AND 6. For Firdapse: Documented trial and failure of Ruzurgi. Reauthorization requires documentation of improvement or stabilization of muscle weakness from baseline.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

ANTI-CANCER AGENTS

MEDICATION(S)

ABIRATERONE ACETATE, ACTIMMUNE, AFINITOR 10 MG TABLET, AFINITOR DISPERZ, ALECENSA, ALUNBRIG, AYWAKIT, BALVERSA, BEXAROTENE, BOSULIF, BRAFTOVI 75 MG CAPSULE, BRUKINSA, CABOMETYX, CALQUENCE, CAPRELSA, COMETRIQ, COPIKTRA, COTELLIC, DAURISMO, ERIVEDGE, ERLEADA, ERLOTINIB HCL, EVEROLIMUS 2.5 MG TABLET, EVEROLIMUS 5 MG TABLET, EVEROLIMUS 7.5 MG TABLET, FARYDAK, GAVRETO, GILOTRIF, IBRANCE, ICLUSIG, IDHIFA, IMATINIB MESYLATE, IMBRUVICA, INLYTA, INQOVI, INREBIC, IRESSA, JAKAFI, KISQALI, KISQALI FEMARA CO-PACK, KOSELUGO, LAPATINIB, LENVIMA, LONSURF, LORBRENA, LYNPARZA, MEKINIST, MEKTOVI, NERLYNX, NEXAVAR, NINLARO, NUBEQA, ODOMZO, ONUREG, ORGOVYX, PEMAZYRE, PIQRAY, POMALYST, QINLOCK, RETEVMO, REVLIMID, ROZLYTREK, RUBRACA, RYDAPT, SPRYCEL, STIVARGA, SUTENT, SYLATRON 200 MCG KIT, SYLATRON 300 MCG KIT, SYNRIPO, TABRECTA, TAFINLAR, TAGRISSO, TALZENNA, TARGRETIN 1% GEL, TASIGNA, TAZVERIK, TIBSOVO, TRETINOIN 10 MG CAPSULE, TUKYSA, TURALIO, VENCLEXTA, VENCLEXTA STARTING PACK, VERZENIO, VITRAKVI, VIZIMPRO, VOTRIENT, XALKORI, XOSPATA, XPOVIO, XTANDI 40 MG CAPSULE, YONSA, ZEJULA, ZELBORAF, ZOLINZA, ZYDELIG, ZYKADIA 150 MG TABLET

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Indications supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with an oncologist, transplant specialist, or neurologist.

COVERAGE DURATION

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

OTHER CRITERIA

N/A

ANTIEPILEPTIC AGENTS

MEDICATION(S)

APTOM, BANZEL 200 MG TABLET, BANZEL 400 MG TABLET, FYCOMPA, RUFINAMIDE, VIGABATRIN, VIGADRONE, VIMPAT 10 MG/ML SOLUTION, VIMPAT 100 MG TABLET, VIMPAT 150 MG TABLET, VIMPAT 200 MG TABLET, VIMPAT 50 MG TABLET, XCOPRI

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, NOXAFIL 40 MG/ML SUSPENSION, POSACONAZOLE DR 100 MG TABLET, 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. voriconazole will be covered for blastomycosis when documented failure, intolerance, or contraindication to itraconazole.
4. For prophylaxis of invasive aspergillosis or invasive candidiasis: posaconazole will be covered in severely immunocompromised patients.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, an infectious disease specialist, hematologist, oncologist, or pulmonologist for all indication except onychomycosis or 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 will be covered.
7. For empiric antifungal therapy in patients with febrile neutropenia: itraconazole, voriconazole or posaconazole will be covered. For reauthorization: Documentation supporting continued use of the requested agent for the intended diagnosis (such as continued active disease, length of therapy is supported by literature or guidelines, for prophylaxis patient continues to be severely immunocompromised).

ANTIPSYCHOTICS

MEDICATION(S)

ASENAPINE MALEATE, CAPLYTA, LATUDA, 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 or bipolar disorder: Documented trial, failure, intolerance or contraindication to two formulary, generic antipsychotics (e.g., quetiapine, olanzapine, ziprasidone, risperidone, aripiprazole).

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

APOKYN

MEDICATION(S)

APOKYN, KYNMOBI

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Concomitant use with 5HT3 receptor antagonists (e.g., ondansetron, granisetron, dolasetron, or palonosetron)

REQUIRED MEDICAL INFORMATION

1. Patient has advanced Parkinson's disease and is experiencing acute intermittent hypomobility ("off" episodes) lasting at least 2 hours AND 2. Patient is on other medications for the treatment of Parkinson's disease (e.g., carbidopa/levodopa, pramipexole, ropinirole, benztropine, etc.)

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

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: Documentation submitted of improvement of symptoms

AGE RESTRICTION

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

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

N/A

BENLYSTA (PENDING CMS APPROVAL)

MEDICATION(S)

BENLYSTA 200 MG/ML AUTOINJECT, BENLYSTA 200 MG/ML SYRINGE

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

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

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

Initial authorization and reauthorization will be approved for 6 months.

OTHER CRITERIA

N/A

BRIVIACT/SPRITAM

MEDICATION(S)

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

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Documentation of trial and failure, contraindication or intolerance to generic levetiracetam tablets or oral solution.

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

BUDESONIDE ER

MEDICATION(S)

BUDESONIDE ER

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Initial authorization for the treatment of active ulcerative colitis: 1. Documented trial, failure, intolerance or contraindication to treatment with an aminosalicylate (e.g., sulfasalazine, mesalamine) AND 2. Documented trial, failure, intolerance or contraindication to one of the following oral corticosteroids: dexamethasone, hydrocortisone, methylprednisolone, prednisone or budesonide extended release capsule. The initial approval will allow for an 8-week treatment course to induce remission. Further approval requires medical rationale why standard maintenance therapy with generic budesonide delayed-release capsules or other medication for ulcerative colitis is not appropriate.

AGE RESTRICTION

Approved for patients 18 years of age and older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial authorization and reauthorization will be approved for 8 weeks.

OTHER CRITERIA

N/A

CABLIVI

MEDICATION(S)

CABLIVI

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

Approved for patients 18 years of age and older

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

Initial authorization and reauthorization will be approved for 90 days.

OTHER CRITERIA

N/A

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

MEDICATION(S)

AIMOVIG AUTOINJECTOR, EMGALITY PEN, EMGALITY SYRINGE

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

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

REQUIRED MEDICAL INFORMATION

Initial authorization for migraine prophylaxis (Aimovig and Emgality): 1. Diagnosis of migraine headaches with at least four (4) headache days per month. 2. One of the following: a. Trial and failure of at least one conventional migraine prophylaxis medication [e.g., anticonvulsants (divalproex, topiramate), beta-blockers (propranolol)] b. Documented intolerance or contraindication to a conventional migraine prophylaxis medication 3. Documentation that if the patient is currently receiving CGRP therapy, treatment with the other CGRP will be discontinued. Initial authorization for cluster headache prophylaxis (Emgality only): 1. Diagnosis of episodic cluster headaches and both of the following: a. A history of at least five (5) cluster headache attacks with at least two of the cluster periods lasting at least 7 days b. Cluster periods are separated by at least three (3) months of pain-free remission. 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

CFTR MODULATORS

MEDICATION(S)

KALYDECO, ORKAMBI, SYMDEKO, TRIKAFTA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For ivacaftor (Kalydeco): Diagnosis of cystic fibrosis with documentation of at least one copy of a cystic fibrosis transmembrane regulator (CFTR) gene mutation that is responsive to ivacaftor (refer to package insert). For lumacaftor-ivacaftor (Orkambi): Diagnosis of cystic fibrosis with documentation of homozygous F508del mutation in the CFTR gene. For tezacaftor-ivacaftor (Symdeko): Diagnosis of cystic fibrosis with documentation of one (1) of the following: 1. Homozygous F508del mutation in the CFTR gene OR 2. A copy of a mutation in the CFTR gene that is responsive to tezacaftor-ivacaftor based on clinical evidence and/or in vitro data (refer to package insert), excluding F508del mutation. For elexacaftor- tezacaftor-ivacaftor (Trikafta): Diagnosis of cystic fibrosis with documentation of at least one F508del mutation in the CFTR gene. Reauthorization: Documented response to therapy as defined as one (1) of the following: a. A lack of decline in lung function as measured by the FEV1 when the patient is clinically stable b. A reduction in the incidence of pulmonary exacerbations c. Reduced respiratory symptoms (e.g., persistent productive cough, wheezing, shortness of breath) d. A significant improvement in BMI by 10% from baseline.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

CHENODAL

MEDICATION(S)

CHENODAL

PA INDICATION INDICATOR

4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES

Cerebrotendinous xanthomatosis.

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For use in gallstone dissolution: 1. Documentation that the patient is not a candidate for surgery AND 2. Documentation of failure of an adequate trial of 6-month duration, contraindication, or intolerance to ursodiol. For cerebrotendinous xanthomatosis: documentation of confirmed diagnosis (e.g. clinical presentation and/or genetic testing). Reauthorization will require documentation of positive response to therapy.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

CHOLBAM

MEDICATION(S)

CHOLBAM

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For bile acid synthesis disorder: Documentation of a single enzyme defect. For peroxisomal disorder: 1. Documentation of manifestations of at least one of the following: a. Liver disease (e.g., jaundice, elevated serum transaminases), b. Steatorrhea, c. Complications from decreased fat-soluble vitamin absorption (e.g., poor growth) AND 2. Documentation that the medication will be used as adjunctive therapy. Reauthorization requires documentation of positive clinical response to therapy.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA

N/A

CINRYZE/HAEGARDA/TAKHZYRO

MEDICATION(S)

CINRYZE, HAEGARDA, TAKHZYRO

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Combination prophylaxis therapy with Cinryze, Haegarda, or Takhzyro

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 50 percent of the lower limit of normal AND ii. One of the following: C1-Inhibitor (C1-INH) protein less than 50 percent of the lower limit of normal or C1-INH function is less than 50 percent of the lower limit of normal. B. For HAE with normal C1-INH or HAE Type III, one of the following: i. Confirmed Factor 12 (FXII) mutation OR ii. Positive family history for HAE AND attacks that lack response with high dose antihistamines or corticosteroids. 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 benefit of therapy with reduction of frequency and severity of HAE attacks.

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

CORLANOR

MEDICATION(S)

CORLANOR

PA INDICATION INDICATOR

4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES

Inappropriate sinus tachycardia.

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

Moderate-severe hepatic impairment (Child Pugh B or C)

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with a pulmonologist

COVERAGE DURATION

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

OTHER CRITERIA

N/A

DIACOMIT

MEDICATION(S)

DIACOMIT

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

Approved for 2 years of age and older

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

DOPTELET

MEDICATION(S)

DOPTELET

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with an oncologist hematologist, gastroenterologist or liver specialist

COVERAGE DURATION

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

OTHER CRITERIA

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

DPP-4 INHIBITORS

MEDICATION(S)

ALOGLIPTIN, ALOGLIPTIN-METFORMIN, ALOGLIPTIN-PIOGLITAZONE, GLYXAMBI, JENTADUETO, JENTADUETO XR, KOMBIGLYZE XR, ONGLYZA, STEGLUJAN, TRADJENTA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Type 1 diabetes

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

N/A

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 six 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 Xolair or with IL-5 (e.g., Fasentra, Nucala) for the requested indication.

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

For atopic dermatitis, patient is 6 years of age or older. For asthma, patient is 12 years of age or older. For chronic rhinosinusitis with nasal polyposis, patient is 18 years of age or older.

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

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

OTHER CRITERIA

For moderate-to-severe asthma, all of the following: 1. Confirmed diagnosis of one of the following: a. Eosinophilic asthma, defined by one of the following: i. Blood eosinophil count greater than 150 cells/microliter while on high-dose inhaled corticosteroids (ICS) or daily oral glucocorticoids, ii. FeNO of at least 20 parts per billion while on high-dose ICS or daily oral corticosteroids, iii. Sputum eosinophils of at least 2% while on high-dose ICS or daily oral corticosteroids, or b. Oral corticosteroid dependent type asthma, 2. Documentation of moderate to severe asthma, defined as one (1) of the following: a. Frequent severe asthma exacerbations requiring two (2) or more courses of systemic corticosteroids within the past 12 months, b. Serious asthma exacerbation requiring hospitalization, mechanical ventilation, or visit to the emergency room/urgent care within the past 12 months, c. Controlled asthma that worsens when doses of inhaled or systemic corticosteroids are tapered, or d. Baseline FEV1 less than 80% of predicted and BOTH the following: i. Treatment with maximally tolerated dose of medium to high-dose ICS in the past 3 months, or documented intolerance, FDA labeled contraindication, or hypersensitivity to an ICS AND, ii. Documentation of treatment within the past 90 days, intolerance, FDA labeled contraindication, or hypersensitivity to one of the following: a. Long-acting beta-2 agonist (LABA), b. Leukotriene receptor antagonist (LRTA), c. Long-acting muscarinic antagonist (LAMA), or d. Theophylline, AND 3. Patient will continue asthma control therapy (e.g., ICS, LABA, LRTA, LAMA, theophylline) in combination with requested agent. Reauthorization: 1. Documentation of response to therapy or disease stabilization, 2. Documentation that patient has continued (unless intolerance, FDA labeled contraindication, or hypersensitivity), and will continue, standard asthma control therapy (e.g., ICS, LABA, LRTA, LAMA, theophylline) in combination with requested agent. For all indications (initial and re-authorization): Dose must be within FDA labeled dosing for the requested indication.

EGRIFTA

MEDICATION(S)

EGRIFTA SV

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial authorization and reauthorization will be approved for 6 months.

OTHER CRITERIA

N/A

EMFLAZA

MEDICATION(S)

EMFLAZA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For Duchenne Muscular Dystrophy, all of the following criteria must be met: 1. Confirmed diagnosis by genetic testing, AND 2. Documentation of one of the following: a. The patient has tried prednisone for at least 6 months and has experienced one of the following clinically significant adverse events: cushingoid appearance, central (truncal obesity), weight gain of at least 10% body weight over a 6-month period or diabetes and/or hypertension that is difficult to manage according to the prescribing physician, OR b. The patient has tried prednisone and has experienced psychiatric/behavioral issues (eg, abnormal behavior, aggression, irritability) and both of the following: i. The psychiatric/behavioral issues persisted beyond the first 6 weeks of treatment with prednisone AND ii. A change in timing of prednisone administration (e.g., afternoon or evening) has been attempted but was unsuccessful in resolving issues, AND 3. The dose requested is within FDA labeled dosing based on the patient's weight (patient's weight must be provided), AND 4. Dose is given in most cost effective manner (e.g., rounding to appropriate tablet strength or use of suspension). Re-authorization: 1. Documentation of clinical benefit from therapy, such as improvement or stabilization of muscle strength or pulmonary function AND 2. The dose requested is within FDA labeled dosing based on the patient's weight (updated weight must be provided) AND dose is given in most cost effective manner (e.g., rounding to appropriate tablet strength or use of suspension)

AGE RESTRICTION

Approved for patients 2 years of age and older

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

ENSPRYNG

MEDICATION(S)

ENSPRYNG

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For Neuromyelitis Optica Spectrum Disorder (NMOSD), all of the following must be met:

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

AGE RESTRICTION

Approved for ages 18 and older

PRESCRIBER RESTRICTION

Must be prescribed by a neurologist or ophthalmologist

COVERAGE DURATION

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

OTHER CRITERIA

N/A

EPIDIOLEX

MEDICATION(S)

EPIDIOLEX

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Initial authorization: 1. Documentation that patient has one of the following: a. Seizures associated with Lennox-Gastaut syndrome (LGS) OR b. Seizures associated with Dravet syndrome (DS), OR c. Tuberous sclerosis complex (TSC) AND 2. Documented trial, failure, intolerance or contraindication to clobazam, AND 3. Documented trial, failure, intolerance or contraindication to one additional of the following: valproate/valproic acid, lamotrigine, levetiracetam, topiramate, felbamate, zonisamide, AND 4. Documentation that it will be used as adjunctive therapy with other antiepileptic drugs, AND 5. Baseline liver function tests must be documented, AND 6. Dose will not exceed 20 mg/kg/day in LGS or DS and 25mg/kg/day in TSC

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

ERYTHROPOIESIS STIMULATING AGENTS

MEDICATION(S)

ARANESP, EPOGEN, PROCRIT, RETACRIT

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

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

REQUIRED MEDICAL INFORMATION

1. All diagnoses with the exception of 2d (preoperative use in anemic patients scheduled for elective noncardiac, nonvascular surgery) must have documented Hemoglobin (HGB) levels of less than or equal to 10g/dl or hematocrit (HCT) levels of less than or equal to 30% within 30 days prior to initiation of therapy, AND 2. Must meet listed criteria below for each specific diagnosis: a. Treatment of Anemia in Chronic Renal Failure: epoetin or darbepoetin may be covered, b. Treatment of anemia due to chemotherapy in cancer and related neoplastic conditions (see exclusion criteria for non-covered indications): epoetin or darbepoetin may be covered with documentation that anemia is secondary to myelosuppressive chemotherapy in solid tumors, multiple myeloma, lymphoma, or lymphocytic leukemia. Note: May only be used up to 8 weeks following the final dose of myelosuppressive chemotherapy (subject to audit), c. Anemia associated with zidovudine-treated HIV-infection patients: epoetin only may be covered with documented endogenous serum erythropoietin level less than or equal to 500 mIU/ml and zidovudine dose less than or equal to 4200 mg/week

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA

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

ESBRIET/OFEV

MEDICATION(S)

ESBRIET, OFEV

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

EVRYSDI

MEDICATION(S)

EVRYSDI

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

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

REQUIRED MEDICAL INFORMATION

Initial authorization 1. The patient has a diagnosis, confirmed by genetic testing, of Spinal Muscular Atrophy (SMA) 2. Baseline assessment with an age appropriate tool that establishes baseline motor ability must be submitted (i.e. HINE-2, HFSME, CHOP-INTEND, MFM-32) 3. Requested dose is within FDA labeling

Reauthorization: 1. Documentation of response to therapy, such as a clinically meaningful improvement in motor function, disease stabilization or a reduction in normal motor decline (e.g., stabilization or improvement in motor function test scores performed at baseline) 2. Requested dose is within FDA labeling

AGE RESTRICTION

Approved for patients aged 2 months or older

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

Initial authorization and reauthorization will be approved for 12 months.

OTHER CRITERIA

N/A

EXTAVIA

MEDICATION(S)

EXTAVIA

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, contraindication, or intolerance to two (2) of the following: interferon-beta 1a (Avonex, Rebif or Plegridy), interferon-beta 1b (Betaseron), dimethyl fumarate (Tecfidera), glatiramer acetate (Copaxone), teriflunomide (Aubagio) or fingolimod (Gilenya).

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA

N/A

FENTANYL CITRATE

MEDICATION(S)

FENTANYL CIT OTFC 1,200 MCG, FENTANYL CIT OTFC 1,600 MCG, FENTANYL CITRATE OTFC 200 MCG, FENTANYL CITRATE OTFC 400 MCG, FENTANYL CITRATE OTFC 600 MCG, FENTANYL CITRATE OTFC 800 MCG

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Initial authorization: Confirmation that treatment is for breakthrough cancer pain (prescriber MUST submit chart notes or other documentation supporting a diagnosis of active cancer pain). Reauthorization: 1. Documentation that patient continues to have breakthrough cancer pain (prescriber MUST submit recent chart notes or other documentation supporting a diagnosis of active cancer pain) AND 2. Documentation of successful response to the medication

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

FINTEPLA

MEDICATION(S)

FINTEPLA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

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

REQUIRED MEDICAL INFORMATION

Initial authorization:

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

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

FIRAZYR

MEDICATION(S)

ICATIBANT

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 Hereditary Angioedema (HAE) Type I, II or III, AND 2. One of the following: A. For HAE Type I and Type II, documentation of at least two (2) complement studies (taken at least one month apart with the patient in their basal condition and after the first year of life) that show: i. C4 less than 50 percent of the lower limit of normal AND ii. One of the following: C1-Inhibitor (C1-INH) protein less than 50 percent of the lower limit of normal or C1-INH function is less than 50 percent of the lower limit of normal. B. For HAE with normal C1-INH or HAE Type III, one of the following: i. Confirmed Factor 12 (FXII) mutation OR ii. Positive family history for HAE AND attacks that lack response with high dose antihistamines or corticosteroids.

AGE RESTRICTION

Approved for patients 18 years of age and older

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

GALAFOLD

MEDICATION(S)

GALAFOLD

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

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

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

Initial authorization and reauthorization will be approved for 1 year.

OTHER CRITERIA

N/A

GAMMA GLOBULIN - IGG

MEDICATION(S)

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

PA INDICATION INDICATOR

4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

Initial authorization for 3 months, up to 6 months. Reauthorization for 12 months.

OTHER CRITERIA

For prevention of infections in patients with chronic B-cell CLL: 1. Documented pre-treatment IgG less than 500 mg/dL AND 2. History of recurrent, severe bacterial infections. For dermatomyositis and polymyositis: 1. Documented trial, failure, intolerance or contraindication to systemic corticosteroids AND 2. Documented trial, failure, intolerance or contraindication to immunosuppressant therapy (e.g., methotrexate, azathioprine, 6-MP) AND 3. Documentation of severe symptoms/disability despite previous therapy with above agents. For multifocal motor neuropathy: 1. Confirmed diagnosis, defined as motor involvement of at least two nerves (for more than one month) without symptoms of sensory abnormalities AND 2. Documentation of severe disease/disability. For MS: 1. Documentation of relapsing/remitting disease AND 2. Documented trial, failure, intolerance or contraindication to at least 2 conventional therapies. For Allogenic Bone Marrow Transplantation or Hematopoietic Stem Cell Transplant (HSCT) Recipients: 1. Therapy is requested for use within 100 days of transplantation (transplantation date must be documented) OR 2. Documentation of that member has hypogammaglobulinemia (see criteria for Secondary Immunodeficiency). For chronic inflammatory demyelinating polyneuropathy (CIDP): 1. Documentation of severe disability and 2. One of the following: a. Documented trial, failure, intolerance or contraindication to systemic corticosteroids, b. Documentation of pure motor CIDP. For autoimmune hemolytic anemia: 1. Documented trial, failure, intolerance or contraindication to systemic corticosteroids AND 2. Documented trial, failure, intolerance or contraindication to another conventional therapy (e.g., cyclophosphamide, azathioprine, cyclosporine). For Guillain-Barre Syndrome: Documentation that symptom onset is within 2 weeks or symptoms are severe (e.g. unable to ambulate independently). For myasthenia gravis exacerbation: 1. Evidence of myasthenic exacerbation, defined by at least one of the following symptoms in the last month: difficulty swallowing, acute respiratory failure, major functional disability responsible for the discontinuation of physical activity. For myasthenia gravis refractory disease: 1. Documentation that patient has severely impaired function due to myasthenia gravis AND 2. Documented trial, failure, intolerance or contraindication to at least 2 of the following conventional therapies: acetylcholinesterase inhibitors (e.g., pyridostigmine), corticosteroids or immunosuppressive agents. For autoimmune mucocutaneous blistering disease [pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatricial) pemphigoid, epidermolysis bullosa acquisita, pemphigoid gestationis, linear IgA bullous dermatosis]: 1. Biopsy proven disease AND 2. Documented trial, failure, intolerance or contraindication to systemic corticosteroids with concurrent immunosuppressive treatment.

GATTEX

MEDICATION(S)

GATTEX

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

Initial authorization and reauthorization will be approved for six months.

OTHER CRITERIA

N/A

GNRH ANTAGONISTS

MEDICATION(S)

ORIAHNN, ORILISSA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Patient has osteoporosis or severe hepatic impairment.

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

Approved for patients 18 years of age and older

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

HEPATITIS C

MEDICATION(S)

LEDIPASVIR-SOFOSBUVIR, SOFOSBUVIR-VELPATASVIR, VOSEVI

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

HETLIOZ

MEDICATION(S)

HETLIOZ

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

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

REQUIRED MEDICAL INFORMATION

For Non-24-Hour Sleep-Wake Disorder (Non-24): All of the following criteria must be met: 1. Member is totally blind (i.e. no light perception), 2. Documented diagnosis of Non-24-Hour Sleep-Wake Disorder (Non-24), as characterized by all of the following: a. Distinct pattern of sleeping and waking that drifts by a consistent time period every night AND b. History of periods of insomnia, excessive sleepiness, or both, which alternate with short asymptomatic periods, 3. Documented sleep study to exclude other sleep disorders. Reauthorization requires documentation of entrainment to the 24-hour circadian period.

For nighttime sleep disturbances in Smith-Magenis Syndrome (SMS): All of the following criteria must be met: 1. Documented diagnosis of SMS, as characterized by: a. Confirmation of the deletion or mutations of retinoic acid-induced 1 (RAI1) gene, 2. Documented sleep study to exclude other sleep disorders, 3. Documentation of at least one of the following: a. difficulties falling asleep, b. shortened sleep cycles, c. frequent and prolonged nocturnal awakenings, d. excessive daytime sleepiness or e. daytime napping. Reauthorization requires documentation of improvement in sleep quality or total sleep time.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

HUMAN GROWTH HORMONES

MEDICATION(S)

OMNITROPE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Treatment of adults: 1. For Growth Hormone Deficiency (GHD) in adults with GHD as a child, one of the following criteria must be met: a. Patient has organic disease (e.g., congenital defects) and one of the following: i. At least 3 pituitary hormone deficiencies (other than GH) AND Insulin-like growth factor (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 confirmatory stimulation tests: 1. Insulin Tolerance Test (ITT) with peak GH less than or equal to 5 mcg/L, 2. Glucagon Stimulation Test (GST) based on body mass index (BMI): a. BMI under 25: Peak GH less than or equal to 3 mcg/L, b. BMI 25 or above: Peak GH less than or equal to 1 mcg/L, 3. If ITT/GST are contraindicated, macimorelin with peak GH less than or equal to 2.8 mcg/L, b. Patient has GHD from other causes and both confirmatory tests completed after GH stopped for 1 month: 1. IGF-1 level below normal and 2. One of confirmatory stimulation tests from criterion 1.a.ii., 2. For GHD diagnosed as adult, one of the following: a. Patient has destructive lesions of the hypothalamic region (e.g., tumors, surgery) and both of the following: i. IGF-1 level below normal and ii. One of confirmatory stimulation tests from criterion 1.a.ii., b. Patients with organic disease, one of the following: i. At least 3 pituitary hormone deficiencies (other than GH) AND IGF-1 level less than or equal to 2 SDS below normal, or ii. IGF-1 level below normal and one of confirmatory stimulation tests from criterion 1.a.ii.. 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 AIDS Wasting, all of the following: a. Involuntary loss of at least 10% body weight, b. Absence of other related illnesses contributing to weight loss, and c. Documented failure, intolerance, or contraindication to appetite stimulants and/or anabolic agents

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

Treatment of children: 1. For GHD, must meet criteria for one of the following: a. Newborn with hypoglycemia and both of the following: i. Serum GH level less than or equal to 5 mcg/L and ii. One of the following: 1. One 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. One additional pituitary hormone deficiency (other than GH), and ii. Evidence of short stature/growth failure 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/growth failure 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: Documented confirmation of diagnosis through genetic testing, 3. For Turner's Syndrome: a. Diagnosis confirmed by genetic testing AND b. Evidence of short stature/growth failure using criteria 1.c.ii. above, 4. For Noonan Syndrome: Diagnosis confirmed by genetic testing or made by pediatric endocrinologist based on clinical features (e.g. classic facies, congenital heart disease, abnormal skeletal features), AND b. Evidence of short stature/growth failure 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/growth failure using criteria 1.c.ii. above, 6. For Small for Gestational Age: a. Birth weight and/or length at least three 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 growth velocity (GV) of greater 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 hyperesoinophilic 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

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: a. Genetic confirmation OR b. Untreated LDL-C greater than 500 mg/dl and xanthoma OR c. Both parents are heterozygous FH, 2. 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 statin intolerance. AND 3. An adequate trial and failure (3 months of therapy), contraindication or intolerance to the use of a formulary PCSK-9 inhibitor. Initial reauthorization must show documentation that LDL-C has decreased 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

KETOROLAC NASAL SPRAY

MEDICATION(S)

KETOROLAC 15.75 MG NASAL SPRAY, SPRIX

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Initial authorization: For short-term pain: 1. The patient is being treated for acute pain, 2. Documented trial and failure, intolerance or contraindication to two formulary generic nonsteroidal anti-inflammatory drugs.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial authorization and reauthorization will be approved for 6 months

OTHER CRITERIA

N/A

KORLYM

MEDICATION(S)

KORLYM

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Current pregnancy

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

KUVAN

MEDICATION(S)

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

N/A

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

PA INDICATION INDICATOR

4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES

Diabetic peripheral neuropathy and cancer-related neuropathic pain.

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial authorization for 3 months. Reauthorization for 6 months.

OTHER CRITERIA

N/A

LONG-ACTING OPIOIDS

MEDICATION(S)

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

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

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

REQUIRED MEDICAL INFORMATION

For patients initiating long-acting opioid therapy for cancer pain: 1. Documentation of active cancer pain, AND 2. Documentation of trial and failure of scheduled short-acting opioid therapy, AND 3. Documentation of trial and failure, contraindication, or intolerance to long-acting morphine sulfate therapy. For patients established on long-acting opioid therapy for cancer pain: 1. Documentation of positive response to therapy AND 2. Documentation of active cancer pain. For patients initiating long-acting opioid therapy for non-malignant pain, all of the following criteria must be met: 1. Documentation of chronic non-malignant pain (lasting longer than 3 months) that is severe enough to require around-the-clock analgesic therapy, AND 2. Documentation of trial and failure of scheduled short-acting opioid therapy, AND 3. Documentation of trial and failure, contraindication, or intolerance to long-acting morphine sulfate therapy, AND 4. Documentation of a signed pain management agreement between the prescriber and patient. For patients established on long-acting opioid therapy for chronic non-malignant pain: 1. Documentation of positive response to therapy AND 2. Documentation of a signed pain management agreement between the prescriber and patient.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year.

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

MEDICATIONS FOR RARE INDICATIONS/ORPHAN DRUGS

MEDICATION(S)

CARBAGLU, CERDELGA, MIGLUSTAT, RAVICTI, SODIUM PHENYLBUTYRATE

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA

N/A

MYALEPT

MEDICATION(S)

MYALEPT

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA

N/A

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 all indications, all of the following must be met: 1. Trial and failure of high-intensity statin therapy for at least 3 months, defined as atorvastatin 40-80 mg daily or rosuvastatin 20-40 mg daily, or the patient has a documented intolerance, FDA labeled contraindication or hypersensitivity to a statin AND 2. Trial and failure of a formulary PCSK-9 inhibitor (i.e., Repatha®) or the patient has a documented intolerance, FDA labeled contraindication or hypersensitivity to a PCSK-9 inhibitor AND 3. Fasting LDL-C greater than or equal to 70 mg/dl despite therapies outlined above AND 4. Must meet listed criteria below for each specific diagnosis: a. For familial hypercholesterolemia, confirmed diagnosis by one of the following: i. Genetic mutation in one of the following genes: LDLR, APOB, ARH adaptor protein 1/LDLRAP1, or PCSK9, ii. A Dutch Lipid Clinic Network Criteria score of greater than or equal to 6, 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. b. For atherosclerotic cardiovascular disease (ASCVD), history of one of the following: i. Acute coronary syndromes, ii. History of myocardial infarction, iii. Stable/unstable angina, iv. Coronary or other arterial revascularization, v. Stroke or transient ischemic attack, vi. Peripheral artery disease presumed to be of atherosclerotic origin, vii. Clinically significant multi-vessel coronary heart disease presumed to be of atherosclerotic origin. Initial reauthorization requires documentation of response to therapy, defined as a decrease in LDL-C levels from pre-treatment levels.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

NORTHERA

MEDICATION(S)

NORTHERA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

Initial authorization will be for two months. Reauthorization will be for six months.

OTHER CRITERIA

N/A

NOURIANZ

MEDICATION(S)

NOURIANZ

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Patients with a major psychotic disorder

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with a neurologist

COVERAGE DURATION

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

OTHER CRITERIA

N/A

NUEDEXTA

MEDICATION(S)

NUEDEXTA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Initial authorization: Documentation of a neurologic disease or brain injury (such as traumatic brain injury, stroke, dementia, multiple sclerosis, amyotrophic lateral sclerosis [ALS], or Parkinson's disease).

Reauthorization: Documentation of response to therapy, defined as a reduction in episodes of laughing, crying, and/or emotional lability.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA

N/A

NUPLAZID

MEDICATION(S)

NUPLAZID

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

OCALIVA

MEDICATION(S)

OCALIVA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

1. Confirmed diagnosis of Primary Biliary Cirrhosis with two of three of the following criteria are met: a. Elevated alkaline phosphatase (greater than upper limit of normal [ULN]), b. Presence of antimitochondrial antibody (AMA) (titer greater than or equal to 1:40), c. Liver biopsy consistent with primary biliary cirrhosis AND 2. Both of the following: a. Use of ursodiol for a minimum of 6 months and failure to achieve: ALP less than or equal to 1.5 X ULN, AST less than or equal to 1.5 X ULN, and total bilirubin (tBili) less than or equal to ULN. If laboratory reference values for ALP are not available, the values used in a clinical trial may be used for this assessment (ULN = 117 U/L for women, 129 U/L for men). AND b. Documentation that ursodiol will be continued unless there were intolerable adverse effects with ursodiol AND 3. Dose is appropriate based on an assessment of hepatic function (Child-Pugh class). If Child-Pugh B or C, start at 5 mg once weekly (can be increased if needed to a maximum of 10mg twice weekly). Reauthorization: 1. Maintenance of biochemical response (ie. alkaline phosphatase (ALP) less than or equal to 1.67 times ULN, total bilirubin (tBili) less than or equal to ULN, and an ALP decrease of at least 15%) 2. Documentation that ursodiol will be continued, if tolerated 3. Hepatic function is assessed at least annually. If Child-Pugh B or C, dose should not exceed 10mg twice weekly)

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

OCTREOTIDE

MEDICATION(S)

OCTREOTIDE ACETATE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For treatment of diarrhea, the patient must have documentation of one of the following: 1. Severe diarrhea or flushing caused by a carcinoid tumor, OR 2. Severe diarrhea caused by a vasoactive intestinal peptide tumors, OR 3. Severe diarrhea caused by chemotherapy or AIDS and has failed treatment with loperamide. Reauthorization will require documentation of response to therapy, defined as a reduction in diarrhea episodes. For acromegaly: 1. Confirmed diagnosis of acromegaly, AND 2. Documentation of an inadequate response to surgery or pituitary irradiation or patient is not a candidate for surgical resection and pituitary irradiation, AND 3. History of failure or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses. Reauthorization will require documentation of a positive clinical response to therapy (e.g., reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size). For variceal bleeding: Documentation that therapy will be used short term (less than 1 month), as use beyond one month is not considered medically necessary.

AGE RESTRICTION

Approved for patients 18 years of age and older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Variceal bleeding: 1 month. Other indications: Initial and reauthorization for 12 months

OTHER CRITERIA

N/A

ORAL OCTREOTIDE

MEDICATION(S)

MYCAPSSA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial authorization and reauthorization for 12 months

OTHER CRITERIA

N/A

ORENCIA

MEDICATION(S)

ORENCIA 125 MG/ML SYRINGE, ORENCIA 50 MG/0.4 ML SYRINGE, ORENCIA 87.5 MG/0.7 ML SYRINGE, ORENCIA CLICKJECT

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA

N/A

ORLADEYO (PENDING CMS APPROVAL)

MEDICATION(S)

ORLADEYO

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Used in combination with other HAE prophylactic therapies (e.g., Cinryze, Haegarda, Takhzyro)

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) 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. Reauthorization requires documentation of benefit of therapy with reduction of frequency and severity of HAE attacks.

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

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

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

OTHER CRITERIA

N/A

OSTEOANABOLIC AGENTS

MEDICATION(S)

TYMLOS

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

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

N/A

OXERVATE

MEDICATION(S)

OXERVATE

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Initial authorization: Confirmed diagnosis of stage 2 (recurrent/persistent epithelial defect) or stage 3 (corneal ulcer) neurotrophic keratitis in the affected eye(s) with diagnosis supported by chart notes.

Reauthorization: 1. Documentation of a positive response to therapy 2. Clinical rationale for re-treatment of the same eye or treatment beyond 8 weeks.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with an ophthalmologist

COVERAGE DURATION

Initial and reauthorization will be approved for 8 weeks

OTHER CRITERIA

N/A

PALYNZIQ

MEDICATION(S)

PALYNZIQ

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Use in combination with sapropterin (Kuvan)

REQUIRED MEDICAL INFORMATION

For initial authorization all of the following criteria must be met: 1. Diagnosis of phenylketonuria (PKU) and 2. Blood phenylalanine concentration greater than 600 micromol/L despite management with sapropterin (Kuvan). For reauthorization, ONE of the following criteria must be met: 1. Documentation that blood phenylalanine concentration levels have decreased by at least 20% from baseline and remain at least 20% below pretreatment baseline OR 2. Documentation of a blood phenylalanine concentration less than or equal to 600 micromol/L. 3. For Initial Reauthorization Only: Documentation of plan for further up-titration to maximum dose of 40 mg once daily. Note: If patient has been on pegvaliase 20 mg daily for at least 24 weeks and has not met the reauthorization criteria above, may consider approval for 6 months for trial of maximum dose of 40 mg once daily.

AGE RESTRICTION

Approved for patients 18 years of age and older

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

Initial authorization for 6 months, reauthorization for 1 year

OTHER CRITERIA

N/A

PARATHYROID HORMONE

MEDICATION(S)

NATPARA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

All of the following criteria must be met: 1. Patient must be diagnosed with permanent/chronic hypoparathyroidism (i.e. not acute post-surgical hypoparathyroidism), 2. Confirmed serum albumin corrected calcium is above 7.5 mg/dL (1.9 mmol/L), AND 3. Confirm serum 25-hydroxyvitamin D is greater than or equal to 30 ng/mL (75 nmol/L).

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

PART D VS PART B

MEDICATION(S)

ABELCET, ACETYLCYSTEINE 10% VIAL, ACETYLCYSTEINE 20% VIAL, ACYCLOVIR SODIUM, ALBUTEROL 100 MG/20 ML SOLN, ALBUTEROL 2.5 MG/0.5 ML SOL, ALBUTEROL 5 MG/ML SOLUTION, ALBUTEROL SUL 0.63 MG/3 ML SOL, ALBUTEROL SUL 1.25 MG/3 ML SOL, ALBUTEROL SUL 2.5 MG/3 ML SOLN, AMBISOME, AMINOSYN II 15% IV SOLUTION, AMPHOTERICIN B 50 MG VIAL, ASTAGRAF XL, AZATHIOPRINE 50 MG TABLET, AZATHIOPRINE SODIUM, BONIVA 3 MG/3 ML SYRINGE, BUDESONIDE 0.25 MG/2 ML SUSP, BUDESONIDE 0.5 MG/2 ML SUSP, BUDESONIDE 1 MG/2 ML INH SUSP, CALCITONIN-SALMON, CALCITRIOL 0.25 MCG CAPSULE, CALCITRIOL 0.5 MCG CAPSULE, CALCITRIOL 1 MCG/ML SOLUTION, CELLCEPT 200 MG/ML ORAL SUSP, CINACALCET HCL, CLINOLIPID, CROMOLYN 20 MG/2 ML NEB SOLN, CUTAQUIG, CUVITRU, CYCLOPHOSPHAMIDE 25 MG CAPSULE, CYCLOPHOSPHAMIDE 50 MG CAPSULE, CYCLOSPORINE 100 MG CAPSULE, CYCLOSPORINE 25 MG CAPSULE, CYCLOSPORINE MODIFIED, DERMACINRX EMPRICAIN, DERMACINRX PRIZOPAK, DOXERCALCIFEROL 0.5 MCG CAP, DOXERCALCIFEROL 1 MCG CAPSULE, DOXERCALCIFEROL 2.5 MCG CAP, ENGERIX-B ADULT, ENGERIX-B PEDIATRIC-ADOLESCENT, ENVARBUS XR, EVEROLIMUS 0.25 MG TABLET, EVEROLIMUS 0.5 MG TABLET, EVEROLIMUS 0.75 MG TABLET, GAMASTAN, GAMASTAN S-D, GANCICLOVIR 500 MG VIAL, GENGRAF, HEPARIN 10,000 UNIT/10 ML VIAL, HEPARIN 2,000 UNIT/2 ML VIAL, HEPARIN 30,000 UNIT/30 ML VIAL, HEPARIN SOD 1,000 UNIT/ML VIAL, HIZENTRA, HYQVIA, IBANDRONATE 3 MG/3 ML SYRINGE, IBANDRONATE 3 MG/3 ML VIAL, INTRALIPID, IPRATROPIUM BR 0.02% SOLN, IPRATROPIUM-ALBUTEROL, LEVOCARNITINE 1 G/10 ML SOLN, LEVOCARNITINE 330 MG TABLET, LIDO-PRILO CAINE PACK, LIDOCAINE 5% OINTMENT, LIDOCAINE-PRILOCAINE, LIDOPRIL, LIDOPRIL XR, LIPROZONEPAK, MEDOLOR PAK, MYCOPHENOLATE 200 MG/ML SUSP, MYCOPHENOLATE 250 MG CAPSULE, MYCOPHENOLATE 500 MG TABLET, MYCOPHENOLIC ACID, NULOJIX, NUTRILIPID, OMEGAVEN, PAMIDRONATE DISODIUM, PARICALCITOL, PENTAMIDINE 300 MG INHAL POWDR, PLENAMINE, PRILOLID, PROGRAF 0.2 MG GRANULE PACKET, PROGRAF 1 MG GRANULE PACKET, PROGRAF 5 MG/ML AMPULE, PULMOZYME, RAPAMUNE 1 MG/ML ORAL SOLN, RECOMBIVAX HB, RELADOR PAK, RELADOR PAK PLUS, SIROLIMUS 0.5 MG TABLET, SIROLIMUS 1 MG TABLET, SIROLIMUS 1 MG/ML SOLUTION, SIROLIMUS 2 MG TABLET, SMOFLIPID, TACROLIMUS 0.5 MG CAPSULE (IR), TACROLIMUS 1 MG CAPSULE (IR), TACROLIMUS 5 MG CAPSULE (IR), TOBRAMYCIN 300 MG/5 ML AMPULE, ZEMPLAR 10 MCG/2 ML VIAL, ZEMPLAR 2 MCG/ML VIAL, ZEMPLAR 5 MCG/ML VIAL, ZOLEDRONIC ACID, ZORTRESS

DETAILS

This drug may be covered under Medicare Part B or D depending on the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

PCSK-9 INHIBITORS

MEDICATION(S)

REPATHA PUSHTRONEX, REPATHA SURECLICK, REPATHA SYRINGE

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Concomitant use with another PCSK9 inhibitor

REQUIRED MEDICAL INFORMATION

For initial authorization, both criteria 1 and 2 must be met. 1. One of the following: a. Provider attestation of a trial and failure of high-intensity statin therapy (e.g., atorvastatin 40-80 mg or rosuvastatin 20-40 mg daily), defined as failure to achieve desired LDL-C lowering OR b. Provider attestation of an intolerance to TWO different statins, defined as inability to tolerate the lowest FDA approved starting dose OR c. The patient has an FDA labeled contraindication to a statin 2. One of the following: a. For primary hyperlipidemia, including Heterozygous Familial Hypercholesterolemia (HeFH) OR Homozygous Familial Hypercholesterolemia (HoFH), confirmed diagnosis by one of the following: i. A 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 b. A diagnosis of ASCVD, defined as one of the following: i. Acute coronary syndromes ii. History of myocardial infarction iii. Stable/unstable angina iv. Coronary or other arterial revascularization v. Stroke or transient ischemic attack vi. Peripheral artery disease presumed to be of atherosclerotic origin vii. Clinically significant multi-vessel coronary heart disease presumed to be of atherosclerotic origin. Initial reauthorization requires provider attestation of response to therapy, defined as a decrease in LDL-C levels from pre-treatment levels.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

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

Initial authorization will be approved for 3 months, up to 100 days post-transplant.

OTHER CRITERIA

N/A

PROCYSBI

MEDICATION(S)

PROCYSBI DR 300 MG GRANULE PKT, PROCYSBI DR 75 MG GRANULE PKT

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA

N/A

PROMACTA

MEDICATION(S)

PROMACTA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For chronic immune thrombocytopenia (ITP) all of the following criteria must be met: 1. Patient is at risk for bleeding with a platelet count of less than 30,000 per microliter AND 2. Documentation of trial and failure, intolerance, or contraindication to at least one of the following: a. Systemic corticosteroids, b. Immune gamma globulin, OR c. Splenectomy. For severe aplastic anemia: 1. Patient is at risk for bleeding with a platelet count of less than or equal to 30,000 per microliter. For reauthorization for ITP or severe aplastic anemia: Platelet levels demonstrating response to therapy as well as documentation that therapy continues to be required to maintain a platelet count of at least 50,000 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 4 months. Reauthorization will be approved for 6 months.

OTHER CRITERIA

N/A

PULMONARY ARTERIAL HYPERTENSION

MEDICATION(S)

ADEMPAS, ALYQ, AMBRISENTAN, BOSENTAN, OPSUMIT, SILDENAFIL 20 MG TABLET, TADALAFIL 20 MG TABLET, TRACLEER 32 MG TABLET FOR SUSP, UPTRAVI

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

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 may 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

Known or suspected gastrointestinal obstruction.

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. 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)

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial authorization and reauthorization will be approved for 1 year.

OTHER CRITERIA

N/A

RESCUE MEDICATION FOR EPILEPSY

MEDICATION(S)

NAYZILAM, VALTOCO

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For patients 18 years of age and older only: Documented trial, failure, intolerance or contraindication to clonazepam oral disintegrating tablets or documentation of why therapy would not be appropriate for member.

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

SAMSCA/JYNARQUE

MEDICATION(S)

JYNARQUE, SAMSCA 15 MG TABLET, TOLVAPTAN

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Hepatic Impairment, Anuria, Hypovolemia

REQUIRED MEDICAL INFORMATION

For autosomal dominant polycystic kidney disease (ADPKD), Jynarque may be covered when all of the following criteria must be met: 1. Diagnosis of ADPKD confirmed by the following: a. Patient with family history of known or suspected ADPKD: at least two cysts per kidney b. Patient without family history of known or suspected ADPKD: genetic confirmation or bilaterally enlarged kidneys with presence of cysts, 2. Confirmed diagnosis of rapidly progressing ADPKD by at least one of the following: a. eGFR decline of at least 5 mL/min/1.73 m² per year over 1 year, b. eGFR decline of at least 2.5 mL/min/1.73 m² per year over a period of 5 years, c. Total kidney volume increase of at least 5% per year confirmed by at least 3 repeated ultrasound or MRI measurements taken at least 6 months apart, 3. Patient does not have significant renal disease other than ADPKD (e.g., renal cancer, acute kidney injury). For hypervolemic and euvolemic hyponatremia, tolvaptan (generic Samsca) may 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, 2. Evidence that initiation and re-initiation of therapy will be in a hospital setting where serum sodium can be monitored closely, 3. Patient does not have an urgent need to raise serum sodium acutely (e.g., acute/transient hyponatremia associated with head trauma)

AGE RESTRICTION

Approved for patients 18 years of age and older

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

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

N/A

COVERAGE DURATION

Initial authorization will be approved for 3 months and reauthorization will be approved for 1 year.

OTHER CRITERIA

N/A

SOMAVERT

MEDICATION(S)

SOMAVERT

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial authorization all of the following criteria must be met: 1. Diagnosis of acromegaly, 2. Documentation of inadequate response to, or that patient is not a candidate for, one of the following treatment options: a. Surgery, b. Radiation therapy, or c. Dopamine agonist (e.g., bromocriptine, cabergoline) therapy, AND 3. Documentation of trial and failure, intolerance or contraindication to octreotide injection therapy. Reauthorization requires documentation of a positive response to therapy, such as a decrease or normalization of insulin like growth factor (IGF)-1.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA

N/A

SUBLINGUAL IMMUNOTHERAPY WITH ALLERGEN-SPECIFIC POLLEN EXTRACTS (SLIT)

MEDICATION(S)

GRASTEK, ODACTRA, ORALAIR, RAGWITEK

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Initial authorization: 1. Diagnosis of allergic rhinitis, with or without conjunctivitis AND 2. Documentation that member remains symptomatic despite treatment with both of the following: a) An intranasal steroid and b) An oral anti-histamine AND 3. Documentation that the sublingual immunotherapy will begin 12 to 14 weeks before the start of the allergy season according to the respective FDA labels. AND 4. Documentation of a positive skin test to the relevant perennial aeroallergen AND 5. Subcutaneous immunotherapy will not be used concurrently. Reauthorization requires documentation of consistent use of medication during treatment period for allergy season previously approved for coverage.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA

N/A

SUNOSI

MEDICATION(S)

SUNOSI

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Idiopathic central nervous system hypersomnia

REQUIRED MEDICAL INFORMATION

Initial Authorization: For Narcolepsy: 1. Diagnosis of narcolepsy as confirmed by sleep study or cerebrospinal fluid hypocretin-1 deficiency (less than 110 pg/mL or less than one-third of the normative values with the same standardized assay) AND 2. Documented trial and failure, intolerance or contraindication to both of the following: a) Stimulant (i.e. amphetamine, methylphenidate) b) Modafinil or Armodafinil. For Obstructive Sleep Apnea (OSA): 1. Diagnosis of OSA as confirmed by sleep study 2. Documented trial and failure, intolerance or contraindication of armodafinil or modafinil. Reauthorization requires documentation that treatment has been effective

AGE RESTRICTION

Approved for patients 18 years of age and older

PRESCRIBER RESTRICTION

Must be prescribed by 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

N/A

SYMPAZAN

MEDICATION(S)

SYMPAZAN

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

1. Documentation of trial and failure, contraindication, or intolerance to clobazam tablets or suspension, AND 2. Documentation of trial and failure, contraindication, or intolerance to one (1) alternative generic formulary agent (e.g., valproic acid, lamotrigine, topiramate, felbamate).

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

SYNAREL

MEDICATION(S)

SYNAREL

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

N/A

TADALAFIL

MEDICATION(S)

TADALAFIL 2.5 MG TABLET, TADALAFIL 5 MG TABLET

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

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

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

N/A

TAFAMIDIS

MEDICATION(S)

VYNDAMAX, VYNDAQEL

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Initial authorization: 1. 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 2. Documentation that patient has a NYHA functional classification of I, II or III 3. 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) 4. Documentation of baseline 6-minute walk test or Kansas City Cardiomyopathy Questionnaire-Overall Summary (KCCQ-OS). Reauthorization: 1. Documentation of a positive clinical response such as evidence of slowing of clinical decline, reduced number of cardiovascular related hospitalizations, improvement or stabilization of the 6-minute walk test or improvement or stabilization in the KCCQ-OS

AGE RESTRICTION

Approved for patients 18 years of age and older

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

TAVALISSE

MEDICATION(S)

TAVALISSE

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

Approved for patients 18 years of age and older

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

TEGSEDI

MEDICATION(S)

TEGSEDI

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Platelet count less than 100×10^9 per liter

REQUIRED MEDICAL INFORMATION

Initial authorization: 1. Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy AND 2. Documentation of a pathogenic TTR mutation AND 3. Patient has a baseline polyneuropathy disability (PND) score of less than or equal to IIIB OR has a baseline familial amyloid polyneuropathy (FAP) stage of I or II AND 4. Baseline neuropathy impairment score (NIS) between 5 and 130 AND 5. Baseline Norfolk Quality of Life-Diabetic Neuropathy Questionnaire (Norfolk-QOL-DN) score AND 6. Demonstrate symptoms consistent with polyneuropathy of hATTR amyloidosis including at least two of the following: Peripheral sensorimotor polyneuropathy (e.g., tingling or increased pain in the hands, feet, hands and/or arms, loss of feeling in the hands and/or feet, numbness or tingling in the wrists, carpal tunnel syndrome, loss of ability to sense temperature, difficulty with fine motor skills, weakness in the legs, difficulty walking), autonomic neuropathy symptoms (e.g., orthostasis, abnormal sweating, sexual dysfunction, recurrent urinary tract infection, dysautonomia [constipation and/or diarrhea, nausea, vomiting, anorexia, early satiety]) AND 7. Not taking in combination with patisiran or tafamidis. Reauthorization: 1. Documentation that patient is tolerating applicable gene therapy AND 2. Documented improvement or stabilization in polyneuropathy symptoms, defined as improvement or stabilization from baseline in the Neuropathy impairment score (NIS) AND at least one of the following measures: a) Baseline polyneuropathy disability (PND) score b) Familial amyloid polyneuropathy (FAP) stage c) Norfolk Quality of Life-Diabetic Neuropathy Questionnaire (Norfolk-QOL-DN) score

AGE RESTRICTION

Approved for patients 18 years of age and older

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

TESTOSTERONE REPLACEMENT THERAPY

MEDICATION(S)

ANDRODERM, 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 PEDIATRIC CROHN'S, HUMIRA PEN, HUMIRA PEN CROHN'S-UC-HS, HUMIRA PEN PSOR-UVEITS-ADOL HS, HUMIRA(CF), HUMIRA(CF) PEDIATRIC CROHN'S, HUMIRA(CF) PEN, HUMIRA(CF) PEN CROHN'S-UC-HS, HUMIRA(CF) PEN PEDIATRIC UC, HUMIRA(CF) PEN PSOR-UV-ADOL HS, OTEZLA, RINVOQ, SKYRIZI (2 SYRINGES) KIT, STELARA 45 MG/0.5 ML SYRINGE, STELARA 45 MG/0.5 ML VIAL, STELARA 90 MG/ML SYRINGE, TREMFYA, XELJANZ, XELJANZ XR

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Patient is currently being treated with another therapeutic immunomodulator or apremilast

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

N/A

THIOLA

MEDICATION(S)

THIOLA, THIOLA EC

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial authorization: Confirmation of cystinuria by at least one 24-hour urine collection with measurement of urinary cysteine levels greater than 500 mg/day. Reauthorization requires documentation of urine cysteine concentration less than 300 mg/L or reduction in production of cysteine stones.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

TOPIRAMATE ER

MEDICATION(S)

TOPIRAMATE ER

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

TRIENTINE

MEDICATION(S)

CLOVIQUE, TRIENTINE HCL

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Cystinuria or rheumatoid arthritis

REQUIRED MEDICAL INFORMATION

Documentation of trial and failure, intolerance, or contraindication to penicillamine (Depen®)

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA

N/A

VASCEPA

MEDICATION(S)

ICOSAPENT ETHYL, VASCEPA 0.5 GM CAPSULE

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For the treatment of hypertriglyceridemia, all of the following criteria must be met: 1. A triglyceride level within the past 6 months that is greater than or equal to 500 mg/dL, AND 2. A two-month trial and failure, intolerance, or contraindication to a formulary agent to treat very high triglycerides (such as fenofibrate). Reauthorization requires documentation of reduction in triglyceride levels. For reducing risk of cardiovascular events, all of the following criteria must be met: 1. Patient must meet one of the following: a. Patients with established cardiovascular disease (i.e., coronary artery disease, cerebrovascular or carotid disease, or peripheral arterial disease), OR b. Diabetic patients with at least one additional risk factor (e.g., smoker, hypertension, low HDL-cholesterol, retinopathy), AND 2. A triglyceride level within the past 6 months of 150 to 499 mg/dL, AND 3. Current use of statin therapy for at least 4 weeks or intolerance/contraindication to their use, AND 4. Documented LDL-cholesterol between 40 and 100 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 irritable bowel disease with diarrhea (IBS-D): 1. Confirmed diagnosis by a gastroenterologist, 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

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

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 more than 37, b. Family history (if known), and c. Classic presentation (choreiform movements, psychiatric problems, and dementia). Reauthorization requires documentation of response to therapy (e.g., improved function through reduction of choreiform movements). For tardive dyskinesia, all of the following criteria must be met: 1. Diagnosis of tardive dyskinesia secondary to therapy with a dopamine receptor blocking agent, 2. Documentation of the patient's baseline Abnormal Involuntary Movement Scale (AIMS) score, 3. Documentation of moderate to severe tardive dyskinesia, as defined by one of the following AIMS scores: a. Total score on items 1-7 of at least 8, b. Score of 3 or 4 on item 8 (severity of abnormal movement overall): AND 4. Documentation of a 30-day trial and failure, contraindication, or intolerance to amantadine. Reauthorization requires documentation of positive clinical response to therapy, as demonstrated by improvement in AIMS.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

WAKIX

MEDICATION(S)

WAKIX

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Idiopathic central nervous system hypersomnia

REQUIRED MEDICAL INFORMATION

Initial Authorization: For Narcolepsy: 1. Diagnosis of narcolepsy as confirmed by one of the following: a. The patient has a Multiple Sleep Latency Test (MSLT) showing both of the following: i. Mean sleep latency of 8 minutes or less AND ii. Two (2) or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs) b. The patient has a Multiple Sleep Latency Test (MSLT) showing all of the following: i. Mean sleep latency of 8 minutes or less AND ii. One (1) SOREMP AND iii. Additionally one SOREMP (within approximately 15 minutes) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS) c. The patient has 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 or daytime lapses into sleep occurring for at least 3 months 3. Documentation of a three (3)-month trial and failure, incomplete response, intolerance, or contraindication to both of the following: a) Stimulant (e.g., amphetamine, methylphenidate) b) Modafinil or armodafinil. For cataplexy in adult patients 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 excessive daytime sleepiness defined as an Epworth Sleepiness Scale (ESS) score ≥ 12 or documentation of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months 3. Documentation of at least 3 weekly cataplexy attacks Reauthorization: Documentation of successful response to the medication, such as a reduction in symptoms of excessive daytime sleepiness or reduction in frequency of cataplexy attacks

AGE RESTRICTION

Approved for patients 18 years of age and older

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

N/A

XERMELO

MEDICATION(S)

XERMELO

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

All of the following criteria must be met: 1. Diagnosis of carcinoid syndrome diarrhea 2. Patient is experiencing four (4) or more bowel movements per day, despite use of long-acting octreotide therapy (e.g., octreotide LAR (Sandostatin LAR), lanreotide (Somatuline®) for at least three (3) months 3. Documentation of failure to the use of short-acting octreotide (Sandostatin) for breakthrough symptoms. Failure is defined as continuing to experience four (4) or more bowel movements per day despite daily use 4. Documentation that long-acting octreotide therapy will be used in combination with the requested medication.

Reauthorization will require documentation of response to therapy, defined as a reduction in frequency of bowel movements

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

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

N/A

REQUIRED MEDICAL INFORMATION

For traveler's diarrhea (200 mg tablets): 1. Diagnosis of traveler's diarrhea caused by noninvasive strains of Escherichia coli, AND 2. Documentation that the patient does not have a fever or blood in the 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): 1. Documentation of trial and failure, contraindication, or intolerance to opioid mu receptor agonists (e.g. loperamide), AND 2. Documentation of trial and failure, contraindication, or intolerance to ONE of the following medications: a. Anti-spasmodic agent [e.g. dicyclomine] b. Tricyclic antidepressants (TCAs) or selective serotonin reuptake (SSRIs) (e.g. amitriptyline, fluoxetine, or sertraline). Reauthorization in IBS-D requires documentation of initial response to treatment with rifaximin and recurrence of IBS-D symptoms.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

Hepatic encephalopathy: 1 year. Traveler's diarrhea: 3 days. IBS-D: 14 days

OTHER CRITERIA

N/A

XOLAIR

MEDICATION(S)

XOLAIR

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For asthma, must meet all of the following criteria: 1. Diagnosis of moderate or severe persistent allergic asthma, 2. IgE baseline levels greater than 30 IU/ml, 3. Positive skin test to common perennial aeroallergens, 4. Documentation of at least a 90-day trial of a combination of a 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. Initial reauthorization for asthma will require documentation of response to therapy with at least one of the following: 1. Improvement in ACT or ACQ score, 2. Reduction in number of asthma exacerbations requiring oral systemic corticosteroids or hospitalization, or 3. Decrease in utilization of rescue medications (This may be verified by pharmacy claims information). Subsequent reauthorization requires documentation of continued benefit from therapy. For chronic idiopathic urticaria, must meet all of the following criteria: 1. Documentation that secondary causes of urticaria (e.g., offending allergens, physical contact, etc.) have been ruled out, 2. Trial and failure, intolerance, or contraindication to 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

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).

COVERAGE DURATION

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

OTHER CRITERIA

N/A

XYREM (PENDING CMS APPROVAL)

MEDICATION(S)

XYREM, XYWAV

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For Narcolepsy: 1. Full nocturnal polysomnogram and a multiple sleep latency test showing mean onset to sleep less than 10 minutes, AND 2. No other polysomnographic reasons to explain sleepiness, AND 3. For adult patients: documentation of trial and failure, contraindication, or intolerance to modafinil AND armodafinil, unless the patient is diagnosed with cataplexy. Reauthorization requires documentation that treatment has been effective.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with a sleep specialist or neurologist.

COVERAGE DURATION

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

OTHER CRITERIA

N/A