

Network Health Insurance Corporation

Network Health Zero (PPO)

Network Health Select (PPO)

Network Health Choice (PPO)

Network Health PlusRx (PPO)

Network Health PremierRx (PPO)

Network Health Go (PPO)

Network Health Anywhere (PPO)

Prior Authorization Criteria

Last Updated 4/2026

ACTEMRA

MEDICATION(S)

TYENNE 162 MG/0.9 ML SYRINGE, TYENNE AUTOINJECTOR

PENDING CMS APPROVAL

ADEMPAS

MEDICATION(S)

ADEMPAS

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Concurrent Use with Phosphodiesterase Inhibitors Used for Pulmonary Hypertension or Other Soluble Guanylate Cyclase Stimulators.

REQUIRED MEDICAL INFORMATION

Diagnosis as confirmed by right heart catheterization, history of pre-requisite medications (as described below)

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

PAH and CTEPH-must be prescribed by or in consultation with a cardiologist or a pulmonologist.

COVERAGE DURATION

3 years

OTHER CRITERIA

Pulmonary arterial hypertension (PAH) WHO Group 1: Patient meets the following (1, 2, 3 and 4):

1. Diagnosis of PAH confirmed on pretreatment right heart catheterization showing all of the following (a, b and c):

a. Mean pulmonary arterial pressure (mPAP) greater than or equal to 25 mm Hg at rest, b. Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg, c. Pulmonary vascular resistance (PVR) greater than 3 Wood units, 2. Individual has WHO functional class II-IV symptoms.

3. At least one of the following (a or b): a. The member has demonstrated a failure, inadequate

response or intolerance to one of the preferred products, ambrisentan or bosentan. Documentation of the failure, including dates of trial and reason for failure is required, OR b. The member has a documented contraindication or would be reasonably expected to have an adverse reaction to both of the preferred products, ambrisentan and bosentan. Documentation including the medication name(s) and contraindication or adverse reaction is required 4. At least one of the following (a or b): a. The member has demonstrated a failure, inadequate response or intolerance to one of the preferred products, sildenafil or tadalafil. Documentation of the failure, including dates of trial and reason for failure is required, OR b. The member has a documented contraindication or would be reasonably expected to have an adverse reaction to both of the preferred products, sildenafil and tadalafil. Documentation including the medication name(s) and contraindication or adverse reaction is required. CTEPH: Patient meets the following (a, b, c, and d): a. Patient has diagnosis of CTEPH that is inoperable or persistent/recurrent after surgical treatment (i.e., pulmonary endarterectomy), b. CTEPH is symptomatic, c. Pulmonary vascular resistance of more than 3 Wood units, d. Mean pulmonary arterial pressure (mPAP) of at least 25 mm Hg.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

AGENTS FOR GAUCHER DISEASE

MEDICATION(S)

CERDELGA, CERZYME, ELELYSO, MIGLUSTAT, VPRIV, YARGESA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis, genetic tests and lab results

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a geneticist, endocrinologist, hepatologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders.

COVERAGE DURATION

1 year

OTHER CRITERIA

Gaucher Disease, Type 1-approve if there is demonstration of deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts OR molecular genetic testing documenting glucocerebrosidase gene mutation.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

AGENTS FOR UREA CYCLE DISORDERS

MEDICATION(S)

SODIUM PHENYLBUTYRATE

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Concurrent use with more than one phenylbutyrate product

REQUIRED MEDICAL INFORMATION

Diagnosis, genetic or enzymatic tests

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)

COVERAGE DURATION

1 year

OTHER CRITERIA

Urea cycle disorders – Initial: approve if genetic or enzymatic testing confirmed a urea cycle disorder. Continuation: Approve if there is confirmation of clinically significant improvement or stabilization in plasma ammonia level.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

AIMOVIG

MEDICATION(S)

AIMOVIG AUTOINJECTOR

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Combination with a CGRP antagonist when the CGRP antagonist is being used for prophylaxis

REQUIRED MEDICAL INFORMATION

Diagnosis

AGE RESTRICTION

18 years of age and older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

12 months

OTHER CRITERIA

For Initial approval: The member must have a diagnosis of Chronic migraine or Episodic migraine.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

ALOSETRON

MEDICATION(S)

ALOSETRON HCL

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Exclude if patient is biologically male

REQUIRED MEDICAL INFORMATION

Diagnosis, Reauth: positive clinical response

AGE RESTRICTION

18 years and older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 6 months, continuation: 1 year

OTHER CRITERIA

Severe diarrhea-predominant Irritable bowel syndrome (IBS): 1. Initial: Approve if the patient meets the following (a, b, c and d):

a. Patient has experienced chronic IBS symptoms for 6 months or longer, b. Patient had anatomic or biochemical abnormalities of the gastrointestinal track excluded, c. Patient has tried and failed one anti-diarrheal agent (e.g. loperamide), d. Patient has tried and failed one antispasmodic agent (e.g. dicyclomine). 2. Continuation: Approve if the patient meets the following (a, b and c):

a. If patient is new to plan, meets initial criteria at time they had started the medication, b. Documented dose and frequency are within the FDA approved dosing and frequency, c. Patient is experiencing a positive clinical response to therapy

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

ALPHA 1 PROTEINASE INHIBITORS

MEDICATION(S)

ARALAST NP, GLASSIA, PROLASTIN C 1,000 MG/20 ML VL, ZEMAIRA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis

AGE RESTRICTION

18 years and older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

Alpha1-Antitrypsin (AAT) Deficiency with Emphysema (or Chronic Obstructive Pulmonary Disease)-
approve if the patient meets both of the following (a and b):

a) Patient has a baseline (pretreatment) AAT serum concentration of less than 11 micromol/L [less than 80 mg/dL if measured by radial immunodiffusion or less than 57 mg/dL if measured by nephelometry].

b) Patient is a current non-smoker

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

AMBRISENTAN

MEDICATION(S)

AMBRISENTAN

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis as confirmed by right heart catheterizations

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by, or in consultation with, a cardiologist or pulmonologist.

COVERAGE DURATION

Lifetime

OTHER CRITERIA

Pulmonary arterial hypertension (PAH) WHO Group 1: Patient meets the following (1 and 2): 1. Diagnosis of PAH confirmed on pretreatment right heart catheterization showing all of the following (a, b and c): a. Mean pulmonary arterial pressure (mPAP) greater than or equal to 25 mm Hg at rest b. Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg c. Pulmonary vascular resistance (PVR) greater than 3 Wood units AND 2. Individual has WHO functional class II-IV symptoms.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

ANTICONVULSANT THERAPY

MEDICATION(S)

BRIVARACETAM 10 MG TABLET, BRIVARACETAM 10 MG/ML ORAL SOL, BRIVARACETAM 100 MG TABLET, BRIVARACETAM 25 MG TABLET, BRIVARACETAM 50 MG TABLET, BRIVARACETAM 75 MG TABLET, 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, DIACOMIT, DILANTIN 30 MG CAPSULE, ESLICARBAZEPINE ACETATE, METHSUXIMIDE, MOTPOLY XR, PERAMPANEL, RUFINAMIDE, SPRITAM, SUBVENITE 10 MG/ML SUSPENSION, TOPIRAMATE 25 MG/ML SOLUTION, VIGABATRIN, VIGAFYDE, XCOPRI, ZONISADE

PENDING CMS APPROVAL

ANTIFUNGALS (IV)

MEDICATION(S)

VORICONAZOLE 200 MG VIAL, VORICONAZOLE (HPBCD)

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

3 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

ARANESP

MEDICATION(S)

ARANESP 10 MCG/0.4 ML SYRINGE, ARANESP 100 MCG/0.5 ML SYRINGE, ARANESP 100 MCG/ML VIAL, ARANESP 150 MCG/0.3 ML SYRINGE, ARANESP 200 MCG/0.4 ML SYRINGE, ARANESP 200 MCG/ML VIAL, ARANESP 25 MCG/0.42 ML SYRING, ARANESP 25 MCG/ML VIAL, ARANESP 300 MCG/0.6 ML SYRINGE, ARANESP 40 MCG/0.4 ML SYRINGE, ARANESP 40 MCG/ML VIAL, ARANESP 500 MCG/1 ML SYRINGE, ARANESP 60 MCG/0.3 ML SYRINGE, ARANESP 60 MCG/ML VIAL

PA INDICATION INDICATOR

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

OFF LABEL USES

Anemia due to myelodysplastic syndrome (MDS)

EXCLUSION CRITERIA

Uncontrolled hypertension. Anemic patients willing to donate autologous blood pre-operatively. Anemia due to factors other than diagnoses noted (iron or folate deficiency, hemolysis, GI bleeding). Patients receiving hormonal agents, therapeutic biological products, or radiotherapy UNLESS also receiving concomitant myelosuppressive chemotherapy. For immediate anemia correction or as a substitute for emergency transfusion. Prophylactic use to prevent chemotherapy included anemia.

REQUIRED MEDICAL INFORMATION

Chronic renal failure patients not on dialysis must have symptomatic anemia with a HGB of 10g/dl or less. Non myeloid malignancy chemotherapy induced anemia must have HGB of 10g/dl or less to start AND serum ferritin greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20% or patient is receiving supplemental iron - if previously receiving Aranesp or epoetin alfa, Hgb must be 12 g/dl or less and the patient has had a response to therapy. For Myelodysplastic Syndrome refractory anemia diagnosis must include excess blasts, or excess blasts in transformation to leukemia when, for medical reasons, the patient is not a candidate for active treatment of active leukemia. For Myelodysplastic Syndrome the patient must have endogenous EPO serum level less than 500mu/ml AND serum ferritin greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20% or patient is receiving supplemental iron. For MDS, if previously receiving Aranesp or epoetin alfa, Hgb must be 12 g/dl or less and the patient has had a response to therapy.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

MDS anemia, prescribed by or in consultation with, a hematologist or oncologist.

COVERAGE DURATION

Chemo-induced anemia: 6 months. All other indications - 1 year.

OTHER CRITERIA

For non myeloid malignancy anemia related to chemotherapy, the member must have received chemotherapy in past 8 weeks and will be receiving chemo for a minimum of 2 months. Part B versus Part D determination will be made at time of prior authorization review per CMS guidance to establish if the drug prescribed is to be used for an end-stage renal disease (ESRD)-related condition.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

ARCALYST

MEDICATION(S)

ARCALYST

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Concurrent use a biologic drug or targeted synthetic drug

REQUIRED MEDICAL INFORMATION

Diagnosis, Reauth: documentation of positive clinical response

AGE RESTRICTION

CAPS, Pericarditis - 12 years or greater.

PRESCRIBER RESTRICTION

CAPS-prescribed by, or in consultation with, a rheumatologist, geneticist, allergist/immunologist, or dermatologist. DIRA - prescribed by, or in consultation with, a rheumatologist, geneticist, dermatologist or a physician specializing in the treatment of autoinflammatory disorders. Pericarditis - prescribed by, or in consultation with, a rheumatologist or cardiologist.

COVERAGE DURATION

CAPS, DIRA: Initial: 6 months, cont 1 year. Pericarditis: Initial 3 months, cont 1 year

OTHER CRITERIA

1. Cryopyrin-Associated Periodic Syndrome: a. Initial: Approve if patient meets all of the following (i, ii and iii): i. Patient has a diagnosis of Familial Cold Autoinflammatory Syndrome (FCAS) with classic signs and symptoms (i.e. recurrent, intermittent fever and rash that are often exacerbated by exposure to generalized cool ambient temperature), Muckle-Wells Syndrome (MWS) with classic signs and symptoms (i.e. chronic fever and rash of waxing and waning intensity, sometimes exacerbated by exposure to generalized cool ambient temperature), ii. Patient must be up to date and have received all recommended vaccines or must receive all recommended vaccinations prior to initiation of therapy, iii. Patient has functional impairment limiting the activities of daily living. b. Continuation: Approve if

patient meets all of the following (i and ii): i. For patients new to plan, must have met initial criteria at time of starting medication, ii. Documentation of positive clinical response (low disease activity or improvement in signs and symptoms of the condition). 2. Deficiency of the Interleukin-1 Receptor Antagonist (DIRA) a. Initial: Approve if patient meets all of the following (i, ii, iii and iv): i. Weighs at least 10 kg, ii. Genetic test confirms a mutation in the IL1RN gene, iii. Patient has demonstrated clinical benefit with anakinra subcutaneous infusion, iv. Patient must be up to date and have received all recommended vaccines or must receive all recommended vaccinations prior to initiation of therapy, b. Continuation: Approve if patient meets all of the following (i and ii): i. For patients new to plan, must have met initial criteria at time of starting medication, ii. Documentation of positive clinical response (low disease activity or improvement in signs and symptoms of the condition), 3. Pericarditis: a. Initial: Approve if the patient meets all of the following (i, ii and iii): i. Patient has recurrent pericarditis, ii. Tried and failed at least two agents of standard therapy (e.g. colchicine, non-steroidal anti-inflammatory drugs, corticosteroids) iii. Patient must be up to date and have received all recommended vaccines or must receive all recommended vaccinations prior to initiation of therapy. b. Continuation: Approve if the patient meets all of the following: i. For patients new to plan, must have met initial criteria at time of starting medication, ii. Documentation of positive clinical response (decreased recurrence, improvement of signs and symptoms [e.g. improvement in pericarditic or pleuritic chest pain, pericardial or pleural rubs, ECG, pericardial effusion, or c-reactive protein]).

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

ARIKAYCE

MEDICATION(S)

ARIKAYCE

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis, Amikacin MIC

AGE RESTRICTION

MAC-18 years and older

PRESCRIBER RESTRICTION

MAC-prescribed by a pulmonologist, infectious disease physician or a physician who specializes in the treatment of MAC lung infections.

COVERAGE DURATION

1 year

OTHER CRITERIA

MAC Lung disease: Initial-approve if the patient has NOT achieved negative sputum cultures for MAC since completion of most recent background multidrug regimen AND Arikayce will be used in conjunction to a background multidrug regimen AND the MAC isolate is susceptible to amikacin with minimum inhibitor concentration (MIC) of less than or equal to 64 microgram/mL. Note-a multidrug regimen typically includes a macrolide (azithromycin or clarithromycin), ethambutol and a rifamycin (rifampin or rifabutin). Continuation: Patient has not achieved negative sputum cultures for MAC OR patient has achieved negative sputum cultures for MAC for less than 12 months.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED
YES

ATYPICAL ANTIPSYCHOTICS

MEDICATION(S)

ASENAPINE MALEATE, CAPLYTA, CLOZAPINE ODT, FANAPT, OLANZAPINE-FLUOXETINE HCL, OPIPZA, PALIPERIDONE ER, PERSERIS, QUETIAPINE FUMARATE ER, REXULTI 0.25 MG TABLET, REXULTI 0.5 MG TABLET, REXULTI 1 MG TABLET, REXULTI 2 MG TABLET, REXULTI 3 MG TABLET, REXULTI 4 MG TABLET, SECUADO, VERSACLOZ

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experience with the preferred product, or the clinical condition for which an exception to the preferred product is requested.)

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

3 years

OTHER CRITERIA

For Fanapt, Caplyta, and Rexulti: The drug must be prescribed within the manufacturer's published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance Lybalvi and Vraylar OR the member has a documented contraindication to Lybalvi and Vraylar OR the member

has had an adverse reaction or would be reasonably expected to have an adverse reaction to Lybalvi and Vraylar OR the member has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature.

For clozapine ODT, olanzapine/fluoxetine, paliperidone ER, Secuado, Versacloz suspension, asenapine, Perseris ER and quetiapine ER: The drug must be prescribed within the manufacturer's published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance to two preferred formulary/preferred drug list alternatives for the given diagnosis OR the member has a documented contraindication to two preferred formulary alternative OR the member has had an adverse reaction or would be reasonably expected to have an adverse reaction to two preferred formulary alternatives OR the member has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature. Preferred formulary alternatives include: aripiprazole (tablet, odt, solution), clozapine (tablet), fluphenazine decanoate/fluphenazine hydrochloride (tablet, oral solution, injectable vial), Haloperidol (tablet, oral solution, injectable vial), loxapine, lurasidone, molindone, olanzapine (tablet, ODT), perphenazine, pimozide, quetiapine (IR tablet), risperidone (tablet, ODT, oral solution), thioridazine, thiothixene, trifluoperazine and ziprasidone are the preferred products.

Requests for Rexulti, quetiapine extended release and fluoxetine-olanzapine will be authorized if using for treatment of Major Depressive Disorder. Fluoxetine-olanzapine or quetiapine extended release will be authorized for bipolar depression. Requests for Rexulti will be authorized if using for treatment of agitation associated with dementia due to Alzheimer's disease. Member will not need to try preferred products.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

BASAL INSULIN

MEDICATION(S)

BASAGLAR KWIKPEN U-100, BASAGLAR TEMPO PEN U-100, INSULIN GLARGINE MAX SOLOSTAR, INSULIN GLARGINE SOLOSTAR U300, REZVOGLAR KWIKPEN, TRESIBA, TRESIBA FLEXTOUCH U-100, TRESIBA FLEXTOUCH U-200

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Previous therapies

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

For Basaglar, Basaglar Tempo, and Rezvoglar approval, the member must meet one of the following criteria (A), (B), (C), OR (D): (A) The member has demonstrated a failure to one of the preferred products, Lantus or insulin glargine-YFGN, for the given diagnosis, (B) The member has demonstrated an intolerance to one of the preferred products, (C) The member has a documented contraindication to one of the preferred products, OR (D) The member had an adverse reaction or would be reasonably expected to have an adverse reaction to one of the preferred products for the requested indication.

For insulin glargine U300, Tresiba, the member must meet one of the following criteria (A), (B), (C), OR (D): (A) The member has demonstrated a failure to one of the preferred products, Lantus, insulin

glargine-YFGN or Toujeo, for the given diagnosis, (B) The member has demonstrated an intolerance to one of the preferred products, (C) The member has a documented contraindication to one of the preferred products, or (D) The member had an adverse reaction or would be reasonably expected to have an adverse reaction to one of the preferred products for the requested indication.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

BENLYSTA

MEDICATION(S)

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

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Concurrent Use with Other Biologics, Lupkynis or Saphnelo, patients with active central nervous system lupus

REQUIRED MEDICAL INFORMATION

Diagnosis, ANA or anti-dsDNA level, SLE: SELENA-SLEDAI score, LN: biopsy proven lupus nephritis

AGE RESTRICTION

5 years and older

PRESCRIBER RESTRICTION

SLE-prescribed by, or in consultation with, a rheumatologist, clinical immunologist, nephrologist, neurologist or dermatologist (initial and continuation). Lupus nephritis nephrologist or rheumatologist (initial and continuation).

COVERAGE DURATION

SLE: 4 mo. initial, 1 yrs cont. Lupus Nephritis 6 mo. initial, 1 year cont.

OTHER CRITERIA

Lupus Nephritis: 1) Initial: Approve if patient meets all of the following (a, b and c): a) The patient is autoantibody-positive in the absence of any drugs for SLE as defined as one of the following (1 or 2): (1) ANA titer greater than or equal to 1:80 OR, (2) Anti-dsDNA level greater than or equal to 30 I/ml, b) The patient has biopsy-proven lupus nephritis Class III, IV and/or V, c) The patient has active renal disease requiring standard therapy of corticosteroids with mycophenolate for induction and maintenance or cyclophosphamide for induction followed by azathioprine for maintenance, 2) Continuation: Approve if patient meets all of the following (a and b): a) If patient is new to plan, must have met initial criteria at time of starting medication, b) According to the prescriber, patient has

experienced improvement with therapy. SLE 1) Initial: Approve if patient meets all of the following (a, b and c): a) The patient is autoantibody-positive in the absence of any drugs for SLE as defined as one of the following (1 or 2): (1) ANA titer greater than or equal to 1:80 OR (2) Anti-dsDNA level greater than or equal to 30 I/ml. b) The patient has active SLE with a score of 6 or greater (as documented by a SELENA-SLEDAI or as scored by a comparable standardized rating scale that reliably measures SLE disease activity) while on treatment with corticosteroid, anti-malarial, or immunosuppressant therapy (alone or as combination), c) Benlysta will be used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) d) Continuation: Approve if patient meets all of the following (a, b and c): a. If patient is new to plan, must have met initial criteria at time of starting medication, b. According to the prescriber, patient has experienced improvement in therapy, c. Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate])

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

BOSENTAN

MEDICATION(S)

BOSENTAN 125 MG TABLET, BOSENTAN 62.5 MG TABLET

PA INDICATION INDICATOR

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

OFF LABEL USES

Chronic thromboembolic pulmonary hypertension (CTEPH)

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis as confirmed by right heart catheterizations

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by, or in consultation with, a cardiologist or pulmonologist.

COVERAGE DURATION

Lifetime

OTHER CRITERIA

Pulmonary arterial hypertension (PAH) WHO Group 1: Patient meets the following (1 and 2): 1. Diagnosis of PAH confirmed on pretreatment right heart catheterization showing all of the following (a, b and c): a. Mean pulmonary arterial pressure (mPAP) greater than or equal to 25 mm Hg at rest b. Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg c. Pulmonary vascular resistance (PVR) greater than 3 Wood units AND 2. Individual has WHO functional class II-IV symptoms. CTEPH: Patient meets the following (1 and 2): 1. Patient has diagnosis of CTEPH that is inoperable or persistent/recurrent after surgical treatment (i.e., pulmonary endarterectomy) AND 2. CTEPH is symptomatic.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

BRUKINSA

MEDICATION(S)

BRUKINSA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

Mantle Cell Lymphoma, Chronic Lymphocytic Lymphoma, Small Lymphocytic Lymphoma – Approve if patient meets one of the following:

- 1.The patient has demonstrated an intolerance to the preferred products, Calquence.
- 2.The patient has a documented contraindication to Calquence.
- 3.The patient had an adverse reaction or would be reasonably expected to have an adverse reaction to Calquence.
- 4.The patient has a clinical condition for which there is no listed preferred formulary alternatives to treat the condition based on published guidelines or clinical literature.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED
YES

CARGLUMIC ACID

MEDICATION(S)

CARGLUMIC ACID

PA INDICATION INDICATOR

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

OFF LABEL USES

Acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA)

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis, genetic test

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by, or in consultation with, a metabolic disease specialist or a specialist who focuses in the treatment of metabolic diseases

COVERAGE DURATION

NAGS – pt meets criteria no genetic test – 3 mo. Pt has genetic test – 12 months. All other: 7 days

OTHER CRITERIA

NAGS deficiency with hyperammonemia: Approve if genetic testing confirmed a mutation leading to N-acetylglutamate synthase deficiency.

PA or MMA with hyperammonemia, acute treatment: Approve if the patient's plasma ammonia level is greater than or equal to 50 micromol/L and the requested medication will be used in conjunction with other ammonia-lowering therapies.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

CAYSTON

MEDICATION(S)

CAYSTON

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis of cystic fibrosis.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

Member has *Pseudomonas aeruginosa* colonization in the lungs and has recurrence despite prior use of tobramycin inhalation solution or tobramycin resistance.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

CHENODAL

MEDICATION(S)

CHENODAL

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Patient with calcified (radiopaque) stones

REQUIRED MEDICAL INFORMATION

Patient has diagnosis of radiolucent gallstones in well-opacifying gallbladder as visualized by oral cholecystography.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial and continuation: 1 year

OTHER CRITERIA

For initial therapy, patient must meet both of the following (1 and 2):

1. Patient has tried and failed or has a contraindication or intolerance to ursodiol.
2. Patient is not a candidate for cholecystectomy

For continuation of therapy: Provider confirms patient's condition requires continued treatment as demonstrated by oral cholecystograms or ultrasonograms.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED
YES

CIALIS

MEDICATION(S)

TADALAFIL 2.5 MG TABLET, TADALAFIL 5 MG TABLET

PENDING CMS APPROVAL

COBENFY

MEDICATION(S)

COBENFY, COBENFY STARTER PACK

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Urinary retention. Mild, moderate or severe hepatic impairment. Gastric retention. Untreated narrow-angle glaucoma. History of hypersensitivity to Cobenfy or trospium. Moderate or severe renal impairment (eGFR less than 60 ml/min).

REQUIRED MEDICAL INFORMATION

Diagnosis, eGFR, medication history with preferred formulary alternatives

AGE RESTRICTION

18 years or older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

3 years

OTHER CRITERIA

Patient meets all of the following (1 and 2):

1.Has documented diagnosis of schizophrenia

2.Meets one of the following (a or b):

a.Patient has tried and had an inadequate response to two of the following: Lybalvi, Vraylar and/or Caplyta for the same indication

b.Patient has an intolerance, hypersensitivity and/or FDA labeled contraindication to Lybalvi, Vraylar and Caplyta

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

COSENTYX

MEDICATION(S)

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

PENDING CMS APPROVAL

CRESEMBA

MEDICATION(S)

CRESEMBA 186 MG CAPSULE, CRESEMBA 74.5 MG CAPSULE

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Concurrent use with strong CYP3A4 inhibitors (e.g. ketoconazole, high-dose ritonavir) or strong CYP3A4 inducers (e.g. rifampin, carbamazepine, St. John's wort, or long acting barbiturates). Use in patients with familial short QT syndrome.

REQUIRED MEDICAL INFORMATION

Diagnosis, other medications tried (as found in other criteria), Documented dose and frequency are within the FDA approved Dosing and Frequency

AGE RESTRICTION

6 years and older

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a infectious disease specialist

COVERAGE DURATION

1 year

OTHER CRITERIA

Treatment of invasive aspergillosis - Approve if the member meets one of the following (1 or 2): 1. The member has demonstrated a failure of or intolerance to at least one of the preferred products, posaconazole or voriconazole. Documentation of the failure, including dates of trial and reason for failure is required, OR 2. The member has a documented contraindication or would be reasonably expected to have an adverse reaction to both of the preferred products, posaconazole and voriconazole. Documentation including the medication name(s) and contraindication or adverse reaction is required.

Treatment of invasive mucormycosis - Approve if the member meets one of the following (1 or 2): 1.

The member has demonstrated a failure of or intolerance to the preferred product, posaconazole. Documentation of the failure, including dates of trial and reason for failure is required, OR 2. The member has a documented contraindication or would be reasonably expected to have an adverse reaction to the preferred product, posaconazole. Documentation including the medication name(s) and contraindication or adverse reaction is required.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

CRINONE GEL

MEDICATION(S)

CRINONE

PA INDICATION INDICATOR

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

OFF LABEL USES

Support of an established pregnancy.

EXCLUSION CRITERIA

Use in patients to supplement or replace progesterone in the management of infertility.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Secondary amenorrhea, 12 months. Support of an established pregnancy, 9 months.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

DALFAMPRIDINE

MEDICATION(S)

DALFAMPRIDINE ER

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

The member has sustained walking impairment AND the member is able to walk.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Neurologist or MS specialist.

COVERAGE DURATION

Initial: 1 year. Continuation: 3 years

OTHER CRITERIA

For continuation, authorization will be granted to members with multiple sclerosis for improvement in walking if the member has experienced an improvement in walking speed OR another objective measure of walking ability since starting dalfampridine.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

DEFERASIROX

MEDICATION(S)

DEFERASIROX

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis, ferritin levels

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a hematologist or oncologist

COVERAGE DURATION

1 year

OTHER CRITERIA

1. For Chronic iron overload due to blood transfusions: Ferritin level consistently greater than 1000 mcg/L
2. For chronic overload in non-transfusion dependent thalassemia syndromes (member meets both a and b): a. Patient has liver iron concentration levels consistently greater than or equal to 5 mg Fe per gram of dry weight prior to initiation of deferasirox AND b. Patient has serum ferritin levels consistently greater than 300 mcg/L prior to initiation of treatment

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

DEFERIPRONE

MEDICATION(S)

DEFERIPRONE, DEFERIPRONE (3 TIMES A DAY)

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Transfusional iron overload in patients with myelodysplastic syndrome or in patients with Diamond Blackfan anemia.

REQUIRED MEDICAL INFORMATION

Diagnosis, ANC

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a hematologist or oncologist

COVERAGE DURATION

1 year

OTHER CRITERIA

Member meets all of the following (1, 2 and 3): 1. Diagnosis of transfusional iron overload due to one of the following a. Thalassemia syndromes, b. Sickle cell disease, c. Transfusional-dependent anemia AND 2. Absolute neutrophil count (ANC) is greater than $1.5 \times 10^9/L$ AND 3. Has tried and failed, has intolerance or contraindication to one chelation therapy (e.g. generic deferasirox).

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

DIABETIC SUPPLIES

MEDICATION(S)

1ST TIER UNIFINE PENTIPS, 1ST TIER UNIFINE PENTIPS PLUS, ADVOCATE PEN NEEDLE, ADVOCATE PEN NEEDLES 5MM 31G, ADVOCATE PEN NEEDLES 8MM 31G, ADVOCATE INS 0.3 ML 30GX5/16", ADVOCATE INS 0.3 ML 31GX5/16", ADVOCATE INS 0.5 ML 30GX5/16", ADVOCATE INS 0.5 ML 31GX5/16", ADVOCATE INS 1 ML 31GX5/16", ADVOCATE INS SYR 1 ML 30GX5/16, AIMSCO MINI ULTRA-THIN II, ALCOHOL PREP PADS, ALCOHOL SWABS, ASSURE ID DUO PRO SFTY PEN NDL, ASSURE ID PEN NEEDLE 30GX5/16", AUTOSHIELD DUO PEN NEEDLE, BAND-AID GAUZE PADS 2"X2", CAREFINE PEN NEEDLE, CARETOUCH INSULIN SYRINGE, CARETOUCH PEN NEEDLE, CLICKFINE, COMFORT EZ 0.3 ML 31G 15/64", COMFORT EZ 0.5 ML 31G 15/64", COMFORT EZ INS 0.3ML 30GX1/2", COMFORT EZ INS 0.3ML 30GX5/16", COMFORT EZ INS 0.5ML 31GX5/16", COMFORT EZ INS 1 ML 31G 15/64", COMFORT EZ INS 1 ML 31GX5/16", COMFORT EZ INSULIN SYR 0.3 ML, COMFORT EZ INSULIN SYR 0.5 ML, COMFORT EZ SYR 0.3 ML 29GX1/2", COMFORT EZ SYR 0.5 ML 28GX1/2", COMFORT EZ SYR 0.5 ML 29GX1/2", COMFORT EZ SYR 0.5 ML 30GX1/2", COMFORT EZ SYR 1 ML 28GX1/2", COMFORT EZ SYR 1 ML 29GX1/2", COMFORT EZ SYR 1 ML 30GX1/2", COMFORT EZ SYR 1 ML 30GX5/16", COMFORT EZ PEN NEEDLE, COMFORT TOUCH PEN NEEDLE, CURITY GAUZE PADS, DROPLET INSULIN SYRINGE, DROPLET MICRON PEN NEEDLE, DROPLET PEN NEEDLE, DROPSAFE PEN NEEDLE 31G 5MM, DROPSAFE PEN NEEDLE 31G 8MM, DROPSAFE PEN NEEDLE 31GX1/4", EASY COMFORT 0.5 ML 30GX1/2", EASY COMFORT 0.5 ML 31GX5/16", EASY COMFORT 0.5 ML 32GX5/16", EASY COMFORT 1 ML 31GX5/16", EASY COMFORT 1 ML 32GX5/16", EASY COMFORT SYR 0.5ML 29G 8MM, EASY COMFORT SYR 1 ML 29G 8MM, EASY COMFORT SYR 1 ML 30GX1/2", EASY COMFORT PEN NDL 29G 4MM, EASY COMFORT PEN NDL 29G 5MM, EASY COMFORT PEN NDL 31GX3/16", EASY COMFORT PEN NDL 31GX5/16", EASY COMFORT PEN NDL 33G 4MM, EASY COMFORT PEN NDL 33G 5MM, EASY COMFORT PEN NDL 33G 6MM, EASY COMFORT PEN NEEDLES, EASY COMFORT SAFETY PEN NEEDLE, EASY GLIDE INSULIN SYRINGE, EASY GLIDE PEN NEEDLE, EASY TOUCH INSULIN SYR 1 ML, EASY TOUCH FLIPLOCK INSULIN, EASY TOUCH INSULIN SYRINGE, EASY TOUCH PEN NEEDLE, EASY TOUCH SAFETY PEN NEEDLE, EASY TOUCH SHEATHLOCK INSULIN, EASY-TOUCH INSULIN SYRINGE, EMBRACE PEN NEEDLE, FREESTYLE PRECISION, CVS COTTON GAUZE 2"X2", STERILE GAUZE PADS 2"X 2", CVS GAUZE PADS 2"X2", GAUZE PAD, STERILE 2"X2", GNP STERILE GAUZE PADS 2" X 2", CVS GAUZE PAD 2"X2" STERILE, CVS GAUZE PADS 2" X 2", EQL GAUZE PADS 2"X2", GAUZE PADS 2" X 2 " STERILE, GAUZE PADS NON-STERILE 2X2, GAUZE PADS STERILE 2X2, GAUZE PADS & DRESSINGS - PADS 2 X 2, HEALTHWISE INSULIN SYRINGE, HEALTHWISE PEN NEEDLE, HEALTHY ACCENTS PENTIP 5MM 31G, HEALTHY ACCENTS PENTIP 6MM 31G, HEALTHY ACCENTS PENTIP 8MM 31G, HM INSULIN SYRINGE,

INCONTROL PEN NEEDLE, COMFORT POINT PEN NDL 29GX1/2", COMFORT POINT PEN NDL 31GX1/4", COMFORT POINT PEN NDL 31GX1/6", INSULIN PEN NEEDLE, AIMSCO INS SYR 0.3 ML 29GX1/2", AIMSCO INS SYR 0.3 ML 30GX5/16, AIMSCO INS SYR 0.5 ML 29GX1/2", AIMSCO INS SYR 1 ML 29GX1/2", AIMSCO INS SYR 1 ML 30GX5/16", AIMSCO INSULIN 0.3 ML SYRINGE, AIMSCO INSULIN 0.3 ML SYRNGE, AIMSCO INSULIN 0.5 ML SYRINGE, AIMSCO INSULIN 0.5 ML SYRNGE, AIMSCO INSULIN 1 ML SYRINGE, AIMSCO SYRING 0.3 ML 31GX5/16", AIMSCO SYRING 0.5 ML 30GX5/16", AIMSCO SYRING 0.5 ML 31GX5/16", B-D INSULIN U100-1 ML SYRNG, B-D INSULIN U100-1 ML SYRNGE, B-D INSULIN U40-1 ML SYRINGE, BL INSULIN 0.3 ML SYRINGE, BL INSULIN 0.5 ML SYRINGE, BL INSULIN 1 ML SYRINGE, BL INSULIN SYRINGE 0.3 ML, BL INSULIN SYRINGE 0.5 ML, BL INSULIN SYRINGE 1 ML, BROOKS INSULIN 0.3 ML SYRN, BROOKS INSULIN 1/2 ML SYRN, BROOKS INSULIN SYRINGE 1 ML, CA INS SYR 0.3 ML 30GX5/16", CA INS SYR 0.3 ML 31GX5/16", CA INS SYR 0.5 ML 30GX5/16", CA INS SYR 0.5 ML 31GX5/16", CA INSULIN SYR 0.3 ML 29GX1/2", CA INSULIN SYR 0.5 ML 29GX1/2", CA INSULIN SYR 1 ML 29GX1/2", CA INSULIN SYR 1 ML 30GX5/16", CA INSULIN SYR 1 ML 31GX5/16", CAREONE INS SYR 1 ML 30GX5/16", CAREONE SYR 0.3 ML 30GX1/2", CAREONE SYR 0.3 ML 31GX5/16", CAREONE SYR 0.5 ML 30GX1/2", CAREONE SYR 0.5 ML 31GX5/16", CAREONE SYR 1 ML 30GX1/2", CAREONE SYR 1 ML 31GX5/16", CVS INSULIN SYR 1 ML 29GX1/2", CVS SYRINGE 1/2 ML, CVS SYRINGE 3/10 ML, D&K INSULIN SYRINGE 0.3 ML, D&K INSULIN SYRINGE 0.5 ML, D&K INSULIN SYRINGE 1 ML, DG INSULIN SYR 29G-3/10 ML, DG INSULIN SYRINGE 28G-0.5 ML, DG INSULIN SYRINGE 28G-1 ML, DG INSULIN SYRINGE 29G-0.5 ML, ECK INSULIN 1 ML SYRINGE, ECK INSULIN 1/2 ML SYRINGE, ECK INSULIN 3/10 ML SRYINGE, ECK INSULIN 3/10 ML SYRINGE, EQL INS SYR 0.3 ML 29GX1/2", EQL INS SYR 0.3 ML 30GX5/16", EQL INS SYR 0.5 ML 29GX1/2", EQL INS SYR 0.5 ML 30GX5/16", EQL INSUL SYR 0.3 ML 31GX5/16", EQL INSUL SYR 0.5 ML 31GX5/16", EQL INSULIN SYR 1 ML 29GX1/2", EQL INSULIN SYR 1 ML 30GX5/16", EQL INSULIN SYR 1 ML 31GX5/16", EXEL INS SYR U100 1 ML 28GX1/2, EXEL INSUL SYR 0.5 ML 28GX1/2", FIFTY50 INS 0.3 ML 31GX5/16", FIFTY50 INS 0.5 ML 31GX5/16", FIFTY50 INS SYR 1 ML 31GX5/16", FIRST CHOICE SYRINGE 0.3 ML, FIRST CHOICE SYRINGE 0.5 ML, FIRST CHOICE SYRINGE 1 ML, FP INSULIN 0.3 ML SYRINGE, FP INSULIN 0.5 ML SYRINGE, FP INSULIN 1 ML SYRINGE, FP INSULIN SYRINGE 0.3 ML, FP INSULIN SYRINGE 0.5 ML, FP INSULIN SYRINGE 1 ML, GENTLE TOUCH 1 ML SYRINGE, GNP INS SYRINGE 1 ML 28G 1/2", GNP INSUL SYR 0.5 ML 31GX5/16", HCA INSULIN SYRINGE 0.3 ML, HCA INSULIN SYRINGE 0.5 ML, HCA INSULIN SYRINGE 1 ML, HM INSULIN SYRINGE 0.3 ML, HM INSULIN SYRINGE 0.5 ML, HM INSULIN SYRINGE 1 ML, HY-VEE INS SYRINGE 0.5 ML, HY-VEE INS SYRINGE 1 ML, HY-VEE INS SYRINGE 3/10 ML, INS SYR U100 0.5 ML 29GX1/2", INSULIN 1 ML SYRINGE, INSULIN 1/2 ML SYRINGE, INSULIN 3/10 ML SYRINGE, INSULIN SYR 0.3ML 31GX1/4(1/2), INSULIN SYR 0.5 ML 28G 12.7MM, INSULIN SYR 1 ML HARD PACK, INSULIN SYRIN 0.3 ML 29GX1/2", INSULIN SYRIN 0.3 ML 30GX1/2", INSULIN SYRIN 0.3 ML 30GX5/16", INSULIN SYRIN 0.3 ML 31GX5/16", INSULIN

SYRIN 0.5 ML 28GX1/2", INSULIN SYRIN 0.5 ML 29GX1/2", INSULIN SYRIN 0.5 ML 30G 5/16",
INSULIN SYRIN 0.5 ML 30GX5/16", INSULIN SYRIN 0.5 ML 31G 5/16", INSULIN SYRIN 0.5 ML
31GX5/16", INSULIN SYRING 0.5 ML 27G 1/2", INSULIN SYRING 0.5 ML 28G 1/2", INSULIN
SYRING 0.5 ML 29G 1/2", INSULIN SYRING 0.5 ML 29GX1/2", INSULIN SYRINGE 0.3 ML, INSULIN
SYRINGE 0.3 ML 31GX1/4, INSULIN SYRINGE 0.5 ML, INSULIN SYRINGE 0.5 ML 31GX1/4,
INSULIN SYRINGE 1 ML, INSULIN SYRINGE 1 ML 27G 1/2", INSULIN SYRINGE 1 ML 27G 16MM,
INSULIN SYRINGE 1 ML 27GX1/2", INSULIN SYRINGE 1 ML 28G 1/2", INSULIN SYRINGE 1 ML
28GX1/2", INSULIN SYRINGE 1 ML 29G 1/2", INSULIN SYRINGE 1 ML 29GX1/2", INSULIN
SYRINGE 1 ML 30G 1/2", INSULIN SYRINGE 1 ML 30GX1/2", INSULIN SYRINGE 1 ML 30GX5/16",
INSULIN SYRINGE 1 ML 31G 5/16", INSULIN SYRINGE 1 ML 31GX1/4", INSULIN SYRINGE 1 ML
31GX5/16", INSULIN SYRINGE 1/2 ML, INSULIN SYRINGE 1ML 28G 12.7MM, INSULIN SYRINGE
28GX0.5 ML, INSULIN SYRINGE 28GX1 ML, INSULIN SYRINGE 29G-0.3 ML, INSULIN SYRINGE
29G-0.5 ML, INSULIN SYRINGE 3/10 ML, INSULIN SYRINGE U-100, INSULIN SYRINGE U100 0.5
ML, INSULIN SYRINGE U100 1 ML, INSULIN SYRINGE U100 1/2 ML, KMART VALU PLUS SYR 3/10
ML, KMART VALU PLUS SYRINGE 1 ML, KRO INS SYRIN 0.3 ML 30GX5/16", KRO INS SYRIN 0.3
ML 31GX5/16", KRO INS SYRIN 0.5 ML 30GX5/16", KRO INS SYRIN 0.5 ML 31GX5/16", KRO INS
SYRING 0.5 ML 29GX1/2", KRO INS SYRINGE 1 ML 29GX1/2", KRO INS SYRINGE 1 ML 30GX5/16",
KRO INS SYRINGE 1 ML 31GX5/16", KROGER 0.5 ML INSULIN SYRINGE, KROGER 1 ML INSULIN
SYRINGE, KROGER INS SYR 1 ML 29GX1/2", KROGER INS SYRINGE 0.5 ML, KROGER INS
SYRINGE 3/10 ML, KROGER INSULIN SYRINGE 0.3 ML, KROGER INSULIN SYRINGE 0.3ML,
LEADER INS SYR 0.3 ML 29GX1/2", LEADER INS SYR 0.5 ML, LEADER INS SYR 0.5 ML 28GX1/2",
LEADER INS SYR 0.5 ML 29GX1/2", LEADER INS SYR 0.5 ML 30GX1/2", LEADER INS SYR 1 ML,
LEADER INS SYR 1 ML 28GX1/2", LEADER INS SYR 1 ML 29GX1/2", LEADER INS SYR 1 ML
30GX1/2", LEADER INS SYR 1 ML 31GX5/16", LEADER INS SYR 3/10 ML, LEADER INSULIN
SYRINGE 0.3 ML, LEADER INSULIN SYRINGE 0.5 ML, LEADER INSULIN SYRINGE 1 ML, LEADER
SYRING 0.3 ML 31GX5/16", LEADER SYRING 0.5 ML 31GX5/16", LONGS INS SYR 0.5 ML
29GX1/2", LONGS INS SYR 1 ML 29GX1/2", LONGS INSULIN SYRINGE 0.3 ML, LONGS INSULIN
SYRINGE 0.5 ML, LONGS INSULIN SYRINGE 1 ML, MAJOR INSULIN SYRINGE 0.3 ML, MAJOR
INSULIN SYRINGE 0.5 ML, MAJOR INSULIN SYRINGE 1 ML, MEDIC DRUG INSULIN SYR 0.3 ML,
MS INS SYR 0.5 ML 29GX1/2", MS INS SYR 1 ML 29GX1/2", MS INS SYRINGE 1 ML 30GX1/2", MS
INSUL SYR 0.3 ML 31GX5/16", MS INSUL SYR 0.5 ML 30GX1/2", MS INSUL SYR 0.5 ML 31GX5/16",
MS INSULIN SYR 0.3 ML 29GX1/2", MS INSULIN SYR 1 ML 31GX5/16", MS INSULIN SYRINGE 0.3
ML, MS INSULIN SYRINGE 0.5 ML, MS INSULIN SYRINGE 1 ML, MS INSULIN SYRINGE 3/10 ML,
PV INS SYRIN 1 ML 29GX1/2", PV INSUL SYR 0.3 ML 31GX5/16", PV INSUL SYR 0.5 ML
31GX5/16", PV INSULIN SYR 1 ML 31GX5/16", PV INSULIN SYRINGE 0.5 ML, QC INSUL SYR 0.5
ML 31GX5/16", QC INSULIN SYR 1 ML 31GX5/16", QC INSULIN SYRINGE 0.3 ML, QC INSULIN
SYRINGE 0.5 ML, QC INSULIN SYRINGE 1 ML, RELI-ON INSULIN 0.3 ML SYR, RELI-ON INSULIN

0.5 ML SYR, RELI-ON INSULIN 1 ML SYR, RELION INS SYR 0.3 ML 31GX6MM, RELION INS SYR 0.5 ML 31GX6MM, RELION INS SYR 1 ML 31GX15/64", RELION INSULIN SYR 0.3 ML, RELION INSULIN SYR 0.5 ML, RELION INSULIN SYRINGE 1 ML, SB INS SYR 0.5 ML 29GX1/2", SB INS SYR 0.5 ML 30GX5/16", SB INS SYR 1 ML 29GX1/2", SB INS SYRINGE 1 ML 30GX5/16", SB INSULIN SYR 1 ML 31GX5/16", SB INSULIN SYRINGE 0.3 ML, SB INSULIN SYRINGE 0.5 ML, SB INSULIN SYRINGE 1 ML, SB INSULN SYR 0.5 ML 30GX5/16", SCHNUCKS SYR 0.5 ML 29GX1/2", SCHNUCKS SYR 0.5 ML 30GX5/16", SM INS SYR 0.5 ML 29GX1/2", SM INS SYR 0.5 ML 30GX5/16", SM INS SYR 1 ML 29GX1/2", SM INS SYRING 0.3 ML 30GX5/16", SM INS SYRINGE 1 ML 28GX1/2", SM INS SYRINGE 1 ML 30GX5/16", SM INSUL SYR 0.3 ML 31GX5/16", SM INSUL SYR 0.5 ML 31GX5/16", SM INSULIN SYR 0.3 ML 29GX1/2", SM INSULIN SYR 0.5 ML 28GX1/2", SM INSULIN SYR 1 ML 31GX5/16", SUNMARK INSULIN SYRINGE 0.3 ML, SUNMARK INSULIN SYRINGE 0.5 ML, SUNMARK INSULIN SYRINGE 1 ML, VALUEPLUS SYR 0.3 ML 29GX1/2", VH INS SYR 0.5 ML 29GX1/2", VH INS SYR 1 ML 29GX1/2", WD MEDIC INSULIN SYR 0.3 ML, WD MEDIC INSULIN SYR 0.5 ML, WD MEDIC INSULIN SYRNGE 1 ML, WD MEDIC SYR 0.3 ML 30GX5/16", WD MEDIC SYR 0.5 ML 29GX1/2", WD MEDIC SYR 0.5 ML 30GX5/16", WD MEDIC SYR 1 ML 29GX1/2", WDMEDIC INS SYR 1 ML 30GX5/16", WDMEDIC SYRING 0.3 ML 29GX1/2", INSULIN SYRINGE (DISP) U-100 0.3 ML, INSULIN SYRINGE (DISP) U-100 1 ML, INSULIN SYRINGE (DISP) U-100 1/2 ML, INSUPEN 31G ULTRAFIN NEEDLE, INSUPEN 32G 6MM PEN NEEDLE, INSUPEN 32G 8MM PEN NEEDLE, INSUPEN PEN NEEDLE 32GX5/32", INSUPEN PEN NEEDLE 29GX1/2", INSUPEN PEN NEEDLE 29GX12MM, INSUPEN PEN NEEDLE 31GX3/16", INSUPEN PEN NEEDLE 31GX5/16", INSUPEN PEN NEEDLE 31GX8MM, INSUPEN PEN NEEDLE 32G 6MM, INSUPEN PEN NEEDLE 32GX4MM, INSUPEN PEN NEEDLE 32GX5/32", ISOPROPYL ALCOHOL 0.7 ML/ML MEDICATED PAD, LITETOUCH INS 0.3 ML 29GX1/2", LITETOUCH INS 0.3 ML 30GX5/16", LITETOUCH INS 0.3 ML 31GX5/16", LITETOUCH INS 0.5 ML 31GX5/16", MAXICOMFORT II PEN NEEDLE, MAXICOMFORT INSULIN SYRINGE, MAXICOMFORT SAFETY PEN NEEDLE, MICRODOT READYGARD PEN NEEDLE, MINI PEN NEEDLE, MINI ULTRA-THIN II, BL MONOJECT SYRINGE 0.5 ML, BL MONOJECT SYRINGE 1 ML, BL MONOJECT SYRINGE 3/10 ML, GNP MONOJECT SYRINGE 0.5 ML, GNP MONOJECT SYRINGE 1 ML, GNP MONOJECT SYRINGE 3/10 ML, KIN-RAY MONOJECT SYRINGE, KP MONOJECT SYRINGE 0.5 ML, KP MONOJECT SYRINGE 1 ML, KP MONOJECT SYRINGE 3/10 ML, LEADER MONOJECT SYR 0.5 ML, LEADER MONOJECT SYR 1 ML, LEADER MONOJECT SYR 3/10 ML, LEGEND MONOJECT SYRINGE 1 ML, LEGEND MONOJECT SYRNGE 0.3 ML, LEGEND MONOJECT SYRNGE 0.5 ML, MED SHOPPE MONOJECT SYR 3/10, MED SHOPPE MONOJECT SYR 0.5, MED SHOPPE MONOJECT SYR 1 ML, MED-FAST MONOJECT SYRINGE, MONOJECT 0.3 ML INSULIN SYR, MONOJECT 0.3 ML SYRN 29GX1/2", MONOJECT 1 ML SYRN 25X5/8", MONOJECT INSUL SYR U100, MONOJECT INSUL SYR U100 0.5 ML, MONOJECT INSUL SYR U100 1 ML, PHARM MONOJECT SYRINGE 0.5 ML, QC MONOJECT SYRINGE 0.5 ML, QC MONOJECT SYRINGE 1 ML, QC MONOJECT SYRINGE 3/10 ML, RUGBY

MONOJECT SYRINGE 0.5 ML, RUGBY MONOJECT SYRINGE 1 ML, TOPCO MONOJECT SYR 3/10 ML, TOPCO MONOJECT SYRINGE 0.5 ML, TOPCO MONOJECT SYRINGE 1 ML, VALUE HEALTH MONOJECT SYRN, NANO 2 GEN PEN NEEDLE 32G 4MM, NANO PEN NEEDLE, NEEDLES, INSULIN DISP., SAFETY, NOVOFINE PLUS, EQL PEN 8MM 31G X 5/16" NEEDLE, EQL PEN NEEDLE 6MM 31G, FIFTY50 PEN 31G X 3/16" NEEDLE, FIFTY50 PEN 31G X 5/16" NEEDLE, FIFTY50 PEN NEEDLE 32G X 1/4", FIFTY50 PEN NEEDLE 32G X 5/32", GNP CLICKFINE PEN NDL 31GX1/4", GNP CLICKFINE PEN NDL 31GX5/16, GNP PEN NEEDLE 31G 5MM, GNP PEN NEEDLE 31G 8MM, GNP PEN NEEDLE 32G 4MM, GNP PEN NEEDLE 32G 6MM, GS PEN NEEDLE 31G X 1/4", GS PEN NEEDLE 31G X 5/16", GS PEN NEEDLE 31G X 5MM, GS PEN NEEDLE 31G X 6MM, GS PEN NEEDLE 31G X 8MM, GS PEN NEEDLE 32G X 4MM, GS PEN NEEDLE 32G X 6MM, KRO PEN NEEDLE 4MM X 32G, KRO PEN NEEDLE 4MM X 33G, KRO PEN NEEDLE 5MM X 31G, KRO PEN NEEDLE 6MM X 31G, KRO PEN NEEDLE 8MM X 31G, KROGER PEN NEEDLES 31G X 5/16", LEADER PEN NEEDLE 6MM 31G, LIVE BETTER PEN NEEDLE 6MM 31G, LIVE BETTER PEN NEEDLES 12MM, LIVE BETTER PEN NEEDLES 8MM, MS PEN NEEDLE 6MM 31G, PEN NEEDLE 12MM 29G, PEN NEEDLE 29G 12MM, PEN NEEDLE 30G 8MM, PEN NEEDLE 31G 5MM, PEN NEEDLE 31G 6MM, PEN NEEDLE 31G 8MM, PEN NEEDLE 31G X 1/4", PEN NEEDLE 31G X 3/16", PEN NEEDLE 31G X 5/16", PEN NEEDLE 32G 4MM, PEN NEEDLE 32G X 1/4", PEN NEEDLE 32G X 3/16", PEN NEEDLE 32G X 5/32", PEN NEEDLE 33G 4MM, PEN NEEDLE 4MM 32G, PEN NEEDLE 5MM 31G, PEN NEEDLE 6MM 31G, PEN NEEDLES 12MM 29G, PEN NEEDLES 29G, PEN NEEDLES 31G, PEN NEEDLES 8MM 31G, PUB PEN 12MM 29G NEEDLES, PUB PEN 8MM 31G NEEDLES, PUB PEN NEEDLE 6MM 31G, PV PEN NEEDLE 6MM 31G, PV PEN NEEDLES 6MM 31G, PX PEN 12MM 29G NEEDLES, PX PEN 8MM 31G NEEDLES, QC UNIFINE PENTIP 6MM 31G, RA PEN NEEDLE 31GX3/16", RA PEN NEEDLE 31GX5/16", RELION MINI PEN 31G X 1/4" NDL, RELION PEN 29G NEEDLE, RELION PEN 31G NEEDLE, RELION PEN NEEDLE 29GX1/2", RELION PEN NEEDLE 31G 6MM, RELION PEN NEEDLE 31GX1/4", RELION PEN NEEDLE 31GX5/16", RELION PEN NEEDLE 32GX5/32", TODAY'S HLT PN NEEDLE 12MM 29G, TODAY'S HLTH PN NEEDLE 6MM 31G, TODAY'S HLTH PN NEEDLE 8MM 31G, PEN NEEDLES, PENTIPS, PENTIPS PEN NEEDLE, PIP PEN NEEDLE, PREVENT DROPSAFE PEN NEEDLE, PRO COMFORT INSULIN SYRINGE, PRO COMFORT PEN NEEDLE, PRODIGY INS SYR 1ML 28GX1/2", PRODIGY SYRNG 0.5 ML 31GX5/16", PURE COMFORT PEN NEEDLE, RELION ULTRA COMFORT, SAFETY PEN NEEDLE, SAFETYGLIDE INSULIN SYRINGE, SECURESAFE PEN NEEDLE, FP STERILE PAD 2" X 2", BL STERILE PADS 2"X2", ECK STERILE PADS 2"X2", FT STERILE PADS 2" X 2", GNP STERILE PADS 2"X2", PV STERILE PADS 2" X 2", QC STERILE PADS 2"X2", RA STERILE PADS, SM STERILE PADS 2" X 2", STERILE PADS 2" X 2", STERILE PADS 2"X2", SURE COMFORT, SURE COMFORT INSULIN SYRINGE, SURE COMFORT PEN NEEDLE, SURE COMFORT SAFETY PEN NEEDLE, SURE-FINE PEN NEEDLES, TECHLITE 0.3 ML 31GX6MM (1/2), TECHLITE 0.3 ML 31GX8MM (1/2), TECHLITE 0.5 ML 30GX12MM (1/2), TECHLITE 0.5 ML 31GX6MM (1/2), TECHLITE

0.5 ML 31GX8MM (1/2), TECHLITE INS SYR 1 ML 30GX12MM, TECHLITE INS SYR 1 ML 31GX6MM, TECHLITE INS SYR 1 ML 31GX8MM, TECHLITE PEN NEEDLE 29GX1/2", TECHLITE PEN NEEDLE 31GX3/16", TECHLITE PEN NEEDLE 31GX5/16", TECHLITE PEN NEEDLE 32GX1/4", TECHLITE PEN NEEDLE 32GX5/32", TECHLITE PLUS PEN NEEDLE, TOPCARE CLICKFINE, TRUE COMFORT INSULIN SYRINGE, TRUE COMFORT PEN NEEDLE, TRUE COMFORT PRO INS SYRINGE, TRUE COMFORT PRO PEN NEEDLE, TRUE COMFORT SAFE INSULIN SYRG, TRUE COMFORT SAFETY PEN NEEDLE, TRUEPLUS PEN NEEDLE, ULTICARE INSULIN SYRINGE, ULTICARE PEN NEEDLE, ULTICARE SAFETY PEN NEEDLE, ULTIGUARD SAFEPACK-INSULIN SYR, ULTIGUARD SAFEPACK 32G 4MM, ULTILET PEN NEEDLE, ULTRA COMFORT, ULTRA FLO INSULIN SYRINGE, ULTRA FLO PEN NEEDLE, ULTRA THIN PEN NDL 32G X 4MM, ULTRA-FINE INSULIN SYRINGE, ULTRA-FINE PEN NEEDLE, ULTRA-THIN II PEN NDL 29GX1/2", ULTRA-THIN II PEN NDL 31GX5/16, ULTRACARE INSULIN SYRINGE, ULTRACARE PEN NEEDLE, UNIFINE OTC PEN NEEDLE, CAREONE UNIFINE PENTIP 4MM 32G, CAREONE UNIFINE PENTIP 5MM 31G, CAREONE UNIFINE PENTIP 6MM 31G, CAREONE UNIFINE PENTIP 8MM 31G, CAREONE UNIFINE PNTIP 12MM 29G, DR UNIFINE PENTIPS 12MM NDL, DR UNIFINE PENTIPS 6MM NDL, DR UNIFINE PENTIPS 8MM NDL, PC UNIFINE PENTIPS 12MM NEEDLE, PC UNIFINE PENTIPS 31GX3/16", PC UNIFINE PENTIPS 6MM NEEDLE, PC UNIFINE PENTIPS 8MM NEEDLE, PV UNIFINE PENTIPS 31GX3/16", PV UNIFINE PENTIPS 32GX5/32", QC UNIFINE PENTIPS 32GX5/32", QC UNIFINE PENTIPS 4MM 32G, SHOPKO UNIFINE PENTIPS 4MM 32G, SHOPKO UNIFINE PENTIPS 5MM 31G, SHOPKO UNIFINE PENTIPS 8MM 31G, SHOPKO UNIFINE PNTIPS 12MM 29G, UNIFINE PENTIP 0.5CC NEEDLE, UNIFINE PENTIPS 12MM 29G, UNIFINE PENTIPS 12MM NEEDLE, UNIFINE PENTIPS 31G 5MM, UNIFINE PENTIPS 31G 6MM, UNIFINE PENTIPS 31G 8MM, UNIFINE PENTIPS 31GX3/16", UNIFINE PENTIPS 32G 4MM, UNIFINE PENTIPS 32G 6MM, UNIFINE PENTIPS 32GX1/4", UNIFINE PENTIPS 32GX5/32", UNIFINE PENTIPS 33GX5/32", UNIFINE PENTIPS 6MM 31G, UNIFINE PENTIPS 6MM NEEDLE, UNIFINE PENTIPS 8MM 31G, UNIFINE PENTIPS 8MM NEEDLE, UNIFINE PENTIPS 8MM NEEDLES, UNIFINE PENTIPS MAXFLOW, UNIFINE PENTIPS PLUS, UNIFINE PENTIPS PLUS MAXFLOW, UNIFINE PROTECT, UNIFINE SAFECONTROL PEN NEEDLE, UNIFINE ULTRA PEN NEEDLE, VANISHPOINT 29GX1/2" 1 ML SR, VANISHPOINT INSULIN SYRINGE, VERIFINE PEN NEEDLE

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

3 years

OTHER CRITERIA

Approve if the prescriber confirms that the medical supply is being requested for a use that is directly associated with delivering insulin to the body.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

DICHLORPHENAMIDE

MEDICATION(S)

DICHLORPHENAMIDE

PENDING CMS APPROVAL

DICLOFENAC

MEDICATION(S)

DICLOFENAC SODIUM 3% GEL

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

DOXEPIN TOPICAL

MEDICATION(S)

DOXEPIN 5% CREAM

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis of moderate pruritus. Patient has atopic dermatitis or lichen simplex chronicus.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 month

OTHER CRITERIA

The patient had an inadequate response, contraindication, or intolerance to at least one medium potency topical corticosteroid, or is not a candidate for topical corticosteroids (e.g., treatment is on face, axilla, or groin).

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

DPP-4 THERAPY

MEDICATION(S)

ALOGLIPTIN, ALOGLIPTIN-METFORMIN, ALOGLIPTIN-PIOGLIT 12.5-30 MG, ALOGLIPTIN-PIOGLIT 25-15 MG TB, ALOGLIPTIN-PIOGLIT 25-30 MG TB, ALOGLIPTIN-PIOGLIT 25-45 MG TB

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experienced with the preferred product, or the clinical condition for which an exception to the preferred product is requested).

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

Janumet, Januvia, Jentadueto, Jentadueto XR, sitagliptin and Tradjenta are the preferred products. The drug must be prescribed within the manufacturers published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance to one preferred formulary/preferred drug list alternatives for the given diagnosis, OR the member has a documented contraindication to one preferred formulary alternative, or the member had an adverse reaction or would be reasonably

expected to have an adverse reaction to one preferred formulary alternative, OR the member has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

DPP-4/SGLT2

MEDICATION(S)

QTERN 5 MG-5 MG TABLET, STEGLUJAN

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experienced with the preferred product, or the clinical condition for which an exception to the preferred product is requested).

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

Glyxambi and Trijardy XR are the preferred products. The drug must be prescribed within the manufacturers published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance to one preferred formulary/preferred drug list alternatives for the given diagnosis, OR the member has a documented contraindication to one preferred formulary alternative, or the member had an adverse reaction or would be reasonably expected to have an adverse reaction to one preferred formulary alternative, OR the member has a clinical condition for which there is no listed preferred

formulary alternative to treat the condition based on published guidelines or clinical literature.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

DROXIDOPA

MEDICATION(S)

DROXIDOPA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis, Medication history, Reauth: positive clinical response to therapy

AGE RESTRICTION

18 years and older

PRESCRIBER RESTRICTION

Prescribed by, or in consultation with, a cardiologist or neurologist

COVERAGE DURATION

Initial: 2 months, Continuation: 1 year

OTHER CRITERIA

Neurogenic orthostatic hypotension (nOH): 1. Initial - approve if the patient meets the following criteria (a and b): a. Patient has been diagnosed with symptomatic nOH due to primary autonomic failure (Parkinson's disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy AND, b. Patient has tried/failed, has contraindication or intolerance to midodrine and fludrocortisone acetate, 2. Continuation – approve if the patient meets the following criteria: a. If patient is new to plan, meets initial criteria at time they had started the medication, b. Documented dose and frequency are within the FDA approved Dosing and Frequency, c. Patient has experienced a positive clinical response to therapy

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

DUPIXENT

MEDICATION(S)

DUPIXENT PEN, DUPIXENT 200 MG/1.14 ML SYRING, DUPIXENT 300 MG/2 ML SYRINGE

PENDING CMS APPROVAL

EGRIFTA

MEDICATION(S)

EGRIFTA SV, EGRIFTA WR

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis is HIV-associated lipodystrophy. Egrifta is prescribed for the reduction of excess abdominal fat. Patient is HIV-infected.

AGE RESTRICTION

Adults, 18 years of age and older.

PRESCRIBER RESTRICTION

Prescribed by or in consultation with an endocrinologist or a physician specializing in the treatment of HIV (eg, infectious disease, oncology).

COVERAGE DURATION

Authorization will be for 12 months.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

EMGALITY

MEDICATION(S)

EMGALITY PEN, EMGALITY SYRINGE

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Combination with a CGRP antagonist when the CGRP antagonist is being used for prophylaxis

REQUIRED MEDICAL INFORMATION

Diagnosis

AGE RESTRICTION

18 years of age and older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Chronic or episodic migraine: 12 months. Episodic cluster (Emgality): 6 months.

OTHER CRITERIA

For chronic or episodic migraine initiation of therapy: The member must have a diagnosis of migraine.

For episodic cluster headache: approve if the patient has diagnosis of episodic cluster headaches.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

ENBREL

MEDICATION(S)

ENBREL 25 MG/0.5 ML SYRINGE, ENBREL 25 MG/0.5 ML VIAL, ENBREL 50 MG/ML SYRINGE, ENBREL MINI, ENBREL SURECLICK

PENDING CMS APPROVAL

ENDARI

MEDICATION(S)

L-GLUTAMINE

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Glutamine will be used to reduce the acute complications of sickle cell disease.

AGE RESTRICTION

The patient is greater than or equal to 5 years of age.

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a hematologist or oncologist.

COVERAGE DURATION

1 year

OTHER CRITERIA

The patient is currently taking Hydroxyurea or has an intolerance or contraindication to Hydroxyurea therapy.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

ENSPRYNG

MEDICATION(S)

ENSPRYNG

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Concomitant use with Soliris (eculizumab), rituximab or Uplizna (inebilizumab-cdon)

REQUIRED MEDICAL INFORMATION

Diagnosis, Previous therapies tried

AGE RESTRICTION

18 years and older

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a neurologist or ophthalmologist

COVERAGE DURATION

Initial or continuation: 1 year

OTHER CRITERIA

For initial therapy, patient must meet following criteria (i, ii, AND iii): i. Neuromyelitis optica spectrum disorder diagnosis was confirmed by blood serum test positive for anti-aquaporin-4 antibody AND ii. Patient is currently receiving or has previously tried two of the following systemic therapies used in the maintenance setting (a, b, c, or d): a. Azathioprine OR b. Corticosteroid OR c. Mycophenolate mofetil OR d. Rituximab AND (Note: An exception to the requirement for a trial of a systemic therapy can be made if the patient has already tried Soliris (eculizumab injection) or Uplizna (inebilizumab-cdon injection) for neuromyelitis optica spectrum disorder. Patients who have already tried Soliris or Uplizna for neuromyelitis optica spectrum disorder are not required to try another systemic agent. iii. Patient has a history of at least one relapse (acute attack from neuromyelitis spectrum disorder) in the last 12 months. If patient is currently receiving Enspryng, approve if the patient meets the following (i AND ii): i. Neuromyelitis optica spectrum disorder diagnosis was confirmed by blood serum test positive for anti-

aquaporin-4 antibody ii. According to the prescriber, patient has had clinical benefit from the use of Enspryng (Note: Examples of clinical benefit include reduction in relapse rate, reduction in symptoms (e.g., pain, fatigue, motor function), and a slowing progression in symptoms.)

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

EPCLUSA

MEDICATION(S)

EPCLUSA, SOFOSBUVIR-VELPATASVIR

PA INDICATION INDICATOR

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

OFF LABEL USES

Indications consistent with current AASLD/IDSA guidance

EXCLUSION CRITERIA

Combination use with other direct acting antivirals, excluding ribavirin

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

3 years or older

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician.

COVERAGE DURATION

Will be consistent with AASLD/IDSA guidance

OTHER CRITERIA

Criteria will be applied consistent with current AASLD/IDSA guidance.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

EPIDIOLEX

MEDICATION(S)

EPIDIOLEX

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

The member is 1 year of age or older.

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a neurologist.

COVERAGE DURATION

Lifetime.

OTHER CRITERIA

For seizures associated with Lennox-Gastaut Syndrome, the patient must have a previous trial of ONE of the following: lamotrigine, topiramate, rufinamide, clobazam, valproate, felbamate or clonazepam.

For seizures associated with Dravet Syndrome, the patient must have a previous trial of ONE of the following: valproate, clobazam, topiramate, Diacomit or Fintepla. For tuberous sclerosis complex approve if the patient has tried at least one other antiepileptic drug.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

EVEKEO

MEDICATION(S)

AMPHETAMINE SULFATE

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Weight loss.

REQUIRED MEDICAL INFORMATION

Diagnosis

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

EVICORE ONCOLOGY DRUGS

MEDICATION(S)

ABIRATERONE ACETATE, ABIRTEGA, ACTIMMUNE, ADCETRIS, ADSTILADRIN, AKEEGA, ALECENSA, ALUNBRIG, ALYMSYS, ANKTIVA, ARSENIC TRIOXIDE, ARZERRA, ASPARLAS, AUGTYRO, AVASTIN 100 MG/4 ML VIAL, AVASTIN 400 MG/16 ML VIAL, AVMAPKI-FAKZYNJA, AYWAKIT, AZACITIDINE, BALVERSA, BAVENCIO, BCG (TICE STRAIN), BEIZRAY 80 MG/4 ML VIAL, BEIZRAY-ALBUMIN, BELEODAQ, BENDAMUSTINE HCL, BESPONSA, BESREMI, BEXAROTENE, BIZENGRI, BLENREP 70 MG VIAL, BLEOMYCIN SULFATE, BLINCYTO, BORTEZOMIB 1 MG VIAL, BORTEZOMIB 2.5 MG VIAL, BORTEZOMIB 3.5 MG IV VIAL, BORTEZOMIB 3.5 MG VIAL, BORTEZOMIB 3.5 MG/1.4 ML VIAL, BOSULIF, BRAFTOVI 75 MG CAPSULE, CABOMETYX, CALQUENCE, CAPRELSA, CARBOPLATIN, CARMUSTINE 100 MG VIAL, CARMUSTINE 300 MG VIAL, CISPLATIN 100 MG/100 ML VIAL, CISPLATIN 200 MG/200 ML VIAL, CISPLATIN 50 MG VIAL, CISPLATIN 50 MG/50 ML VIAL, CLADRIBINE 10 MG/10 ML VIAL, CLOFARABINE, COLUMVI, COMETRIQ, COPIKTRA, COTELLIC, CYRAMZA, CYTARABINE, DACARBAZINE, DACTINOMYCIN, DANYELZA, DANZITEN, DARZALEX, DARZALEX FASPRO, DASATINIB, DATROWAY, DAUNORUBICIN HCL, DAURISMO, DECITABINE, DOCETAXEL, DOXORUBICIN HCL, DOXORUBICIN HCL LIPOSOME, ELAHERE, ELIGARD, ELREXFIO, ELZONRIS, EMPLICITI, EMRELIS, ENHERTU, ENSACOVE, EPIRUBICIN 200 MG/100 ML VIAL, EPIRUBICIN 50 MG/25 ML VIAL, EPKINLY, ERBITUX, ERIBULIN MESYLATE, ERIVEDGE, ERLEADA, ERLOTINIB HCL 100 MG TABLET, ERLOTINIB HCL 150 MG TABLET, ERLOTINIB HCL 25 MG TABLET, ERWINASE, ETOPOSIDE 1,000 MG/50 ML VIAL, ETOPOSIDE 100 MG/5 ML VIAL, ETOPOSIDE 500 MG/25 ML VIAL, EVEROLIMUS 10 MG TABLET, EVEROLIMUS 2 MG TAB FOR SUSP, EVEROLIMUS 2.5 MG TABLET, EVEROLIMUS 3 MG TAB FOR SUSP, EVEROLIMUS 5 MG TAB FOR SUSP, EVEROLIMUS 5 MG TABLET, EVEROLIMUS 7.5 MG TABLET, FIRMAGON, FLOXURIDINE, FLUDARABINE PHOSPHATE, FLUOROURACIL 1 GRAM/20 ML VIAL, FLUOROURACIL 2.5 GRAM/50 ML VL, FLUOROURACIL 5 GRAM/100 ML VL, FLUOROURACIL 500 MG/10 ML VIAL, FOTIVDA, FRINDOVYX, FRUZAQLA, FULVESTRANT, FYARRO, GAVRETO, GAZYVA, GEFITINIB, GEMCITABINE HCL, GILOTRIF, GOMEKLI, GRANIX, HERCEPTIN, HERCEPTIN HYLECTA, HERCESSI, HERNEXEOS, HERZUMA, HYRNUO, IBRANCE, IBTROZI, ICLUSIG, IDARUBICIN HCL, IDHIFA, IFOSFAMIDE, IMDELLTRA, IMFINZI, IMJUDO, IMLYGIC, INLEXZO, INLURIYO, INLYTA, INQOVI, INREBIC, IRINOTECAN HCL, ITOVEBI, IWILFIN, IXEMPRA, JAYPIRCA 100 MG TABLET, JEMPERLI, JEVTANA, JOBEVNE, KADCYLA, KANJINTI, KEYTRUDA, KEYTRUDA QLEX, KIMMTRAK, KISQALI, KISQALI FEMARA 400 MG CO-PACK, KISQALI FEMARA 600 MG CO-PACK, KOMZIFTI, KRAZATI, KYPROLIS, LAPATINIB, LAZCLUZE, LENALIDOMIDE, LENVIMA, LEUCOVORIN CAL 100 MG/10 ML VL, LEUCOVORIN CAL 500 MG/50 ML VL, LEUCOVORIN CALCIUM 100 MG VIAL, LEUCOVORIN CALCIUM 200 MG VIAL, LEUCOVORIN

CALCIUM 350 MG VIAL, LEUCOVORIN CALCIUM 50 MG VIAL, LEUCOVORIN CALCIUM 500 MG VIAL, LEUKERAN, LEUPROLIDE DEPOT, LEVOLEUCOVORIN CALCIUM, LIBTAYO, LONSURF, LOQTORZI, LORBRENA, LUMAKRAS, LUNSUMIO, LUNSUMIO VELO, LYNOZYFIC, LYNPARZA, LYTGOBI, MARGENZA, MEKINIST, MEKTOVI, MELPHALAN HCL, MITOMYCIN 20 MG VIAL, MITOMYCIN 40 MG VIAL, MITOMYCIN 5 MG VIAL, MITOXANTRONE HCL, MODEYSO, MONJUVI, MVASI, MYLOTARG, NELARABINE, NERLYNX, NILOTINIB HCL, NINLARO, NIPENT, NUBEQA, NYVEPRIA, ODOMZO, OGIVRI, OGSIVEO, OJEMDA, OJJAARA, ONCASPAR, ONIVYDE, ONTRUZANT, ONUREG, OPDIVO, OPDIVO QVANTIG, OPDUALAG, ORGOVYX, ORSERDU, OXALIPLATIN, PACLITAXEL, PACLITAXEL PROTEIN-BOUND, PADCEV, PANRETIN, PAZOPANIB HCL, PEMAZYRE, PEMETREXED 1 GM/40 ML VIAL, PEMETREXED 100 MG VIAL, PEMETREXED 100 MG/4 ML VIAL, PEMETREXED 500 MG VIAL, PEMETREXED 500 MG/20 ML VIAL, PEMETREXED DISODIUM, PERJETA, PHESGO, PIQRAY, POLIVY, POMALIDOMIDE, POTELIGEO, PRALATREXATE, PROLEUKIN, QINLOCK, RETEVMO, REVUFORJ, REZLIDHIA, RITUXAN HYCELA, ROMIDEPSIN, ROMVIMZA, ROZLYTREK, RUBRACA, RYBREVANT, RYBREVANT FASPRO, RYDAPT, RYLAZE, RYTELO, SARCLISA, SCEMBLIX, SORAFENIB, STIMUFEND, STIVARGA, SUNITINIB MALATE, SYLVANT, TABRECTA, TAFINLAR, TAGRISSO, TALVEY, TALZENNA, TAZVERIK, TECENTRIQ, TECENTRIQ HYBREZA, TECVAYLI, TEMODAR, TEMSIROLIMUS, TEPADINA 200 MG BAG, TEPMETKO, TEVIMBRA, THIOTEPA 100 MG VIAL, THIOTEPA 15 MG VIAL, TIBSOVO, TIVDAK, TOPOTECAN HCL 4 MG VIAL, TOPOTECAN HCL 4 MG/4 ML VIAL, TORPENZ, TRAZIMERA, TRELSTAR, TRETINOIN 10 MG CAPSULE, TRODELVY, TRUQAP, TUKYSA, TURALIO, UNITUXIN, VALRUBICIN, VANFLYTA, VECTIBIX, VEGZELMA, VENCLEXTA, VENCLEXTA STARTING PACK, VINBLASTINE SULFATE, VINOUREBIN TARTRATE, VITRAKVI, VIZIMPRO, VONJO, VORANIGO, VYLOY, VYXEOS, WELIREG, XALKORI, XERMELO, XOSPATA, XPOVIO, XTANDI, YERVOY, YONDELIS, YONSA, ZALTRAP, ZEJULA 100 MG TABLET, ZEJULA 200 MG TABLET, ZEJULA 300 MG TABLET, ZELBORAF, ZEPZELCA, ZIIHERA, ZIRABEV, ZOLADEX, ZOLINZA, ZYDELIG, ZYKADIA, ZYNLONTA, ZYNYZ

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

EXXUA

MEDICATION(S)

EXXUA

PENDING CMS APPROVAL

FASENRA

MEDICATION(S)

FASENRA, FASENRA PEN

PENDING CMS APPROVAL

FILGRASTIM

MEDICATION(S)

ZARXIO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Severe chronic neutropenia: 6 mo. AIDS: 4 mo. Aplastic or agranulocytosis: 1 mo. All others: 1 year.

OTHER CRITERIA

1. Severe Chronic Neutropenia - Member must have a diagnosis of congenital, cyclic or idiopathic neutropenia
2. Neutropenia associated with acquired immunodeficiency syndrome - Member has diagnosis of AIDS with neutropenia
3. Aplastic anemia – approve
4. Agranulocytosis - Member must have diagnosis of congenital or drug-induced agranulocytosis
5. Hematopoietic Syndrome of Acute Radiation Syndrome – approve
6. Patients with cancer receiving myelosuppressive chemotherapy – approve
7. Patients with acute myeloid leukemia receiving induction or consolidation chemotherapy – approve
8. Patients with cancer undergoing bone marrow transplantation – approve
9. Patients undergoing autologous peripheral blood progenitor cell collection and therapy - approve

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

FINTEPLA

MEDICATION(S)

FINTEPLA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis

AGE RESTRICTION

2 years and older (initial therapy)

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a neurologist (initial therapy)

COVERAGE DURATION

1 year

OTHER CRITERIA

Dravet Syndrome-Initial therapy-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs or patient has tried or is concomitantly receiving Epidiolex or Diacomit. Dravet Syndrome-Continuation-approve if the patient is responding to therapy. Lennox-Gastaut Syndrome-Initial therapy-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs. Lennox-Gastaut Syndrome-continuation-approve if the patient is responding to therapy.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

FIRAZYR

MEDICATION(S)

ICATIBANT, SAJAZIR

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Underlying lymphoproliferative, malignant, or autoimmune disorder that causes angioedema attacks, use for prophylaxis of HAE attacks, Use in combination with other agents approved for acute treatment of HAE attack (e.g. Berinert, Kalbitor, Ruconest)

REQUIRED MEDICAL INFORMATION

Diagnosis, lab results (C1-INH inhibitor, C1-INH functional level, C4 levels, C1q levels), genetic testing (if applicable)

AGE RESTRICTION

18 years and older

PRESCRIBER RESTRICTION

Prescribed by an immunologist, allergist, otolaryngologist or rheumatologist

COVERAGE DURATION

1 year

OTHER CRITERIA

Hereditary Angioedema - Treatment of acute attacks – initial therapy – patient meets all of the following (1 and 2): 1. The patient has HAE as confirmed by one the following diagnostic criteria: i. Hereditary angioedema due to a deficiency of C1INH - patient has documentation of measurements for each of the following tests (a, b and c): a. Low serum complement factor 4 (C4) level at baseline, as defined by the laboratory reference values AND b. Low C1 inhibitor (C1-INH) level OR low C1-INH functional level (i.e. functional C1-INH less than 50% or below lower limit of normal laboratory reference range) at baseline, as defined by the laboratory reference values AND b. C1q levels are within normal limits at baseline, as defined by the laboratory reference values or ii. Hereditary angioedema with normal

C1INH - patient has documentation of all of the following (a, b and c): a. A history of recurrent angioedema in the absence of concomitant urticaria and no concomitant use of medication known to cause angioedema, b. Documentation of normal or near normal C4, C1-INH antigen and C1-INH function, c. One of the following (1 or 2): 1. Demonstration of a mutation associated with the disease or 2. A positive family history of recurrent angioedema and documented lack of efficacy of high-dose antihistamine therapy (for example, cetirizine at 40 mg/d or the equivalent) for at least 1 month or an interval expected to be associated with 3 or more attacks of angioedema, whichever is longer AND 2. The patient is experiencing at least one symptom of moderate to severe HAE attacks (e.g. airway swelling, severe abdominal pain, facial swelling, painful facial distortion, extremity swelling causing disability). Treatment of acute attacks – continuation therapy – patient meets all of the following (1 and 2): 1. If patient is new to plan, they met initial criteria at time of starting the medication, 2. Patients has had a favorable clinical response (e.g. decrease in the duration of HAE attacks, quick onset of symptom relief, complete resolution of symptoms, decrease in HAE acute attack frequency or severity) with icatibant treatment

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

GATTEX

MEDICATION(S)

GATTEX

PENDING CMS APPROVAL

GIP/GLP-1 AGONIST

MEDICATION(S)

MOUNJARO

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Concomitant use with other GLP-1 or GIP/GLP-1 agonists (e.g. Ozempic, Rybelsus, Trulicity, Victoza)

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Lifetime

OTHER CRITERIA

For Type 2 diabetes mellitus (T2DM), member must have diagnosis of T2DM

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

GLP-1 AGONIST

MEDICATION(S)

OZEMPIC 0.25-0.5 MG/DOSE PEN, OZEMPIC 1 MG/DOSE (4 MG/3 ML), OZEMPIC 2 MG/DOSE (8 MG/3 ML), RYBELSUS, TRULICITY

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Concomitant use with other GLP-1 or GIP/GLP-1 agonists (e.g. Ozempic, Rybelsus, Trulicity, Victoza, Mounjaro)

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Lifetime

OTHER CRITERIA

For Type 2 diabetes mellitus (T2DM), member must have diagnosis of T2DM

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

GROWTH HORMONE

MEDICATION(S)

GENOTROPIN

PENDING CMS APPROVAL

HAEGARDA

MEDICATION(S)

HAEGARDA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Concomitant Use with Other HAE Prophylactic Therapies (e.g., Orladeyo, Takhzyro), use for acute treatment of HAE attacks, underlying lymphoproliferative, malignant, or autoimmune disorder that causes angioedema attacks

REQUIRED MEDICAL INFORMATION

Diagnosis, lab results (C1-INH inhibitor, C1-INH functional level, C4 levels, C1q level), number and severity of HAE attacks

AGE RESTRICTION

6 years or older

PRESCRIBER RESTRICTION

Prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders

COVERAGE DURATION

Initial: 6 months, Continuation: 1 year

OTHER CRITERIA

Hereditary Angioedema (HAE) – Prophylaxis. Initial Therapy: Approve if the patient meets all of the below (1 and 2): 1. The patient has one of the following diagnoses: HAE type I or type II as confirmed by the following diagnostic criteria: Documentation of TWO separate measurements for each test (i, ii and iii): i.Low serum complement factor 4 (C4) level at baseline, as defined by the laboratory reference values AND ii. Low C1 inhibitor (C1-INH) level OR low C1-INH functional level (i.e. functional C1-INH less than 50% or below lower limit of normal laboratory reference range) at baseline, as defined by the laboratory reference values AND iii. C1q levels are within normal limits at baseline, as defined by the

laboratory reference values or HAE with normal C1INH (HAE-nl-C1INH) as confirmed by the following diagnostic criteria: (i, ii and iii): i. A history of recurrent angioedema in the absence of concomitant urticaria and no concomitant use of medication known to cause angioedema, ii. Documentation of normal or near normal C4, C1-INH antigen and C1-INH function, iii. One of the following (a or b): a. Demonstration of a mutation associated with the disease or b. A positive family history of recurrent angioedema and documented lack of efficacy of high-dose antihistamine therapy (for example, cetirizine at 40 mg/d or the equivalent) for at least 1 month or an interval expected to be associated with 3 or more attacks of angioedema, whichever is longer AND 2. Patient has a history of severe HAE attacks (i.e. airway swelling, facial swelling, painful facial distortion, extremity swelling causing disability). Continuation of therapy: Patient meets both of the following (1, 2 and 3): 1. If patient is new to plan without previous prior authorization, must meet initial criteria at time treatment had been started, 2. Medical chart documentation of the number and severity of HAE attacks occurring in the previous 6 months, 3. Patient has experienced a reduction in the number and/or severity of HAE attacks from baseline

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

HARVONI

MEDICATION(S)

HARVONI 33.75-150 MG PELLETT PK, HARVONI 45-200 MG PELLETT PACKT, HARVONI 45-200 MG TABLET, LEDIPASVIR-SOFOSBUVIR

PA INDICATION INDICATOR

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

OFF LABEL USES

Indications consistent with current AASLD/IDSA guidance

EXCLUSION CRITERIA

Combination use with other direct acting antivirals, excluding ribavirin.

REQUIRED MEDICAL INFORMATION

Hep C genotype, cirrhosis status.

AGE RESTRICTION

3 years or older

PRESCRIBER RESTRICTION

Prescribed by or in consultation with GI, hepatologist, ID, or liver transplant MD.

COVERAGE DURATION

12 weeks or 24 weeks. Criteria will be applied consistent with current AASLD/IDSA guidance.

OTHER CRITERIA

Criteria will be applied consistent with current AASLD/IDSA guidance.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

HETLIOZ

MEDICATION(S)

HETLIOZ LQ, TASIMELTEON

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis. Non-24 hour sleep-wake disorder: physiologic circadian phase marker or actigraphy and sleep logs. Symptoms of disease.

AGE RESTRICTION

Non-24: 18 years or older. SMS - 3 years and older.

PRESCRIBER RESTRICTION

Prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of sleep disorders

COVERAGE DURATION

6 months initial, 12 months cont.

OTHER CRITERIA

Non-24 hour sleep-wake cycle disorder:

Initial: Approve if patient meets all of the following (1, 2 and 3):

1. Patient is totally blind with no perception of light,
2. Diagnosis is confirmed by either assessment of one physiologic circadian phase marker (e.g., measurement of urinary melatonin levels, dim light melatonin onset, assessment of core body temperature), or if assessment of physiologic circadian phase marker cannot be done, the diagnosis must be confirmed by actigraphy performed for at least 1 week plus evaluation of sleep logs recorded for at least 1 month,
3. Symptoms of insomnia are causing function impairment (i.e. excessive daytime drowsiness, reduced

daytime activity, etc.).

Continuation - Approve if patient meets all of the following (1,2 and 3):

- 1.If patient is new to plan, meets initial criteria at the time they had started the medication,
- 2.Documented dose and frequency are within the FDA approved dosing and frequency,
- 3.Patient received at least 4 months of therapy and there is documentation of a positive clinical response to therapy (i.e. improvement in nighttime total sleep time compared to baseline, improvement in nighttime sleep quality).

Smith Magenis Syndrome (SMS):

Initial – Approve if patient is experiencing nighttime sleep disturbances (i.e. difficulty falling asleep, frequent nighttime waking, early waking, etc.).

Continuation - Approve if patient meets all of the following (1, 2 and 3):

- 1.If patient is new to plan, meets initial criteria at the time they had started the medication,
- 2.Documented dose and frequency are within the FDA approved dosing and frequency,
- 3.Patient received at least 4 months of therapy and there is documentation of a positive clinical response to therapy (i.e. improvement in nighttime total sleep time compared to baseline, improvement in nighttime sleep quality).

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

HIGH RISK MEDICATION - FIRST GENERATION ANTIHISTAMINES

MEDICATION(S)

PROMETHAZINE 12.5 MG TABLET, PROMETHAZINE 12.5 MG/10 ML CUP, PROMETHAZINE 25 MG TABLET, PROMETHAZINE 50 MG TABLET, PROMETHAZINE 6.25 MG/5 ML CUP, PROMETHAZINE 6.25 MG/5 ML SOLN, PROMETHAZINE 6.25 MG/5 ML SYRP

PA INDICATION INDICATOR

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

OFF LABEL USES

Nausea and vomiting associated with chemotherapy.

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Authorization will be for 12 months.

OTHER CRITERIA

Unless specifically referenced, all other FDA approved indications not excluded from Part D will be covered as first line therapy without other previous drug trial criteria requirements. For anti-emetic use, approve promethazine hydrochloride tablets or syrup if the patient has either tried a prescription oral anti-emetic agent (ondansetron, granisetron, dolasetron, aprepitant) for the current condition OR approve if the member requires promethazine use secondary to cancer/chemotherapy related emesis. Prior to approval of any drug, the physician must have assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that the physician would still like to initiate/continue therapy.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

HUMIRA

MEDICATION(S)

HADLIMA, HADLIMA PUSHTOUCH, HADLIMA(CF), HADLIMA(CF) PUSHTOUCH, SIMLANDI(CF), SIMLANDI(CF) AUTOINJECTOR

PENDING CMS APPROVAL

HYFTOR

MEDICATION(S)

HYFTOR

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis

AGE RESTRICTION

6 years of age and older

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a dermatologist or a physician who specializes in the management of patients with tuberous sclerosis complex

COVERAGE DURATION

Initial-3 months. Continuation-1 year

OTHER CRITERIA

Facial angiofibroma associated with tuberous sclerosis, initial- approve if the patient meets the following criteria (i. and ii.): i.Patient has a definitive diagnosis of tuberous sclerosis complex by meeting one of the following (a or b): a)There is identification of a pathogenic variant in the tuberous sclerosis complex 1 (TSC1) gene or tuberous sclerosis complex 2 (TSC2) gene by genetic testing, OR b)According to the prescriber, clinical diagnostic criteria suggest a definitive diagnosis of tuberous sclerosis complex by meeting either two major features or one major feature with two minor features, AND Note: Major feature criteria involve angiofibroma (three or more) or fibrous cephalic plaque, angiomyolipomas (two or more), cardiac rhabdomyoma, hypomelanotic macules (three or more, at least 5 mm in diameter), lymphangiomyomatosis, multiple cortical tubers and/or radial migration lines, multiple retinal hamartomas, Shagreen patch, subependymal giant cell astrocytoma, subependymal

nodules (two or more), or ungula fibromas (two or more). Minor feature criteria include confetti skin lesions, dental enamel pits (three or more), intraoral fibromas (two or more), multiple renal cysts, nonrenal hamartomas, retinal achromic patch, and sclerotic bone lesions. ii. Patient has three or more facial angiofibromas that are at least 2 mm in diameter with redness in each. Continuation-approve if the patient meets the following criteria (i. and ii.): i. Patient has a definitive diagnosis of tuberous sclerosis complex by meeting one of the following (a or b): a) There is identification of a pathogenic variant in the tuberous sclerosis complex 1 (TSC1) gene or tuberous sclerosis complex 2 (TSC2) gene by genetic testing, OR b) According to the prescriber, clinical diagnostic criteria suggest a definitive diagnosis of tuberous sclerosis complex by meeting either two major features or one major feature with two minor features, AND Note: Major feature criteria include angiofibroma (three or more) or fibrous cephalic plaque, angiomyolipomas (two or more), cardiac rhabdomyoma, hypomelanotic macules (three or more, at least 5 mm in diameter), lymphangiomyomatosis, multiple cortical tubers and/or radial migration lines, multiple retinal hamartomas, Shagreen patch, subependymal giant cell astrocytoma, subependymal nodule (two or more), or ungula fibromas (two or more). Minor feature criteria include confetti skin lesions, dental enamel pits (three or more), intraoral fibromas (two or more), multiple renal cysts, nonrenal hamartomas, retinal achromic patch, and sclerotic bone lesions. ii. Patient has responded to Hyftor as evidenced by a reduction in the size and/or redness of the facial angiofibromas

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

IDIOPATHIC PULMONARY FIBROSIS

MEDICATION(S)

OFEV, PIRFENIDONE

PENDING CMS APPROVAL

IMATINIB

MEDICATION(S)

IMATINIB MESYLATE 100 MG TAB, IMATINIB MESYLATE 400 MG TAB, IMKELDI

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

For chronic graft versus host disease – approve if the patient has tried at least one conventional systemic treatment (e.g. corticosteroids, Imbruvica).

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

IMBRUVICA

MEDICATION(S)

IMBRUVICA 140 MG CAPSULE, IMBRUVICA 140 MG TABLET, IMBRUVICA 280 MG TABLET, IMBRUVICA 420 MG TABLET, IMBRUVICA 70 MG CAPSULE, IMBRUVICA 70 MG/ML SUSPENSION

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis, previous therapies tried

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

- 1.Graft versus host disease (GVHD) – approve if the patient has tried one conventional systemic treatment for GVHD (e.g. corticosteroids [methylprednisolone, prednisone], cyclosporine, tacrolimus, mycophenolate mofetil, imatinib).
- 2.Adults with chronic lymphocytic leukemia (CLL)/small lymphocytic leukemia (SLL) – approve.
- 3.Adults with CLL/SLL with 17p deletion – approve.
- 4.Adult patients with Waldenstrom’s macroglobulinemia – approve.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

IMPAVIDO

MEDICATION(S)

IMPAVIDO

PA INDICATION INDICATOR

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

OFF LABEL USES

Amoeba related infections.

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by or in consultation with an infectious disease specialist

COVERAGE DURATION

1 month

OTHER CRITERIA

For Amoeba related infections: Approve if the patient is being treated for an infection due to one of the following: Acanthamoeba, Balamuthia mandrillaris, or Naegleria fowleri. Note: Examples of amoeba related infections are Acanthamoeba keratitis, granulomatous amoebic encephalitis (GAE), and primary amoebic meningoencephalitis (PAM).

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

INCRELEX

MEDICATION(S)

INCRELEX

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Concurrent use with growth hormone

REQUIRED MEDICAL INFORMATION

Diagnosis, response to therapy

AGE RESTRICTION

2 years and older

PRESCRIBER RESTRICTION

Prescribed by or in consultation with an endocrinologist

COVERAGE DURATION

1 year

OTHER CRITERIA

Treatment of growth failure in pediatric patients with severe primary IGF1 deficiency—Initial: Approve if patient meets all of the following (1, 2, 3, and 4): 1. The epiphyses are open, 2. Height standard deviation score is less than or equal to -3.0 at baseline (prior to initiation of Increlex), 3. Basal IGF-1 standard deviation score is less than or equal to -3.0 at baseline (prior to initiation of Increlex) (Note: Reference ranges for IGF-1 vary among laboratories and are dependent upon age, gender, and puberty status), 4. Growth hormone concentration is normal or increased at baseline. Continuation of therapy: the epiphyses are open and the patient continues to receive benefit with therapy, according to the prescriber's assessment. Treatment of growth failure in pediatric patients with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH: Initial: Approve if patient meets all of the following (1, 2, and 3): 1. The epiphyses are open, 2. Patient has a proven gene defect [examples include pathologic mutations in the GH receptor gene (Laron syndrome), signal transducer

and activator of transcription 5B (STAT5B) gene, or IGF1 gene], 3. Patient has developed neutralizing antibodies to growth hormone. Continuation of therapy: the epiphyses are open and the patient continues to receive benefit with therapy, according to the prescriber's assessment

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

INHALED LAMA

MEDICATION(S)

TUDORZA PRESSAIR

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Previous therapies

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

For Tudorza approval, the member must meet one of the following criteria (A), (B), (C), OR (D): (A) The member has demonstrated a failure of or intolerance to both of the preferred products, Spiriva and Incruse, for the given diagnosis, (B) The member has a documented contraindication to both of the preferred products, Spiriva and Incruse, (C) The member had an adverse reaction or would be reasonably expected to have an adverse reaction to both of the preferred products, Spiriva and Incruse, OR (D) The member has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED
YES

INSULIN THERAPY

MEDICATION(S)

ADMELOG, ADMELOG SOLOSTAR, APIDRA, APIDRA SOLOSTAR, HUMALOG, HUMALOG JUNIOR KWIKPEN, HUMALOG KWIKPEN U-100, HUMALOG KWIKPEN U-200, HUMALOG MIX 50-50 KWIKPEN, HUMALOG MIX 75-25, HUMALOG MIX 75-25 KWIKPEN, HUMALOG TEMPO PEN U-100, HUMULIN 70-30, HUMULIN 70/30 KWIKPEN, HUMULIN N, HUMULIN N KWIKPEN, HUMULIN R, HUMULIN R U-500, HUMULIN R U-500 KWIKPEN, LYUMJEV, LYUMJEV KWIKPEN U-100, LYUMJEV KWIKPEN U-200, LYUMJEV TEMPO PEN U-100

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experienced with the preferred product, or the clinical condition for which an exception to the preferred product is requested).

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Lifetime.

OTHER CRITERIA

NovoNordisk and insulin lispro are considered preferred. The drug must be prescribed within the manufacturers published dosing guidelines or the dose falls within dosing guidelines found in accepted

compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance to the preferred formulary/preferred drug list alternative for the given diagnosis, OR the member has a documented contraindication to the preferred formulary alternative, or the member had an adverse reaction or would be reasonably expected to have an adverse reaction to the preferred formulary alternative, OR the member has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature. Part B versus D determination per CMS guidance to establish if drug used in an insulin pump.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

INTRAROSA/OSPHENA

MEDICATION(S)

INTRAROSA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

ISTURISA

MEDICATION(S)

ISTURISA 1 MG TABLET, ISTURISA 5 MG TABLET

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis, prior treatments, Reauth: clinical response

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by or in consultation with an endocrinologist

COVERAGE DURATION

1 year

OTHER CRITERIA

Endogenous hypercortisolemia in adults with Cushing's syndrome – Initial – patient is not able to undergo pituitary surgery or surgery has not been curative for condition AND patient has trialed/failed, has intolerance or contraindication to both ketoconazole and cabergoline. Continuation: Meets initial criteria and has documentation of positive clinical response to therapy (e.g. clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs/symptoms of disease).

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

ITRACONAZOLE

MEDICATION(S)

ITRACONAZOLE 10 MG/ML SOLUTION, ITRACONAZOLE 100 MG CAPSULE, ITRACONAZOLE 100 MG/10 ML CUP

PA INDICATION INDICATOR

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

OFF LABEL USES

Superficial tinea, vaginal candidiasis.

EXCLUSION CRITERIA

Vaginal candidiasis hypersensitivity syndrome.

REQUIRED MEDICAL INFORMATION

Onychomycosis must be due to dermatophytes, and treatment must not be solely for cosmetic purposes as cosmetic use is excluded under Medicare Part D.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

For blastomycosis, histoplasmosis and aspergillosis: 1 year. All other indications: Twelve weeks.

OTHER CRITERIA

Tinea or Pityriasis Versicolor requires one trial and failure of ketoconazole or a topical antifungal agent first. Tinea Capitis and Barbae require failure of one trial of griseofulvin or ketoconazole first. Tinea Cruris, Faciei, Manuum, Imbricata and Pedis (non moccasin or chronic type) require failure of one topical antifungal agent. Tinea Corporis requires failure of one topical antifungal agent first, except when condition is considered extensive. Vaginal Candidiasis requires failure of both one topical antifungal regimen and one trial of oral fluconazole (patients of age less than 16 years are excluded from a trial of a topical vaginal antifungal preparation). For oral and esophageal candidiasis, must try and fail ketoconazole or fluconazole first. Itraconazole will be covered for other systemic infection if used for continuation of itraconazole therapy that has already been started and stabilized. Itraconazole

is covered first line when the prescriber is a Pulmonologist or an Infectious Disease physician.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

IVERMECTIN

MEDICATION(S)

IVERMECTIN 3 MG TABLET

PA INDICATION INDICATOR

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

OFF LABEL USES

Pediculosis, Scabies, Ascariasis, Enterobiasis (pinworm infection), Hookworm-related cutaneous larva migrans, Mansonella ozzardi infection, Mansonella streptocerca infection, Trichuriasis, and Wucheria bancrofti infections.

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

30 days

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

IVIG

MEDICATION(S)

GAMMAGARD LIQUID, GAMMAGARD LIQUID ERC, GAMMAGARD S-D, GAMUNEX-C, PRIVIGEN

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For all indications: Diagnosis, Reauth: positive clinical response. PI initial (Pt meets 1, 2 or 3): 1) Dx of congenital agammaglobulinemia, X-linked agammaglobulinemia, other agammaglobulinemia d/t absence of B-cells, Wiskott-Aldrich syndrome, ataxia telangiectasia, DiGeorge syndrome, SCID, Hyper-Immunoglobulin M (IgM) syndromes, an IgG level lower than 250 mg/dL, or a PID confirmed by genetic or molecular testing OR 2) Dx of CVID, unspecified hypogammaglobulinemia, or other immunodeficiencies with significant hypogammaglobulinemia and meets the following (a and b) a) pre-tx IgG below normal range (age-adjusted and according to normal reference range for reporting laboratory AND b) Impaired antibody (Ab) response (i.e. failure to produce Abs to specific antigens) OR patient has recurrent infx OR 3) IgG subclass deficiency, selective Ab deficiency (SAD), or other confirmed PID and meets the following (a and b): a) Impaired Ab response AND b) Recurrent infx. CIDP initial: Has at least three of the following electrodiagnostic criteria for CIDP dx (1, 2, 3 and/or 4): 1) Partial conduction block of 1 or more motor nerve, 2) Reduced conduction velocity of 2 or more motor nerves, 3) Prolonged distal latency of 2 or more motor nerves, 4) Prolonged F-wave latencies of 2 or more nerves or absence of F waves. MMN Initial: dx confirmed by all of the following (i, ii, and iii): i) Weakness with slowly progressive or stepwise progressive course lasting at least 1 month, 2) Asymmetric involvement of 2 or more nerves AND 3) Absence of motor neuron and bulbar signs.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

CIDP, MMN, LEMS, MG, GBS: prescribed by or in consultation with a neurologist.

COVERAGE DURATION

Init:PI/MG maint. 1 yr, CIDP 6 mo, MMN 6 mo, GBS/LEMS/MG acute 1 mo. Cont-GBS 1 mo, Others 1 yr.

OTHER CRITERIA

All requests will be subject to a Part B vs Part D review. If patient is new to plan, must meet initial criteria at time they had started the medication. Documented dose and frequency must be within the FDA approved dosing and frequency or consistent with compendial sources (e.g. Micromedex, current clinical guidelines, etc.). PI Cont: Pt dx with PI and, according to the prescriber, the patient is continuing to receive benefit from the product (e.g. increased IgG levels or prevention and/or controlling of infections.) CIDP initial: Pt meets following criteria: has had progressive sx present for at least 2 months AND Has had symptomatic polyradiculoneuropathy with progressive or relapsing motor or sensory impairment in more than 1 limb. CIDP and MMN Cont.: Pt has had clinically significant improvement to tx as measured by an objective scale (e.g. Rankin, Modified Rankin, Medical Research Council [MRC] scale). GBS initial: Pt has dx of severe GBS requiring aid to walk AND onset occurred within the last 4 weeks. GBS cont: Approve a second course of tx if requested within 3 weeks after the first course. LEMS initial: Pt is having refractory weakness after symptomatic treatment of LEMS with an amifampridine, guanidine or pyridostigmine AND Pt meets one of the following (1 or 2): 1) Has paraneoplastic LEMS or 2) Has non-paraneoplastic LEMS and has TF/CI to corticosteroids and/or another immunosuppressive agent (e.g. azathioprine). LEMS cont: Pt has had response or continued effectiveness from therapy (e.g. improved muscle strength or other clinical response). MG initial acute exacerbations: Approve if pt is experiencing any of the following sx in the past month: Difficulty swallowing, Acute respiratory failure or Major functional disability leading to inability to continue physical activity. MG initial for maintenance therapy: Approve if pt meets all of the following (i, ii and iii): i) Patient has refractory MG, ii) Pt has TF/CI to pyridostigmine AND iii) Pt has tried and failed immunosuppressive therapy with at least 1 of the following agents: azathioprine, cyclosporine, cyclophosphamide, mycophenolate mofetil, methotrexate, tacrolimus AND has had an inadequate response. MG cont. therapy for maintenance: Approve if pt has responded to tx according to the prescriber.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

JAKAFI

MEDICATION(S)

JAKAFI

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

JAYPIRCA

MEDICATION(S)

JAYPIRCA 50 MG TABLET

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

Mantle Cell Lymphoma, Chronic lymphocytic lymphoma, small lymphocytic lymphoma – Approve if patient meets one of the following (1, 2, 3 or 4):

- 1.The patient has demonstrated a failure of or intolerance to one of the preferred products, Calquence and Brukinsa.
- 2.The patient has a documented contraindication to one of the preferred products, Calquence and Brukinsa.
- 3.The patient had an adverse reaction or would be reasonably expected to have an adverse reaction to one of the preferred products, Calquence and Brukinsa.
- 4.The patient has a clinical condition for which there is no listed preferred formulary alternatives to treat the condition based on published guidelines or clinical literature.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

JYLAMVO

MEDICATION(S)

JYLAMVO

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis, Reason unable to take oral methotrexate (tablets)

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

All requests will be subject to a Part B vs Part D review. Patient must meet one of the following (1, 2, 3 or 4): 1.Patient has demonstrated an intolerance to oral methotrexate (tablets) for the given diagnosis 2.Patient has a documented contraindication to oral methotrexate (tablets) 3.Patient has had an adverse reaction or would be reasonably expected to have an adverse reaction to oral methotrexate (tablets) 4.Patient has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

JYNARQUE

MEDICATION(S)

TOLVAPTAN

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

History of signs or symptoms of significant liver impairment or injury (does not include uncomplicated polycystic liver disease). Concomitant use of strong CYP 3A inhibitors. Uncorrected abnormal blood sodium concentrations. Unable to sense or respond to thirst. Hypovolemia. Hypersensitivity to tolvaptan or any of its components. Uncorrected urinary outflow obstruction. Anuria. eGFR less than 25 ml/min/1.73m². Concomitant use with Samsca.

REQUIRED MEDICAL INFORMATION

Diagnosis, eGFR, Imaging results (e.g. ultrasound, MRI and/or CT), genetic testing (if applicable)

AGE RESTRICTION

18 years of age and older

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a nephrologist

COVERAGE DURATION

Initial: 6 months, Continuation: 1 year

OTHER CRITERIA

Initial criteria: Patient meets all of the following (1 and 2): 1. Patient is at risk of rapidly progressing autosomal dominant polycystic kidney disease as defined by one of the following (a, b or c): a. Mayo Classes 1C, 1D or 1E, b. Age is less than or equal to 55 years of age AND patient has eGFR less than 65 ml/min/1.73m², c. Kidney length (by ultrasound, MRI or CT) is greater than 16.5 cm in a patient less than 50 years old. 2. Patient meets one of the following criteria for diagnosis of autosomal dominant polycystic kidney disease (ADPKD) (a or b): a. Patient with family history of ADPKD and meets one of the following (i, ii, iii or iv): i. For ages 15 and older, but less than 40 years of age at time of ultrasound:

Has at least 3 cysts on each kidney if measured by sonography, ii. For ages 40-59 at time of ultrasound: Has at least 2 cysts on each kidney if measured by sonography, iii. For ages 60 or older at time of ultrasound: Has at least 4 cysts on each kidney if measured by sonography, iv. Has 5 cysts on each kidney if measured by CT or MRI or b. In patient without family history of ADPKD (patients meets both i and ii): i. Genetic testing shows a pathogenic mutation in the PKD1 or PKD2 gene and ii. Has at least 5 cysts on each kidney if measured by sonography or 10 cysts on each kidney if measured by CT or MRI

Continuation criteria: Approve if patient meets all of the following (1, 2 and 3): 1. If patient is new to plan without a previous prior authorization, meets initial criteria at time they had started the medication, 2. Documented dose and frequency are within FDA-approved Dosing and Frequency, 3. Patient has demonstrated a beneficial response to therapy (for example, slowed kidney function decline, decreased kidney pain).

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

KALYDECO

MEDICATION(S)

KALYDECO

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Use in patients homozygous for the F508del mutation. Combination use with Orkambi, Trikafta or Symdeko.

REQUIRED MEDICAL INFORMATION

Diagnosis, evidence of abnormal CFTR function, relevant mutation

AGE RESTRICTION

1 month and older

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a pulmonologist or physician who specializes in the treatment of cystic fibrosis

COVERAGE DURATION

3 years

OTHER CRITERIA

1. Diagnosis is cystic fibrosis AND 2. Patient must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF AND 3. Evidence of abnormal CFTR function as demonstrated by a, b or c: a. Elevated sweat chloride test, b. Two CFTR mutations, c. Abnormal nasal potential difference AND 4. The patient has one mutation in the CFTR gene that is considered to be pathogenic or likely pathogenic AND 5. The patient has at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive to the requested medication

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

KERENDIA

MEDICATION(S)

KERENDIA

PENDING CMS APPROVAL

KINERET

MEDICATION(S)

KINERET

PENDING CMS APPROVAL

KORLYM

MEDICATION(S)

MIFEPRISTONE 300 MG TABLET

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Pregnancy.

REQUIRED MEDICAL INFORMATION

Diagnosis, reauth: positive response

AGE RESTRICTION

Aged 18 years or older.

PRESCRIBER RESTRICTION

Prescribed by or in consultation with an endocrinologist or specialist in treating Cushing's syndrome

COVERAGE DURATION

Initial – 6 months, Continuation: 1 year

OTHER CRITERIA

The member must have failed surgery, or is not a candidate for surgery. Members must utilize adequate measures such as non-hormonal contraceptive methods to prevent pregnancy. Hyperglycemia secondary to hypercortisolism:

1. Initial – Approve if the patient meets all of the following (a, b, c and d):

- a. Patient must have endogenous Cushing's syndrome, requiring control of hyperglycemia secondary to hypercortisolism,
- b. Patient has type 2 diabetes mellitus or glucose intolerance,
- c. Patient has failed surgery or is not a candidate for surgery,
- d. Patient must not be pregnant as evidenced by a documented negative pregnancy test prior to the initiation of treatment and must use adequate measures such as non-hormonal contraceptive methods to prevent pregnancy.

2.Continuation: Approve if the patient meets all of the following (a and b):

a.If patient is new to plan, must have met initial criteria at time of starting the medication,

b.Patient must have experienced a beneficial response from therapy (e.g. improvement in fasting glucose, oral glucose tolerance or hemoglobin A1c results)

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

KOSELUGO

MEDICATION(S)

KOSELUGO

PENDING CMS APPROVAL

KUVAN

MEDICATION(S)

SAPROPTERIN DIHYDROCHLORIDE, ZELVYSIA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Concurrent use with Palynziq (continuation only)

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial 3 months, if positive response, then 1 year. In pregnancy, through term.

OTHER CRITERIA

For continuation of therapy, allow for continuation of therapy if the patient has experienced improvement after the initial three months of therapy, as determined by the prescriber.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

LIVTENCITY

MEDICATION(S)

LIVTENCITY

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Concomitant use with ganciclovir or valganciclovir

REQUIRED MEDICAL INFORMATION

Diagnosis

AGE RESTRICTION

12 years and older

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a hematologist, infectious disease specialist, oncologist, or a physician affiliated with a transplant center.

COVERAGE DURATION

2 months

OTHER CRITERIA

Cytomegalovirus Infection, Treatment-approve if the patient meets the following criteria (A, B, and C):
A) Patient weighs greater than or equal to 35 kg, AND B) Patient is post-transplant (Note: This includes patients who are post hematopoietic stem cell transplant or solid organ transplant.) AND C) Patient has cytomegalovirus infection/disease that is refractory to treatment with at least one of the following: cidofovir, foscarnet, ganciclovir, or valganciclovir

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

LUPRON DEPOT

MEDICATION(S)

LUPRON DEPOT, LUPRON DEPOT (LUPANETA)

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis, Reauth: lifetime duration with which member has been on therapy

AGE RESTRICTION

Premenstrual disorders – 18 years and older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Endometriosis: 1 year, Uterine leiomyomata: 6 months All others: 1 year

OTHER CRITERIA

1. Endometriosis: a. For initial therapy – member meet all of the following (i, ii, and iii):
 - i. Has had surgical ablation to prevent recurrence OR trial/failure, contraindication or intolerance to one NSAID and one oral contraceptive, ii. Medication will be used in combination with add-back therapy in combination with norethindrone 5 mg, iii. Total lifetime duration of use does not exceed 12 months.
2. Uterine leiomyomata (fibroids): - member meets all of the following (i, ii and iii):
 - i. Will be used prior to surgery to reduce size of fibroids OR treatment of anemia,
 - ii. Will be used in combination with iron therapy,
 - iii. Total lifetime duration of use does not exceed 6 months.
3. Gender dysphoric/gender-incongruent persons, Persons undergoing gender reassignment (female-to-male or male-to-female) – approve.
4. Premenstrual disorders (including premenstrual syndrome and premenstrual dysphoric disorder) –

Approve if patient meets both of the following (a and b):

a. Patient has severe refractory premenstrual symptoms,

b. Patient has tried a selective serotonin reuptake inhibitor (SSRI) AND a combined oral contraceptive for treatment of premenstrual disorder.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

MAVYRET

MEDICATION(S)

MAVYRET

PA INDICATION INDICATOR

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

OFF LABEL USES

Indications consistent with current AASLD/IDSA guidance

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Member has been tested for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with Mavyret.

AGE RESTRICTION

Member is 3 years of age or older.

PRESCRIBER RESTRICTION

The medication must be prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician.

COVERAGE DURATION

8, 12, or 16 weeks. Criteria will be applied consistent with current AASLD/IDSA guidance.

OTHER CRITERIA

Criteria will be applied consistent with current AASLD/IDSA guidance.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

MEMANTINE

MEDICATION(S)

MEMANTINE 5-10 MG TITRATION PK, MEMANTINE HCL 10 MG/5 ML CUP, MEMANTINE HCL 2 MG/ML SOLUTION, MEMANTINE HCL ER

PA INDICATION INDICATOR

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

OFF LABEL USES

Memantine titration pack or solution-Mild to moderate vascular dementia.

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Lifetime

OTHER CRITERIA

For members requesting memantine ER, titration pack or solution: must have trialed and failed memantine 5 mg or 10 mg tablets.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

MYALEPT

MEDICATION(S)

MYALEPT

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Partial lipodystrophy, HIV-related lipodystrophy, Liver disease, including nonalcoholic steatohepatitis, Metabolic disease including diabetes mellitus and hypertriglyceridemia (without concurrent evidence of generalized lipodystrophy)

REQUIRED MEDICAL INFORMATION

Diagnosis, Reauth: positive clinical response

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by or in consultation with an endocrinologist or a geneticist

COVERAGE DURATION

Authorization will be for 3 years.

OTHER CRITERIA

Initial criteria – Approve if patient meets both of the following (1 and 2):

1. Patient has diagnosis of congenital or acquired generalized lipodystrophy,
2. Patient has experienced one or more signs of leptin deficiency (e.g. hyperinsulinemia, type 2 diabetes mellitus, and hypertriglyceridemia).

Continuation Criteria – Approve if patient meets all of the following (1, 2 and 3):

1. If patient is new to plan, meets initial criteria at time they had started the medication,
2. Documented dose and frequency are within the FDA approved Dosing and Frequency,
3. Patient has experienced a positive clinical response to treatment (e.g. sustained improvement in triglyceride levels, hemoglobin A1c from baseline)

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

NASAL CORTICOSTEROIDS

MEDICATION(S)

MOMETASONE FUROATE 50 MCG SPRY, RYALTRIS

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experience with the preferred product, or the clinical condition for which an exception to the preferred product is requested.)

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

3 years

OTHER CRITERIA

Requests for mometasone will be authorized if using for treatment of nasal polyps - member will not need to try preferred products. Flunisolide and fluticasone propionate are the preferred products. The drug must be prescribed within the manufacturer's published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance to one preferred formulary/preferred drug list alternatives for the given diagnosis OR the member has a documented contraindication to one preferred formulary alternative OR the member has had an adverse reaction or would be reasonably

expected to have an adverse reaction to one preferred formulary alternatives OR the member has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

NEXLETOL

MEDICATION(S)

NEXLETOL, NEXLIZET

PENDING CMS APPROVAL

NITISINONE

MEDICATION(S)

NITISINONE

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by, or in consultation with, a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)

COVERAGE DURATION

1 year

OTHER CRITERIA

Hereditary Tyrosinemia, Type 1 – approve if diagnosis was confirmed by genetic testing confirming a mutation of the FAH gene OR elevated serum levels of alpha-fetoprotein (AFP) and succinylacetone.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

NUCALA

MEDICATION(S)

NUCALA

PENDING CMS APPROVAL

NUEDEXTA

MEDICATION(S)

NUEDEXTA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis, CNS-LS score, Reauth: documented improvement with medication (e.g. reduction in episodes of inappropriate laughing or crying)

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by a neurologist or a psychiatrist.

COVERAGE DURATION

1 year

OTHER CRITERIA

Pseudobulbar Affect - Diagnosis is confirmed by all of the following:

- a. Physician attestation that the patient has experienced involuntary, sudden, or frequent episodes of laughing and/or crying consistent with PBA at baseline
- b. Documentation of a Center for Neurologic Study-Lability Scale (CNS-LS) baseline score of at least 13.
- c. Patient has a brain injury or neurologic disease associated with pseudobulbar affect (for example, amyotrophic lateral sclerosis, multiple sclerosis, Parkinson's disease, stroke or traumatic brain injury)

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

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

Diagnosis of Parkinson's disease psychosis, Reauth: documentation of response

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a neurologist.

COVERAGE DURATION

1 year

OTHER CRITERIA

Parkinson's disease psychosis: Initial – Patient meets the following criteria:

- 1.Symptoms of psychosis developed after the PD diagnosis
- 2.Symptoms include at least one of the following: visual hallucinations, auditory hallucinations or delusions
- 3.Symptoms have been present for at least one month AND individual has experienced symptoms at least once weekly
- 4.Psychiatric symptoms cannot be attributed to disorders such as schizophrenia, schizoaffective disorder, delusional disorder, or mood disorder with psychotic features, or a general medical condition including delirium.

Continuation: Individual has experienced a reduction in psychosis symptoms compared to baseline.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

NURTEC ODT

MEDICATION(S)

NURTEC ODT

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

For preventative treatment: Combination with a CGRP antagonist when the CGRP antagonist is being used for prophylaxis.

REQUIRED MEDICAL INFORMATION

Diagnosis

AGE RESTRICTION

18 years of age and older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

Acute treatment: Approve if the patient has trialed and failed two different triptans (must be different active ingredients and documentation required) or has an intolerance or contraindication [documentation required] to triptans. Contraindications to triptans include history of coronary artery disease, peripheral vascular disease, uncontrolled hypertension, and other vascular risk factors or disorders. Preventative treatment of episodic migraine: For: Approve if the patient has a diagnosis of episodic migraine.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED
YES

OMNIPOD

MEDICATION(S)

OMNIPOD 5 (G6/LIBRE 2 PLUS), OMNIPOD 5 DEXG7G6 INTRO(GEN 5), OMNIPOD 5 DEXG7G6 PODS (GEN 5), OMNIPOD 5 G6-G7 INTRO KT(GEN5), OMNIPOD 5 G6-G7 PODS (GEN 5), OMNIPOD 5 INTRO(G6/LIBRE2PLUS), OMNIPOD DASH INTRO KIT (GEN 4), OMNIPOD DASH PODS (GEN 4)

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis, insulin therapy regimen

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

3 years

OTHER CRITERIA

Patient must meet ALL of the following requirements (A, B, C, and D):

A. Diagnosis of diabetes, as indicated by 1 or more of the following (1 or 2):

(1.) Type 1 diabetes mellitus OR

(2.) Type 2 diabetes mellitus and 1 or more of the following (a. or b.): (a.) Daily insulin requirement of 0.7 to 1.8 units per kg or (b.) Total daily insulin dose is 220 units or less

B. Failure of multiple daily injection insulin administration, as indicated by 1 or more of the following:

- (1.) Abnormal early-morning increase in blood glucose (“dawn phenomenon”), unresponsive to management with long-acting insulin analogue (eg, insulin glargine, insulin detemir) regimens
- (2.) Child for whom multiple daily insulin injections are impractical or inappropriate
- (3.) Diabetes complications (eg, neuropathy, nephropathy, retinopathy), and need for more intensive management
- (4.) Extreme insulin sensitivity
- (5.) HbA1c greater than 7% (53 mmol/mol), despite intensified multiple daily injection insulin therapy
- (6.) Hypoglycemia requiring third-party assistance, including unconsciousness, seizure, glucagon administration, and emergency attendance or admission to hospital
- (7.) Patient is pregnant or planning pregnancy
- (8.) Wide swings in glycemic control

C. Patient or caregiver is motivated, adherent, knowledgeable, and able to monitor blood glucose 3 or more times per day.

D. Provider team is experienced and expert in management and support of patient with insulin pumps

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

OPHTHALMIC BETA BLOCKER

MEDICATION(S)

BETOPTIC S, TIMOLOL MALEATE PF EYE DROPS 0.25%, TIMOLOL MALEATE PF EYE DROPS 0.5%

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experience with the preferred product, or the clinical condition for which an exception to the preferred product is requested.)

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

3 years

OTHER CRITERIA

Betaxalol, carteolol, dorzolamide/timolol, levobunolol, timolol (excluding timolol maleate preservative free dropperette) are the preferred products. The drug must be prescribed within the manufacturers published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance to one preferred formulary/preferred drug list alternatives for the given diagnosis OR the member has a documented contraindication to one preferred formulary alternative OR the member has had an

adverse reaction or would be reasonably expected to have an adverse reaction to one preferred formulary alternatives OR the member has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

OPHTHALMIC PROSTAGLANDIN

MEDICATION(S)

LUMIGAN, ROCKLATAN, TAFLUPROST, TRAVOPROST, VYZULTA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experience with the preferred product, or the clinical condition for which an exception to the preferred product is requested.)

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

3 years

OTHER CRITERIA

Latanoprost and bimatoprost are the preferred products. The drug must be prescribed within the manufacturers published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance to one preferred formulary/preferred drug list alternatives for the given diagnosis OR the member has a documented contraindication to one preferred formulary alternative OR the member has had an adverse reaction or would be reasonably expected to have an adverse reaction to one preferred formulary alternatives OR the member has a clinical condition for which there is no listed

preferred formulary alternative to treat the condition based on published guidelines or clinical literature.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

OPZELURA

MEDICATION(S)

OPZELURA

PENDING CMS APPROVAL

ORKAMBI

MEDICATION(S)

ORKAMBI

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Combination use with Kalydeco, Trikafta or Symdeko.

REQUIRED MEDICAL INFORMATION

Diagnosis, evidence of abnormal CFTR function, relevant mutation

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a pulmonologist or physician who specializes in the treatment of cystic fibrosis

COVERAGE DURATION

3 years

OTHER CRITERIA

1. Diagnosis is cystic fibrosis, AND 2. Patient must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF AND 3. Evidence of abnormal CFTR function as demonstrated by a, b or c:

a. Elevated sweat chloride test, b. Two CFTR mutations, c. Abnormal nasal potential difference, 4. For Orkambi: The patient who has two mutated copies of F508del mutation in the CFTR gene.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

OTEZLA

MEDICATION(S)

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

PENDING CMS APPROVAL

PARATHYROID HORMONE AGENTS

MEDICATION(S)

BONSITY, TERIPARATIDE

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

2 years

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

PART D VS PART B

MEDICATION(S)

ABELCET, ACETYLCYSTEINE 10% VIAL, ACETYLCYSTEINE 20% VIAL, ACYCLOVIR 1,000 MG/20 ML VIAL, ACYCLOVIR 500 MG/10 ML VIAL, ALBUTEROL 100 MG/20 ML SOLN, ALBUTEROL 15 MG/3 ML SOLUTION, ALBUTEROL 2.5 MG/0.5 ML SOL, ALBUTEROL 25 MG/5 ML SOLUTION, ALBUTEROL 5 MG/ML SOLUTION, ALBUTEROL 75 MG/15 ML SOLN, ALBUTEROL SUL 0.63 MG/3 ML SOL, ALBUTEROL SUL 1.25 MG/3 ML SOL, ALBUTEROL SUL 2.5 MG/3 ML SOLN, AMPHOTERICIN B 50 MG VIAL, AMPHOTERICIN B LIPOSOME, APREPITANT, ARFORMOTEROL TARTRATE, ASTAGRAF XL, AZATHIOPRINE 50 MG TABLET, BUDESONIDE 0.25 MG/2 ML SUSP, BUDESONIDE 0.5 MG/2 ML SUSP, BUDESONIDE 1 MG/2 ML INH SUSP, CINACALCET HCL, CLINIMIX, CLINIMIX E, CROMOLYN 20 MG/2 ML NEB SOLN, CYCLOPHOSPHAMIDE 1 GM VIAL, CYCLOPHOSPHAMIDE 1 GM/5 ML VL, CYCLOPHOSPHAMIDE 2 GM VIAL, CYCLOPHOSPHAMIDE 2 GM/10 ML VL, CYCLOPHOSPHAMIDE 25 MG CAPSULE, CYCLOPHOSPHAMIDE 25 MG TABLET, CYCLOPHOSPHAMIDE 50 MG CAPSULE, CYCLOPHOSPHAMIDE 50 MG TABLET, CYCLOPHOSPHAMIDE 500 MG VIAL, CYCLOPHOSPHAMIDE 500 MG/2.5 ML, CYCLOSPORINE 100 MG CAPSULE, CYCLOSPORINE 25 MG CAPSULE, CYCLOSPORINE MODIFIED, DRONABINOL, ENGERIX-B ADULT, ENGERIX-B PEDIATRIC-ADOLESCENT, ENVARSUS XR, EVEROLIMUS 0.25 MG TABLET, EVEROLIMUS 0.5 MG TABLET, EVEROLIMUS 0.75 MG TABLET, EVEROLIMUS 1 MG TABLET, FORMOTEROL 20 MCG/2 ML NEB VL, FOSCARNET SODIUM, GANCICLOVIR SODIUM, GENGRAF 100 MG CAPSULE, GENGRAF 25 MG CAPSULE, GRANISETRON HCL 1 MG TABLET, HEPLISAV-B, IMOVAX RABIES VACCINE, INTRALIPID, IPRATROPIUM BR 0.02% SOLN, IPRATROPIUM-ALBUTEROL, JYNNEOS, JYNNEOS (NATIONAL STOCKPILE), LEVALBUTEROL CONCENTRATE, LEVALBUTEROL HCL, METHOTREXATE 1 GM VIAL, METHOTREXATE 2.5 MG TABLET, METHOTREXATE 250 MG/10 ML VIAL, METHOTREXATE 50 MG/2 ML VIAL, METHOTREXATE SODIUM, MYCOPHENOLATE 200 MG/ML SUSP, MYCOPHENOLATE 250 MG CAPSULE, MYCOPHENOLATE 500 MG TABLET, MYCOPHENOLIC ACID, ONDANSETRON 4 MG/5 ML SOLN CUP, ONDANSETRON 4 MG/5 ML SOLUTION, ONDANSETRON HCL 4 MG TABLET, ONDANSETRON HCL 8 MG TABLET, ONDANSETRON ODT 4 MG TABLET, ONDANSETRON ODT 8 MG TABLET, PENTAMIDINE 300 MG INHAL POWDR, PLENAMINE, PREMASOL, PROGRAF 0.2 MG GRANULE PACKET, PROGRAF 1 MG GRANULE PACKET, PROSOL, PULMOZYME, RABAVERT, RECOMBIVAX HB, RIABNI, RITUXAN, RUXIENCE, SIROLIMUS 0.5 MG TABLET, SIROLIMUS 1 MG TABLET, SIROLIMUS 1 MG/ML SOLUTION, SIROLIMUS 2 MG TABLET, TACROLIMUS 0.5 MG CAPSULE, TACROLIMUS 0.5 MG CAPSULE (IR), TACROLIMUS 1 MG CAPSULE, TACROLIMUS 1 MG CAPSULE (IR), TACROLIMUS 5 MG CAPSULE, TACROLIMUS 5 MG CAPSULE (IR), TACROLIMUS 5 MG/ML VIAL, TOBRAMYCIN 300 MG/4 ML AMPULE, TOBRAMYCIN 300 MG/5 ML AMPULE, TRAVASOL, TROPHAMINE, TRUXIMA,

VINCASAR PFS, VINCRISTINE SULFATE

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.

PHOSPHATE BINDERS

MEDICATION(S)

CALCIUM ACETATE, SEVELAMER CARBONATE 800 MG TAB

PENDING CMS APPROVAL

PREVYMIS

MEDICATION(S)

PREVYMIS 120 MG PELLETT PACKET, PREVYMIS 20 MG PELLETT PACKET, PREVYMIS 240 MG TABLET, PREVYMIS 480 MG TABLET

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Severe hepatic impairment (Child-Pugh C). Members on dialysis or with end-stage renal disease (CrCl less than 10 ml/min) (unless receiving Prevymis for kidney transplant indication).

REQUIRED MEDICAL INFORMATION

Diagnosis, CMV lab value

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a hematologist, oncologist, infectious disease specialist, or transplant specialist (or nephrologist if for kidney transplant indication)

COVERAGE DURATION

7 months

OTHER CRITERIA

CMV prophylaxis in patients who have received an allogeneic hematopoietic stem cell transplant must meet all of the following (1, 2 and 3) 1.Member is CMV-seropositive, 2.Medication is started within 28 days post-transplant AND 3. Patient does not have active CMV infection (CMV PCR level over 250 IU/ml)

CMV prophylaxis in kidney transplant recipients must meet all of the following (1, 2, 3 and 4):

- 1.Member is a recipient of a kidney transplant
- 2.Member is CMV-seronegative
- 3.Donor is CMV-seropositive

4.Provider attests Prevymis will be initiated between Day 0 and 7 post-transplantation

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

PROMACTA

MEDICATION(S)

ALVAIZ, ELTROMBOPAG OLAMINE

PENDING CMS APPROVAL

PROVIGIL/NUVIGIL

MEDICATION(S)

ARMODAFINIL, MODAFINIL 100 MG TABLET, MODAFINIL 200 MG TABLET

PA INDICATION INDICATOR

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

OFF LABEL USES

Modafinil will be allowed for patients with Multiple Sclerosis-related fatigue, Excessive daytime sleepiness (EDS) associated with myotonic dystrophy, Adjunctive/augmentation for treatment of depression in adults.

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Confirmed diagnosis for a covered use. For Sleep Work Shift Disorder, other sleep disorders or contributing factors to sleep disorder have been ruled out, such as sleep apnea, restless leg syndrome/periodic limb movements, insomnia, or other causes for circadian rhythm misalignment (depression, gastrointestinal problems).

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

For narcolepsy, the prescriber is a neurologist or sleep specialist

COVERAGE DURATION

For Sleep Work Disorder, 12 months. All others, Lifetime.

OTHER CRITERIA

For narcolepsy, therapy will be allowed if one of the following is met: The member tried and failed or has a contraindication to TWO first line products: Amphetamine/dextroamphetamine (amphetamine salt combinations), Dextroamphetamine, Methamphetamine, Methylphenidate, OR the member has a history of substance abuse. For Sleep Work Shift Disorder, the member must have a documented shift work schedule (night shifts, rotating shifts). Modafinil will be allowed for patients with Multiple Sclerosis-related fatigue. Adjunctive/augmentation for treatment of depression in adults (modafinil only) -

Approve if the patient is concurrently receiving other medication therapy for depression.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

QULIPTA

MEDICATION(S)

QULIPTA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Combination with a CGRP antagonist when the CGRP antagonist is being used for prophylaxis

REQUIRED MEDICAL INFORMATION

Diagnosis

AGE RESTRICTION

18 years of age and older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 3 months, Continuation: 12 months

OTHER CRITERIA

Preventative treatment of migraine: For initial therapy: Approve if the patient meets (A and B): A) Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication) B) Patient has tried and failed one of the following prior to approval of Qulipta: Nurtec ODT, Aimovig or Emgality. For continuation of therapy: Prescriber confirms that the member demonstrates improvement after a 3-month trial.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

RETACRIT

MEDICATION(S)

RETACRIT

PA INDICATION INDICATOR

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

OFF LABEL USES

Anemia related to Multiple Myeloma. Refractory Anemia related to Myelodysplastic Syndrome. Anemia in patients with Hepatitis C who are being treated with the combination ribavirin and interferon alfa or ribavirin and peginterferon alfa. Anemia due to myelodysplastic syndrome (MDS).

EXCLUSION CRITERIA

Uncontrolled hypertension. Anemic patients willing to donate autologous blood pre-operatively. Anemia due to factors other than diagnoses noted (iron or folate deficiency, hemolysis, GI bleeding). Patients receiving hormonal agents, therapeutic biological products, or radiotherapy UNLESS also receiving concomitant myelosuppressive chemotherapy. For immediate anemia correction or as a substitute for emergency transfusion. Prophylactic use to prevent chemotherapy included anemia.

REQUIRED MEDICAL INFORMATION

Chronic renal failure patients not on dialysis must have symptomatic anemia with a HGB of 10g/dl or less. HIV-infected Zidovudine use requires a Zidovudine dose of 4200mg/week or less and an endogenous serum EPO level less than or equal to 500mUnits/ml. Non myeloid malignancy chemotherapy induced anemia must have HGB of 10g/dl or less to start AND serum ferritin greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20% or patient is receiving supplemental iron - if previously receiving Aranesp or epoetin alfa, Hgb must be 12 g/dL or less and the patient must have had a response to therapy. For MDS refractory anemia diagnosis must include excess blasts, or excess blasts in transformation to leukemia when, for medical reasons, the patient is not a candidate for active treatment of active leukemia. For MDS the patient must have endogenous EPO serum level less than 500mu/ml AND serum ferritin greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20% or patient is receiving supplemental iron - if previously receiving Aranesp or epoetin alfa, Hgb must be 12 g/dL or less and the patient has had a response to therapy. Anemia patients scheduled to undergo elective surgery require hemoglobin greater than 10 but 13 or less. Anemia related to ribavirin therapy in Hepatitis C treatment requires a pretreatment hemoglobin 10g/dl or less.

AGE RESTRICTION

For Hep C treatment related anemia, 18 or older.

PRESCRIBER RESTRICTION

For Hep C treatment related anemia, hematologist, hepatologist, gastroenterologist, or infectious disease physician who specializes in the management of Hep C.

COVERAGE DURATION

Chemo-induced anemia: 6 months. All other indications - 1 year.

OTHER CRITERIA

For non myeloid malignancy anemia related to chemotherapy, the member must have received chemotherapy in past 8 weeks and will be receiving chemo for a minimum of 2 months. In anemic patients scheduled to undergo surgery, the surgery must be elective, noncardiac and nonvascular, or in patients at high risk for perioperative transfusion with significant anticipated blood loss who are receiving anticoagulant prophylaxis. Part B versus Part D determination will be made at time of prior authorization review per CMS guidance to establish if the drug prescribed is to be used for an end-stage renal disease (ESRD)-related condition.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

REVATIO

MEDICATION(S)

ALYQ, SILDENAFIL 20 MG TABLET, TADALAFIL 20 MG TABLET

PA INDICATION INDICATOR

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

OFF LABEL USES

Raynaud's phenomenon

EXCLUSION CRITERIA

Erectile dysfunction. Benign Prostatic hyperplasia.

REQUIRED MEDICAL INFORMATION

Diagnosis, previous medication trials (if applicable)

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Lifetime.

OTHER CRITERIA

Pulmonary arterial hypertension – approve if member has confirmed diagnosis of PAH [documentation required].

Raynaud's phenomenon – approve if the member meets both of the following (a and b): a. Member has confirmed diagnosis of Raynaud's phenomenon [documentation required], AND b. Member has a previous trial, intolerance or contraindication to a calcium channel blocker, such as amlodipine or nifedipine.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

REVCovi

MEDICATION(S)

REVCovi

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis, genetic tests.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by or in consultation with, an immunologist, hematologist/oncologist, or physician that specializes in ADA-SCID or related disorders.

COVERAGE DURATION

12 months

OTHER CRITERIA

ADA-SCID - approve if the patient had absent or very low (less than 1% of normal) ADA catalytic activity at baseline (i.e., prior to initiating enzyme replacement therapy) OR if the patient had molecular genetic testing confirming bi-allelic mutations in the ADA gene.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

REYVOW

MEDICATION(S)

REYVOW

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis

AGE RESTRICTION

18 years of age or older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

Approve if the patient has trialed and failed or has a contraindication [documentation required] Nurtec ODT.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

REZDIFFRA

MEDICATION(S)

REZDIFFRA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Hepatic decompensation, presence of cirrhosis

REQUIRED MEDICAL INFORMATION

Diagnosis, Liver biopsy or elastography results (fibrosis results, NAS score)

AGE RESTRICTION

18 years of age or older

PRESCRIBER RESTRICTION

Prescribed by or in consultation with an endocrinologist, gastroenterologist or hepatologist

COVERAGE DURATION

1 year

OTHER CRITERIA

NASH Initial: Approve if patient meets all of the following (1, 2 and 3):

1. Patient meets one of the following (a or b): a. Has undergone liver biopsy in past 3 years preceding treatment with Rezdifra showing Non-alcoholic fatty liver disease activity score (NAS) of at least 1 in each of the following NAS components: 1) Steatosis, 2) Ballooning degeneration, and 3) Lobular inflammation or b. Patient has hepatic steatosis as shown by elastography (e.g. vibration-controlled transient elastography [e.g. FibroScan], transient elastography, magnetic resonance elastography, acoustic radiation force impulse imaging, shear wave elastography) within 6 months preceding treatment with Rezdifra, 2. Patient has been diagnosed with stage F2 or F3 liver fibrosis via liver biopsy or elastography and 3. Patient does not have evidence of cirrhosis.

NASH Continuation of therapy: Approve if patient meets all of the following (1,2,3 and 4):

1. If patient is new to plan and does not have previous prior authorization, meets initial criteria at time

they had started the medication

2.Documented dose and frequency are within FDA-approved Dosing and Frequency

3.Patient has completed greater than or equal to 10 months of therapy and has not had worsening of fibrosis or NASH

4.Patient has not progressed to cirrhosis

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

RHOPRESSA

MEDICATION(S)

RHOPRESSA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Prior therapies

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

Member must try and fail latanoprost AND one Ophthalmic Beta Blocker (ex. Timolol, betaxolol, levobunolol, metipranolol) prior to Rhopressa therapy

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

RILUTEK

MEDICATION(S)

TEGLUTIK, TIGLUTIK

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Neurologist.

COVERAGE DURATION

Lifetime.

OTHER CRITERIA

Requires documentation of exclusion of other diagnoses by neurologist.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

RINVOQ

MEDICATION(S)

RINVOQ, RINVOQ LQ

PENDING CMS APPROVAL

SANDOSTATIN

MEDICATION(S)

OCTREOTIDE ACETATE, OCTREOTIDE ACETATE ER

PA INDICATION INDICATOR

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

OFF LABEL USES

Pheochromocytoma/paraganglioma, Meningioma, Thymoma and thymic carcinoma, Management of volume depletion from enterocutaneous fistula

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Acromegaly-prescr/consult w/endocrinologist. All neuroendocrine tumors-prescr/consult w/oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescr/consult w/endo/onc/neuro. Meningioma-prescr/consult w/oncologist, radiologist or neurosurgeon. Thymoma/Thymic carcinoma-prescr/consult w/oncologist

COVERAGE DURATION

Enterocutaneous fistula: 3 months, All others: 1 year

OTHER CRITERIA

Acromegaly-approve if the patient has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory AND the patient meets i., ii., or iii: i. has had an inadequate response to surgery and/or radiotherapy or ii. is not an appropriate candidate for surgery and/or radiotherapy or iii. the patient is experiencing negative effects due to tumor size (e.g., optic nerve compression). Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptides-secreting tumors [VIPomas], insulinomas)-approve.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

SCIG

MEDICATION(S)

CUVITRU, HIZENTRA, HYQVIA, XEMBIFY

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis, Reauth: positive clinical response

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

CIDP: prescribed by or in consultation with a neurologist.

COVERAGE DURATION

PI initial and continuation: 1 year. CIDP initial: 3 months, continuation: 1 year.

OTHER CRITERIA

All requests will be subject to a Part B vs Part D review. If patient is new to plan, must meet initial criteria at time they had started the medication. Documented dose and frequency must be within the FDA approved dosing and frequency or consistent with compendial sources (e.g. Micromedex, current clinical guidelines, etc.). PI: Initial therapy: Approve if pt meets ONE of the following (1, 2 or 3): 1. Pt has diagnosis of congenital agammaglobulinemia, X-linked agammaglobulinemia, other agammaglobulinemia due to absence of B-cells, Wiskott-Aldrich syndrome, ataxia telangiectasia, DiGeorge syndrome, severe combined immunodeficiency, Hyper-Immunoglobulin M (IgM) syndromes, an IgG level lower than 250 mg/dL, or a primary immune deficiency which has been confirmed by genetic or molecular testing OR 2. Pt has a diagnosis of common variable immunodeficiency, unspecified hypogammaglobulinemia, or other immunodeficiencies with significant hypogammaglobulinemia and meets the following (a and b) a. Pts pretreatment IgG level is below

normal range (age-adjusted and according to normal reference range for reporting laboratory AND b. Pt has an impaired antibody response (i.e. failure to produce antibodies to specific antigens) OR pt has recurrent infections OR 3. Pt has an IgG subclass deficiency, selective antibody deficiency (SAD), or other confirmed primary immunodeficiency and meets the following (a and b): a. Pt has an impaired antibody response (i.e. failure to produce antibodies to specific antigens) AND b. Patient has recurrent infections. PI Continuation of therapy: Approve if pt has been diagnosed with PI and, according to the prescriber, the pt is continuing to receive benefit from the product (e.g. increased IgG levels or prevention and/or controlling of infections). CIDP or Polyradiculoneuropathy: Initial therapy: Approve if member meets following criteria (i, ii and iii) i. Member has had progressive symptoms present for at least 2 months ii. Has had symptomatic polyradiculoneuropathy with progressive or relapsing motor or sensory impairment in more than one limb iii. Member meets at least three of the following electrodiagnostic criteria for CIDP diagnosis (1, 2, 3 and/or 4): 1. Partial conduction block of one or more motor nerve, 2. Reduced conduction velocity of 2 or more motor nerves, 3. Prolonged distal latency of 2 or more motor nerves, 4. Prolonged F-wave latencies of 2 or more nerves or absence of F waves. CIDP Continuation therapy: Approve if pt has had clinically significant improvement to treatment as measured by an objective scale (e.g. Rankin, Modified Rankin, Medical Research Council [MRC] scale).

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

SGLT-2

MEDICATION(S)

SEGLUROMET, STEGLATRO

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experienced with the preferred product, or the clinical condition for which an exception to the preferred product is requested).

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

One year.

OTHER CRITERIA

Invokana, Invokamet, Farxiga (dapagliflozin), Jardiance, Synjardy, Synjardy XR and Xigduo are the preferred products. The drug must be prescribed within the manufacturers published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance to one preferred formulary/preferred drug list alternatives for the given diagnosis, OR the member has a documented contraindication to one preferred formulary alternative, or the member had an adverse reaction or would be reasonably expected to have an adverse reaction to one preferred formulary alternative, OR

the member has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

SIGNIFOR

MEDICATION(S)

SIGNIFOR

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

18 years and older (initial therapy)

PRESCRIBER RESTRICTION

Cushings disease/syndrome: Prescribed by, or in consultation with, an endocrinologist or a physician that specializes in the treatment of Cushings syndrome.

COVERAGE DURATION

Cushings int: 4 mo. Cont 1 yr.

OTHER CRITERIA

For Cushings disease/syndrome Approve Signifor if the following criteria are met: Initial therapy: Approve if, according to the prescribing physician, the patient is not a candidate for surgery, or surgery has not been curative. Continuation therapy: Approve if the patient has already been started on Signifor and, according to the prescribing physician, the patient has had a response and continuation of therapy is needed to maintain response.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

SIMBRINZA

MEDICATION(S)

SIMBRINZA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experienced with the preferred product, or the clinical condition for which an exception to the preferred product is requested).

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

Preferred products include generic eye drops used to treat glaucoma. The drug must be prescribed within the manufacturers published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance to two preferred formulary/preferred drug list alternatives for the given diagnosis, OR the member has a documented contraindication to two preferred formulary alternatives, or the member had an adverse reaction or would be reasonably expected to have an adverse reaction to two preferred formulary alternative, OR the member has a clinical condition for which there is no

listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

SKYCLARYS

MEDICATION(S)

SKYCLARYS

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Severe hepatic impairment (Child-Pugh C)

REQUIRED MEDICAL INFORMATION

Diagnosis based on genetic test, BNP

AGE RESTRICTION

16 years of age and older

PRESCRIBER RESTRICTION

Prescribed by, or in consultation with, a neurologist or a physician who specializes in ataxias and/or neuromuscular disorders

COVERAGE DURATION

1 year

OTHER CRITERIA

Friedreich's Ataxia: Initial Therapy – approve if patient meets all of the following (1, 2, and 3):

1. Patient has had a trinucleotide repeat expansion assay genetic test confirming the diagnosis of Friedreich's ataxia (mutation of the FXN gene),

2. Patient has a B-type natriuretic peptide (BNP) less than or equal to 200 pg/mL, AND 3. Patient is ambulatory. Continuation Therapy – approve if patient meets all of the following (1, 2, 3 and 4):

1. If patient is new to plan without a previous prior authorization, meets initial criteria at time they had started the medication, 2. Documented dose and frequency are within the FDA approved Dosing and Frequency, 3. Patient has had a trinucleotide repeat expansion assay genetic test confirming the diagnosis of Friedreich's ataxia, 4. Patient continues to benefit from therapy, as demonstrated by improvement or stabilization on the modified Friedreich's Ataxia Rating Scale

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

SKYRIZI

MEDICATION(S)

SKYRIZI 150 MG/ML SYRINGE, SKYRIZI ON-BODY, SKYRIZI PEN

PENDING CMS APPROVAL

SOMATULINE

MEDICATION(S)

LANREOTIDE 120 MG/0.5 ML SYRNG

PA INDICATION INDICATOR

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

OFF LABEL USES

Pheochromocytoma/paraganglioma

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis, previous treatments/therapies

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Acromegaly-prescribed by or in consultation with an endocrinologist. Carcinoid syndrome-prescribed by or in consultation with an oncologist, endocrinologist or gastroenterologist. All neuroendocrine tumors-prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescribed by or in consultation with an endo/onc/neuro.

COVERAGE DURATION

1 year

OTHER CRITERIA

Acromegaly-approve if the patient has a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory AND the patient meets i., ii., or iii: i. has had an inadequate response to surgery and/or radiotherapy or ii. is not an appropriate candidate for surgery and/or radiotherapy or iii. the patient is experiencing negative effects due to tumor size (e.g., optic nerve compression). Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptide-secreting tumors [VIPomas], insulinomas)-approve. Carcinoid Syndrome-approve.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

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

Diagnosis

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by or in consultation with an endocrinologist

COVERAGE DURATION

1 year

OTHER CRITERIA

Acromegaly approve if patient meets has a pre-treatment (baseline) IGF-1 level above the upper limit of normal based on age and gender for the reporting laboratory and ONE of the following (1, 2 or 3): 1. Patient has had an inadequate response to surgery and/or radiotherapy OR 2. The patient is not an appropriate candidate for surgery and/or radiotherapy OR 3. The patient is experiencing negative effects due to tumor size (e.g. optic nerve compression)

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

SOVALDI

MEDICATION(S)

SOVALDI

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

18 years or older. 3 and older in Genotype 2 and 3

PRESCRIBER RESTRICTION

Prescribed by or in consultation w/ GI, hepatologist, ID, or a liver transplant MD

COVERAGE DURATION

12 wk, 16 wk, 24 wk, or 48 wk. Criteria will be applied consistent with current AASLD/IDSA guidance.

OTHER CRITERIA

Criteria will be applied consistent with current AASLD/IDSA guidance.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

STELARA

MEDICATION(S)

SELARSDI 45 MG/0.5 ML SYRINGE, SELARSDI 45 MG/0.5 ML VIAL, SELARSDI 90 MG/ML SYRINGE, STARJEMZA 45 MG/0.5 ML SYRINGE, STARJEMZA 45 MG/0.5 ML VIAL, STARJEMZA 90 MG/ML SYRINGE, USTEKINUMAB-AEKN, YESINTEK 45 MG/0.5 ML SYRINGE, YESINTEK 45 MG/0.5 ML VIAL, YESINTEK 90 MG/ML SYRINGE

PENDING CMS APPROVAL

STRENSIQ

MEDICATION(S)

STRENSIQ

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis, lab values, radiographic reports

AGE RESTRICTION

Disease onset-less than or equal to 18

PRESCRIBER RESTRICTION

Prescribed by an endocrinologist or specialist experienced in treatment of metabolic bone disorders

COVERAGE DURATION

Initial – 6 months. Continuation – 12 months.

OTHER CRITERIA

Initial Coverage – member meets all of the following requirements (1, 2 and 3): 1. Documented diagnosis of perinatal/infantile- or juvenile-onset hypophosphatasia (HPP) AND diagnosis supported by one of the following (a or b): a. Molecular genetic testing documenting tissue non-specific alkaline phosphatase (ALPL) gene mutation OR b. Documentation of ALL of the following (i, ii and iii): i. An elevated level of tissue non-specific alkaline phosphatase (TNSALP) substrate (i.e., serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPi] level) ii. Findings on radiographic imaging support diagnosis of hypophosphatasia (e.g. infantile rickets, alveolar bone loss, osteoporosis, low bone mineral content for age [as detected by DXA scan])

iii. Low baseline ALP activity (age adjusted), 2. Member is 18 years or less at age of disease onset 3.

Member has clinical manifestations consistent with hypophosphatasia (e.g., skeletal abnormalities, respiratory problems, hypercalcemia, seizures). Continuation of coverage – member meets the following (1, 2 and 3) 1. Member meets criteria for initial approval, 2. Documentation of positive clinical response to Strensiq (e.g. improvement in clinical symptoms, improvement in Radiographic Global Impression of Change), 3. Clinically relevant decrease from baseline in tissue non-specific alkaline phosphatase (TNSALP) substrate (i.e., serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPi] level).

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

TARPEYO

MEDICATION(S)

TARPEYO

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

eGFR less than 30 ml/min/1.73m²

REQUIRED MEDICAL INFORMATION

Diagnosis, medication history

AGE RESTRICTION

18 years of age and older

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a nephrologist

COVERAGE DURATION

10 months

OTHER CRITERIA

For Primary IgAN: Initial therapy. Approve if patient meets the following (i, ii and iii): i.Diagnosis has been confirmed by biopsy AND ii.Patient is at high risk of disease progression, defined by meeting the following criteria (a and b): a.Patient meets ONE of the following (1 or 2): 1.Proteinuria greater than 0.5 g/day OR 2. Urine protein-to-creatinine ratio equal to or greater than 0.8 g/g AND b. Patient has been receiving the maximum or maximally tolerated dose of ONE of the following for 90 days or greater (1 and 2): 1. Angiotensin converting enzyme inhibitor OR 2. Angiotensin receptor blocker, AND iii. Member trial and failed or has a contraindication to use of either prednisone, prednisolone or methylprednisolone, AND iv. Patient has not previously been treated with Tarpeyo. Continuation of therapy. Approve for up to 10 months (total) if the patient meets the following criteria (i and ii): i.Diagnosis has been confirmed by biopsy AND ii. Patient has been receiving the maximum or maximally tolerated dose of ONE of the following for 90 days or greater (1 and 2): 1. Angiotensin

converting enzyme inhibitor OR 2. Angiotensin receptor blocker

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

TAVNEOS

MEDICATION(S)

TAVNEOS

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis, Lab values for antibodies (as described in other criteria), Reauth: positive response

AGE RESTRICTION

18 years and older (initial and continuation therapy)

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a rheumatologist, nephrologist, or immunologist

COVERAGE DURATION

Initial 6 months, Continuation 1 year

OTHER CRITERIA

Anti-Neutrophil Cytoplasmic Autoantibody (ANCA)-Associated Vasculitis, initial-approve if the patient meets (i, ii, iii and iv):

i. Patient has granulomatosis with polyangiitis or microscopic polyangiitis, AND

Note: Granulomatosis with polyangiitis is also known as Wegener's granulomatosis.

ii. Patient has active disease, AND

Note: This includes patients that have newly diagnosed or relapsed disease. This does not include patients already in remission.

iii. Patient is positive for proteinase 3 antibodies, anti-neutrophil cytoplasmic autoantibody (ANCA) or myeloperoxidase antibodies, AND

iv. Patient is using this medication in combination with at least one immunosuppressant

Note: Examples of immunosuppressants include cyclophosphamide, rituximab, azathioprine, or

mycophenolate mofetil.

Anti-Neutrophil Cytoplasmic Autoantibody (ANCA)-Associated Vasculitis, continuation-approve if the patient meets at least one of the following (a and b):

a) If patient is new to plan, meets initial criteria at time they had started the medication,

b) Patient meets one of the following (1 or 2):

(1) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Tavneos), OR

Note: Examples of objective measure include improvement in estimated glomerular filtration rate, decrease in urinary albumin creatinine ratio, or improvement in the Birmingham Vasculitis Activity Score [BVAS].

(2) Compared with baseline (prior to receiving Tavneos), patient experienced an improvement in at least one symptom, such as joint pain, ulcers, myalgia, persistent cough, abdominal pain, or improvement in function or activities of daily living.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

TAZAROTENE

MEDICATION(S)

TAZAROTENE 0.1% CREAM, TAZAROTENE 0.1% GEL

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Pregnancy. Fine wrinkle disorder/fine wrinkles on face.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Lifetime.

OTHER CRITERIA

Diagnosis of acne vulgaris requires failure on at least two other formulary anti-acne preparations (e.g. topical retinoid products, topical antibacterial products). Members must utilize adequate measures to prevent pregnancy.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

TESTOSTERONE

MEDICATION(S)

TESTOSTERONE 1% (25MG/2.5G) PK, TESTOSTERONE 1% (50 MG/5 G) PK, TESTOSTERONE 1.62% (2.5 G) PKT, TESTOSTERONE 1.62% GEL PUMP, TESTOSTERONE 1.62%(1.25 G) PKT, TESTOSTERONE 10 MG GEL PUMP, TESTOSTERONE 12.5 MG/1.25 GRAM, TESTOSTERONE 30 MG/1.5 ML PUMP, TESTOSTERONE 50 MG/5 GRAM GEL, TESTOSTERONE 50 MG/5 GRAM PKT

PA INDICATION INDICATOR

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

OFF LABEL USES

Gender dysphoria in transgender male patients.

EXCLUSION CRITERIA

Erectile dysfunction. Decreased Libido.

REQUIRED MEDICAL INFORMATION

Diagnosis of primary hypogonadism (congenital or acquired) in males. Diagnosis of secondary (hypogonadotropic) hypogonadism (congenital or acquired) in males. Hypogonadism (primary or secondary) in males, serum testosterone level. [Man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.]

AGE RESTRICTION

Aged 18 years or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Lifetime.

OTHER CRITERIA

Hypogonadism (primary or secondary) in males initial therapy, approve if all of the following criteria are met: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) [eg, depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis AND 2) patient has had two pre-treatment serum testosterone (total or available) measurements, each taken in the morning on two separate days, AND 3) the two serum testosterone levels are both low, as defined

by the normal laboratory reference values. Hypogonadism has been confirmed by a low for age serum testosterone (total or free) level defined by the normal laboratory reference values. Hypogonadism (primary or secondary) in males continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. [Note: male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.]

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

TEZSPIRE

MEDICATION(S)

TEZSPIRE

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Concurrent use with other monoclonal antibodies for asthma (e.g. Cinqair, Fasenra, Nucala, Dupixent, or Xolair)

REQUIRED MEDICAL INFORMATION

Diagnosis, medication history

AGE RESTRICTION

12 years of age and older

PRESCRIBER RESTRICTION

For asthma: Prescribed by or in consultation with an allergist, immunologist, or pulmonologist. For CRSwNP: Prescribed by or in consultation with an allergist, immunologist, or otolaryngologist.

COVERAGE DURATION

Initial: 1 year, Continuation: Lifetime

OTHER CRITERIA

Severe Asthma: Initial Therapy: Approve if the patient meets the following criteria (i and ii): i. Patient has received at least 3 consecutive months of combination therapy with BOTH of the following (a and b): a. The member must have received at least 3 months of combination therapy with an oral corticosteroid or inhaled corticosteroid AND one of the following b. At least one additional asthma controller or asthma maintenance medication (examples include inhaled long-acting beta-agonists, inhaled long-acting muscarinic antagonists, leukotriene receptor antagonists, or theophylline. Use of a combination inhaler containing both an inhaled corticosteroid and a long-acting beta-agonist would fulfill the requirement for both criteria a and b). ii. The patient's asthma continues to be uncontrolled as defined by one of the following (a, b, c, d, or e): a. Patient experienced two or more asthma

exacerbations requiring treatment with systemic corticosteroids in the previous year OR b. Patient experienced one or more asthma exacerbation(s) requiring hospitalization or an Emergency Department visit in the previous year OR c. Patient has a forced expiratory volume in 1 second (FEV1) less than 80 percent predicted OR d. Patient has an FEV1/forced vital capacity (FVC) less than 0.80 OR e. The patient has asthma that worsens upon tapering of oral corticosteroid therapy. Continuation of Therapy. Approve if the patient meets the following criteria (i, ii and iii): i. Patient has already received at least 6 months of therapy with Tezspire AND ii. The patient continues to receive therapy with an oral or inhaled corticosteroid AND iii. The patient has responded to Tezspire therapy as determined by the prescribing physician (e.g., decreased asthma exacerbations, decreased asthma symptoms, decreased hospitalizations/emergency department/urgent care/physician visits due to the asthma, decreased requirement for oral corticosteroid therapy).

Chronic rhinosinusitis with nasal polyposis:

Initial Therapy: Approve if the patient meets the following criteria (i and ii):

i. Patient has experienced significant nasal congestion/obstruction/discharge and/or reduction/loss of smell, AND

ii. Patient is currently receiving therapy with intranasal corticosteroid AND

Continuation of Therapy: Approve if the patient has received at least 6 months of therapy, continues to receive treatment with an intranasal corticosteroid and has responded to treatment.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

THALOMID

MEDICATION(S)

THALOMID 100 MG CAPSULE, THALOMID 50 MG CAPSULE

PA INDICATION INDICATOR

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

OFF LABEL USES

Discoid lupus erythematosus or cutaneous lupus erythematosus, Myelofibrosis, Prurigo nodularis, Recurrent aphthous ulcers or aphthous stomatitis, Kaposi sarcoma, Castleman's Disease, Histiocytic neoplasms

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis, previous therapies tried

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

For Erythem Nodosum Leprosum approve. For Multiple myeloma approve if Thalomid is being taken in combination with dexamethasone. For Discoid lupus erythematosus or cutaneous lupus erythematosus approve if the patient has tried at least two other therapies (e.g. corticosteroids [oral, topical, intralesional], hydroxychloroquine, tacrolimus [Protopic], methotrexate, dapsone, acitretin [Soriatane]). For Myelofibrosis approve if, according to the prescriber, the patient has anemia and has serum erythropoietin levels greater than or equal to 500 mU/ml OR the patient has serum erythropoietin levels less than 500 mU/ml and no response or loss of response to erythropoietic stimulating agents. For Prurigo nodularis approve. For Recurrent aphthous ulcers or aphthous stomatitis approve if the patient has tried at least two other therapies (e.g. topical or intralesional

corticosteroids, systemic corticosteroids, topical anesthetics/analgesics [e.g. benzocaine lozenges], antimicrobial mouthwashes [e.g. tetracycline], acyclovir, colchicine) 7.Kaposis sarcoma approve if the patient has tried at least one regimen or therapy and has relapsed or refractory disease 8.Castlemans disease approve if patient meets ALL of the following criteria: a. Has multicentric Castlemans disease AND b. Is negative for the human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8). Histiocytic neoplasms – approve if the patient has Langerhans cell histiocytosis with single-system multifocal skin disease or Rosai-Dorfman cutaneous disease.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

TIOPRONIN

MEDICATION(S)

TIOPRONIN, VENXXIVA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis of severe homozygous cystinuria

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by, or in consultation with, a nephrologist or urologist

COVERAGE DURATION

1 year

OTHER CRITERIA

Initiation of therapy: patient has urinary cysteine concentration greater than 250 mg/L.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

TOPICAL ALPHA-ADRENERGIC AGENTS FOR ROSACEA

MEDICATION(S)

BRIMONIDINE 0.33% GEL PUMP

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

18 years of age or older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

TOPICAL RETINOID PRODUCTS

MEDICATION(S)

ADAPALENE 0.1% CREAM, ADAPALENE 0.3% GEL, AKLIEF, TRETINOIN 0.01% GEL, TRETINOIN 0.025% CREAM, TRETINOIN 0.025% GEL, TRETINOIN 0.05% CREAM, TRETINOIN 0.1% CREAM, TRETINOIN MICROSPHERE

PENDING CMS APPROVAL

TRIKAFTA

MEDICATION(S)

TRIKAFTA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Combination therapy with Orkambi, Kalydeco or Symdeko. Patients with unknown CFTR gene mutations.

REQUIRED MEDICAL INFORMATION

Diagnosis, evidence of abnormal CFTR function, relevant mutation

AGE RESTRICTION

2 years of age and older.

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF.

COVERAGE DURATION

3 years.

OTHER CRITERIA

1. Diagnosis is cystic fibrosis AND 2. Patient must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF AND 3. Evidence of abnormal CFTR function as demonstrated by a, b or c: a. Elevated sweat chloride test, b. Two CFTR mutations, c. Abnormal nasal potential difference AND 4. The patient has one mutation in the CFTR gene that is considered to be pathogenic or likely pathogenic AND 5. The patient has at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive to the requested medication

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

TRINTELLIX

MEDICATION(S)

TRINTELLIX

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Lifetime

OTHER CRITERIA

For Major depressive disorder: Member must have tried and failed one generic serotonin selective reuptake inhibitor (SSRI)

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

TRIPTAN THERAPY

MEDICATION(S)

ZOLMITRIPTAN 2.5 MG NASAL SPRY, ZOLMITRIPTAN 2.5MG NASAL SPRAY, ZOLMITRIPTAN 5 MG NASAL SPRAY

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experience with the preferred product, or the clinical condition for which an exception to the preferred product is requested.)

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

3 years

OTHER CRITERIA

Almotriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan (tablet and ODT), and eletriptan are the preferred products. The drug must be prescribed within the manufacturers published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance to the preferred formulary drug OR the member has a documented contraindication to the preferred formulary drug OR the member has had an adverse reaction or would be reasonably expected to have an

adverse reaction to the preferred formulary drug OR the member has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

UBRELVY

MEDICATION(S)

UBRELVY

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

For acute treatment: Combination with a CGRP antagonist when the CGRP antagonist is being used for acute treatment.

REQUIRED MEDICAL INFORMATION

Diagnosis

AGE RESTRICTION

18 years of age and older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

Approve if the patient has trialed and failed or has a contraindication [documentation required] to Nurtec ODT.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

UPTRAVI

MEDICATION(S)

UPTRAVI 1,000 MCG TABLET, UPTRAVI 1,200 MCG TABLET, UPTRAVI 1,400 MCG TABLET, UPTRAVI 1,600 MCG TABLET, UPTRAVI 200 MCG TABLET, UPTRAVI 200-800 TITRATION PACK, UPTRAVI 400 MCG TABLET, UPTRAVI 600 MCG TABLET, UPTRAVI 800 MCG TABLET

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Concomitant use with strong CYP2C8 inhibitors (for example abiraterone [Zytiga] and gemfibrozil [Lopid]). Severe hepatic impairment (Child-Pugh Class C).

REQUIRED MEDICAL INFORMATION

Diagnosis, Right heart catheterizations results, Previous medication trials as outlined in other criteria

AGE RESTRICTION

Patient is 18 years or older

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a cardiologist or pulmonologist

COVERAGE DURATION

1 year

OTHER CRITERIA

Pulmonary arterial hypertension (PAH) WHO Group 1 - Initial criteria: approve if patient meets the following (1, 2, 3, or 4):

- 1.Diagnosis of PAH confirmed on pretreatment right heart catheterization showing all of the following (a, b and c): a.Mean pulmonary arterial pressure (mPAP) greater than or equal to 25 mm Hg at rest, b.Pulmonary artery wedge pressure (PAWP) less than or equal to 15 mm Hg, c.Pulmonary vascular resistance (PVR) greater than 3 Wood units, 2.Individual has WHO functional class II-IV symptoms.
- 3.At least one of the following (a or b): a.The member has demonstrated a failure, inadequate response or intolerance to one of the preferred products, ambrisentan or bosentan. Documentation of the failure,

including dates of trial and reason for failure is required, OR b.The member has a documented contraindication or would be reasonably expected to have an adverse reaction to both of the preferred products, ambrisentan and bosentan. Documentation including the medication name(s) and contraindication or adverse reaction is required. 4.At least one of the following (a or b): a.The member has demonstrated a failure, inadequate response or intolerance to one of the preferred products, sildenafil or tadalafil. Documentation of the failure, including dates of trial and reason for failure is required, OR b.The member has a documented contraindication or would be reasonably expected to have an adverse reaction to both of the preferred products, sildenafil and tadalafil. Documentation including the medication name(s) and contraindication or adverse reaction is required. Continuation criteria: Approve if patient meets all of the following (1, 2 and 3): 1.If patient is new to plan, meets initial criteria at time they had started the medication, 2.Documented dose and frequency are within FDA-approved Dosing and Frequency, 3.Patient has demonstrated a beneficial response to therapy (for example, improvement in signs and symptoms of PAH).

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

VEOZAH

MEDICATION(S)

VEOZAH

PENDING CMS APPROVAL

VERZENIO

MEDICATION(S)

VERZENIO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

For advanced or metastatic breast cancer – the member must meet one of the following criteria (1, 2, 3 or 4):

- 1.The member has demonstrated a failure of or intolerance to one of the preferred products, Ibrance and Kisqali, for the given diagnosis
- 2.The member has a documented contraindication to one of the preferred products, Ibrance and Kisqali
- 3.The member had an adverse reaction or would be reasonably expected to have an adverse reaction to one of the preferred products, Ibrance and Kisqali, OR
- 4.The member has a clinical condition for which there is no listed preferred formulary alternatives to treat the condition based on published guidelines or clinical literature.

For early breast cancer at high risk of recurrence:

- 1.The member has demonstrated a failure of or intolerance to the preferred product, Kisqali.
- 2.The member has a documented contraindication to the preferred product, Kisqali.
- 3.The member had an adverse reaction or would be reasonably expected to have an adverse reaction to the preferred product, Kisqali.
- 4.The member has a clinical condition for which there is no listed preferred formulary alternatives to treat the condition based on published guidelines or clinical literature.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

VOQUEZNA

MEDICATION(S)

VOQUEZNA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Concurrent use with rilpivirine-containing products

REQUIRED MEDICAL INFORMATION

Diagnosis, previous medications trialed as described in other criteria

AGE RESTRICTION

Patient is 18 years or older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Erosive esophagitis/GERD: 1 year. H. pylori: 1 month.

OTHER CRITERIA

Treatment of erosive esophagitis and Relief of heartburn associated with non-erosive GERD— approve if member meets one of the following (1 or 2): 1. Member has documented intolerance or inadequate response to TWO or more proton pump inhibitors (PPIs) with twice-daily dosing (with the exception of dexlansoprazole), OR 2. Member has documented contraindication or would be reasonably expected to have an adverse reaction to use of all the preferred products, including dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole and rabeprazole. Documentation including the medication name(s) and contraindication or adverse reaction is required. Treatment of H. pylori in combination with amoxicillin or amoxicillin and clarithromycin— approve if member meets one of the following (1 or 2): 1. Member has documented intolerance or inadequate response to TWO or more proton pump inhibitors (PPIs) with twice-daily dosing (with the exception of dexlansoprazole), OR 2. Member has documented contraindication or would be reasonably expected to have an adverse

reaction to use of all the preferred products, including dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole and rabeprazole. Documentation including the medication name(s) and contraindication or adverse reaction is required.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

VOSEVI

MEDICATION(S)

VOSEVI

PA INDICATION INDICATOR

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

OFF LABEL USES

Indications consistent with current AASLD/IDSA guidance

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Previous therapy. Member has been tested for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment of Vosevi.

AGE RESTRICTION

18 years of age or older

PRESCRIBER RESTRICTION

The medication must be prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician.

COVERAGE DURATION

12 weeks. Criteria will be applied consistent with current AASLD/IDSA guidance.

OTHER CRITERIA

Criteria will be applied consistent with current AASLD/IDSA guidance.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

VOWST

MEDICATION(S)

VOWST

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis

AGE RESTRICTION

18 years and older

PRESCRIBER RESTRICTION

Prescribed by or in consultation with an infectious disease physician or gastroenterologist

COVERAGE DURATION

One month

OTHER CRITERIA

Prevention of *C. difficile* infection (CDI): Patient must meet all of the following (1, 2, 3 and 4):

1. Patient has a diagnosis of recurrent CDI as defined by all of the following (a, b and c):

a. Greater than or equal to 3 episodes of CDI in a 12 month period, b. A positive *C. difficile* stool sample during each episode, c. A CDI episode of diarrhea greater than or equal to 3 unformed stools per day for at least 2 consecutive days during each episode, 2. The patient has completed at least 10 days of standard of oral vancomycin or fidaxomicin for recurrent CDI at least 2 to 4 days before initiating treatment with the requested medication,

3. The patient has had an adequate clinical response to standard of care oral antibiotic regimen as defined by less than 3 unformed stools in 24 hours for 2 or more consecutive days,

4. The patient will not be using the requested agent in combination with any antibiotic regimen for any indication

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

WAKIX

MEDICATION(S)

WAKIX

PENDING CMS APPROVAL

WINREVAIR

MEDICATION(S)

WINREVAIR, WINREVAIR (2 PACK)

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis, Right heart catheterizations results, Previous medication trials (as mentioned in other criteria)

AGE RESTRICTION

Patient is 18 years or older

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a cardiologist or pulmonologist

COVERAGE DURATION

1 year

OTHER CRITERIA

Pulmonary arterial hypertension (PAH) WHO Group 1 - Initial criteria: approve if patient meets the following (1, 2, 3, and 4):

1.Diagnosis of PAH confirmed on pretreatment right heart catheterization showing all of the following (a, b and c):

a.Mean pulmonary arterial pressure (mPAP) greater than 20 mm Hg at rest, b.Pulmonary artery wedge pressure (PAWP) less than or equal to 15 mm Hg, c.Pulmonary vascular resistance (PVR) greater than 2 Wood units.

2.Individual has WHO functional class II or III symptoms. 3.At least one of the following (a or b):

a.The member has demonstrated a failure, inadequate response or intolerance to one of the preferred products, ambrisentan or bosentan. Documentation of the failure, including dates of trial and reason for

failure is required, OR

b.The member has a documented contraindication or would be reasonably expected to have an adverse reaction to both of the preferred products, ambrisentan and bosentan. Documentation including the medication name(s) and contraindication or adverse reaction is required. 4.At least one of the following (a or b): a.The member has demonstrated a failure, inadequate response or intolerance to one of the preferred products, sildenafil or tadalafil. Documentation of the failure, including dates of trial and reason for failure is required, OR b.The member has a documented contraindication or would be reasonably expected to have an adverse reaction to both of the preferred products, sildenafil and tadalafil. Documentation including the medication name(s) and contraindication or adverse reaction is required. Continuation criteria: Approve if patient meets all of the following (1, 2 and 3): 1. If patient is new to plan without a previous prior authorization, meets initial criteria at time they had started the medication, 2.Documented dose and frequency are within FDA-approved Dosing and Frequency, 3.Patient has demonstrated a beneficial response to therapy (for example, improvement in signs and symptoms of PAH).

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

XDEM VY

MEDICATION(S)

XDEM VY

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by or in consultation with an ophthalmologist or optometrist

COVERAGE DURATION

2 months

OTHER CRITERIA

Demodex blepharitis: Approve if the patient meets all of the following (1 and 2): 1. Patient's diagnosis of Demodex blepharitis has been verified by the presence of collarettes and presence of at least mild erythema on the upper eyelid margin, 2. Patient has moderate to severe blepharitis symptoms that interfere with daily life (e.g. ocular irritation, itching, dryness, visual disturbances)

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

XELJANZ

MEDICATION(S)

XELJANZ, XELJANZ XR

PENDING CMS APPROVAL

XENAZINE

MEDICATION(S)

TETRABENAZINE

PA INDICATION INDICATOR

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

OFF LABEL USES

Tardive dyskinesia (TD). Tourette syndrome. Hyperkinetic dystonia. Hemiballism.

EXCLUSION CRITERIA

Impaired hepatic function, concomitant use of monoamine oxidase inhibitors (minimum of 14 days should elapse after stopping MAOI and starting tetrabenazine), Concomitant use of reserpine (minimum of 20 days should elapse after stopping reserpine and before starting tetrabenazine), Concomitant use with Austedo or Ingrezza, current suicidality, untreated or inadequately treated depression, Non-Huntington's disease related chorea

REQUIRED MEDICAL INFORMATION

Diagnosis, TD: AIMS or DISCUS score, HD reauth: positive clinical response

AGE RESTRICTION

18 years of age or older

PRESCRIBER RESTRICTION

For treatment of chorea associated with Huntington's disease, Tourette syndrome, hyperkinetic dystonia, or hemiballism, must be prescribed by or after consultation with a neurologist. For TD, must be prescribed by or after consultation with a neurologist or psychiatrist.

COVERAGE DURATION

TD – initial 4 months, continuation 1 year, all others: 1 year

OTHER CRITERIA

1.Chorea associated with Huntington's disease: a.Initial: approve if the patient's diagnosis is confirmed by genetic testing (for example, an expanded HTT CAG repeat sequence of at least 36), b. Continuation: Approve if patient meets both of the following (i and ii): i.If new to plan, patient met initial criteria at time of starting medication, ii. Patient has had a positive clinical response to therapy 2. Tardive Dyskinesia: a. Initial: Approve if patient meets all of the following (i, ii, and iii): i. Patient has had

at least 60 days of stable (drug and dose) medication exposure to one of the following (1, 2 or 3):
1. Typical or first generation antipsychotic agents (e.g. chlorpromazine, haloperidol, fluphenazine) 2. Atypical or second-generation antipsychotic agents (e.g. clozapine, risperidone, olanzapine) 3. Dopamine receptor-blocker used in treatment of nausea and gastroparesis (e.g. prochlorperazine, promethazine, metoclopramide), iii. Symptoms persist despite one of the following (1 or 2): 1. Discontinuation or reduction in dose of offending agent(s) 2. Discontinuation or reduction in dose of offending agent(s) is not possible, iv. Patient has presence of involuntary athetoid or choreiform movements lasting at least 30 days b. Continuation: Approve if patient meets all of the following (i and ii): i. If new to plan, patient met initial criteria at time of starting medication, i. Following at least 3 months of therapy, patient has experienced an improvement or maintenance of symptoms while on therapy based on reduction in abnormal involuntary movement scale (AIMS) or Dyskinesia Identification System: Condensed User Scale (DISCUS) from baseline. 3. Tourette's syndrome a. Initial – Approve if patient has diagnosis of Tourette's Syndrome b. Continuation – Approve if patient has had disease stabilization or improvement in signs and symptoms of Tourette's Syndrome due to tetrabenazine therapy

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

XIFAXAN

MEDICATION(S)

XIFAXAN

PA INDICATION INDICATOR

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

OFF LABEL USES

Small Intestinal Bacterial Overgrowth (SIBO)

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis

AGE RESTRICTION

Travelers diarrhea: 12 years of age or older. HE, IBS-D, SIBO: 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

HE: 1 year. IBS-D: 14 days. Travelers' diarrhea: 3 days. SIBO: Initial and Cont 14 days.

OTHER CRITERIA

1. Hepatic encephalopathy: trial/failure, intolerance or contraindication to lactulose.
2. Travelers' diarrhea: trial/failure, intolerance or contraindication to ciprofloxacin, levofloxacin, ofloxacin or azithromycin.
3. IBS-D - member meets all of the following (a, b and c):
 - a. Moderate to severe disease, including bloating without constipation,
 - b. Inadequate response to an antispasmodic (e.g. dicyclomine) AND an antidiarrheal agent (e.g. loperamide, diphenoxylate/atropine),
 - c. Dose is limited to 550 mg three times daily for 14 days. Retreatment is limited to patients with a positive response with a maximum of two, 14-day treatments.
4. Small Intestinal Bacterial Overgrowth (SIBO):
 - a. Initial Criteria: Patient meets all of the following (i, ii and iii):
 - i. Documentation of one of the following (1, 2 or 3):

1. Endoscopic culture with greater than 10³ bacteria colony forming units/mL
 2. Positive lactulose or glucose breath test with hydrogen increase of 20 ppm or greater above baseline within 90 minutes
 3. Positive lactulose or glucose breath test for methane (10 ppm or greater at any point during testing)
- ii. Member must have a history of trial and failure to two of the following systemic antibiotics (alternatively, patient must have intolerance and/or contraindication to all of the following systemic antibiotics):
1. Amoxicillin/clavulanic acid
 2. Ciprofloxacin
 3. Doxycycline
 4. Metronidazole
 5. Neomycin
 6. Sulfamethoxazole/trimethoprim
 7. Tetracycline
- iii. For methane-predominant bacterial overgrowth, must be used in combination with neomycin
- b. Continuation Criteria: Patient must meet both of the following (i and ii):
- i. There must be documented, significant improvement with prior courses of treatment
 - ii. Retreatment is limited to once every 90 days

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

XOLAIR

MEDICATION(S)

XOLAIR

PENDING CMS APPROVAL

ZEPATIER

MEDICATION(S)

ZEPATIER

PA INDICATION INDICATOR

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

OFF LABEL USES

Indications consistent with current AASLD/IDSA guidance

EXCLUSION CRITERIA

Combination use with other direct acting antivirals, excluding Sovaldi and ribavirin.

REQUIRED MEDICAL INFORMATION

Hep C genotype, concurrent medications, medication history to include preferred product as outlined in other criteria

AGE RESTRICTION

12 years or older

PRESCRIBER RESTRICTION

Prescribed by or in consultation w/ GI, hepatologist, ID, or liver transplant MD.

COVERAGE DURATION

Criteria will be applied consistent with current AASLD/IDSA guidance.

OTHER CRITERIA

Criteria will be applied consistent with current AASLD/IDSA guidance. Harvoni, Epclusa, Sovaldi, Vosevi and Mavyret are the preferred products. Authorization for Zepatier requires that the member must have confirmation of one of the following: A documented failure to one of the preferred products, OR A documented intolerance to one the preferred products, OR A documented contraindication to one of the preferred products, OR A documented adverse reaction to one of the preferred products.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

ZORYVE

MEDICATION(S)

ZORYVE

PENDING CMS APPROVAL

ZTALMY

MEDICATION(S)

ZTALMY

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis Reauth: positive response

AGE RESTRICTION

2 years of age and older

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a neurologist

COVERAGE DURATION

1 year

OTHER CRITERIA

Seizures associated with CDKL5 deficiency disorder: 1. Initial criteria - approve if the patient has a molecularly confirmed pathogenic or likely pathogenic mutation in the CDKL5 gene. 2. Continuation criteria – approve if the patient meets the following criteria:

- a. If patient is new to plan without a previous prior authorization, meets initial criteria at time they had started the medication,
- b. Documented Dose and Frequency are within the FDA approved Dosing and Frequency,
- c. Patient has experienced beneficial clinical response (e.g. reduced seizure activity, frequency and/or duration)

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

ZURZUVAE

MEDICATION(S)

ZURZUVAE

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Prior use of Zurzuvae for the current pregnancy

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

18 years of age or older

PRESCRIBER RESTRICTION

Prescribed by, or in consultation with, a psychiatrist, Perinatal Psychiatry Access Program, or obstetrician

COVERAGE DURATION

30 days

OTHER CRITERIA

Postpartum depression: Member must meet all of the following: 1. Diagnosis of major depressive episode that began no earlier than the third trimester and no later than the first 4 weeks following delivery, as diagnosed by Structured Clinical Interview for DSM-5 2. No more than 12 months have passed since member has given birth

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A