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 Cares (PPO D-SNP)

Network Health Go (PPO)

Network Health Anywhere (PPO)

Prior Authorization Criteria

Last Updated 10/2024

ABIRATERONE

MEDICATION(S)
ABIRATERONE ACETATE

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

ACTEMRA

MEDICATION(S)
ACTEMRA 162 MG/0.9 ML SYRINGE, ACTEMRA ACTPEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.

REQUIRED MEDICAL INFORMATION
The diagnosis is moderate to severe rheumatoid arthritis and the disease must be active. For Juvenile Idiopathic Arthritis, the member must have a confirmed diagnosis of Juvenile Idiopathic Arthritis and the disease must be active.

AGE RESTRICTION
Interstitial lung disease - 18 years and older (initial and continuation)

PRESCRIBER RESTRICTION
RA/GCA/PJIA/SIJA - Prescribed by or in consultation with a Rheumatologist. Interstitial lung disease - prescribed by or in consultation with a pulmonologist or rheumatologist (initial and continuation).

COVERAGE DURATION
RA/GCA/PJIA/SIJA - Lifetime. Interstitial lung disease - 1 year.

OTHER CRITERIA
For Rheumatoid Arthritis, approve if the patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Orencia (IV/SC), Rinvoq or Xeljanz/XR (Note: if the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the try TWO requirement: Cimzia, infliximab, golimumab SC/IV, or a non-preferred adalimumab product) OR if, according to the prescribing physician, the patient has heart failure or a previously treated lymphoproliferative disorder. For Polyarticular Juvenile Idiopathic Arthritis, approve if the patient has tried TWO of the following: etanercept, Orencia, a preferred adalimumb product, Rinvoq or Xeljanz. (Note: the patient does not have to have a trial with etanercept, Orencia, a preferred adalimumb

product, Rinvoq or Xeljanz if they have had a trial with infliximab or a non-preferred adalimumab in the past.) For Systemic Juvenile Idiopathic Arthritis -approve. For Giant Cell Arteritis - approve. For interstitial lung disease associated with systemic sclerosis initial approve if the patient has elevated acute phase reactants AND the diagnosis is confirmed by high-resolution computed tomography. Continuation approve if the patient had adequate efficacy while on Actemra in the past year. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074), adalimumab-adaz, adalimumab-fkjp, Simlandi and Yusimry.

PART B PREREQUISITE

N/A

ADBRY

MEDICATION(S)
ADBRY, ADBRY AUTOINJECTOR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with other Anti-Interleukin Monoclonal Antibodies (e.g. Dupixent)

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
12 years of age and older

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

COVERAGE DURATION
1 year

OTHER CRITERIA
Atopic dermatitis: Initial Therapy. Approve if the patient meets one of the following (a or b): A. Patient has chronic atopic dermatitis AND B. Patient has atopic dermatitis involvement estimated to be greater than or equal to 10% of the body surface area (BSA) according to the prescribing physician AND C. Patient meets all of the following (1 and 2): 1. History of failure, contraindication, or intolerance to one of the following therapeutic classes of topical therapies (document drug, date of trial, and/or contraindication to medication (a, b, or c) a. Medium to very-high potency topical corticosteroid for 2 weeks, b. Topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)] for 6 weeks OR c. Eucrisa (crisaborole) AND 2. One of the following: a. Phototherapy (UVB or PUVA) has failed to achieve and maintain remission of low or mild disease activity state OR b. Trial of one systemic treatment [e.g., oral corticosteroid, intramuscular corticosteroid, oral cyclosporine, oral azathioprine, oral methotrexate, or oral mycophenolate mofetil]

PART B PREREQUISITE

N/A

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

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 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

ADSTILADRIN

MEDICATION(S)
ADSTILADRIN

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

AGENTS FOR GAUCHER DISEASE

MEDICATION(S)
CERDELGA, CEREZYME, 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, 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

AGENTS FOR UREA CYCLE DISORDERS

MEDICATION(S)
RAVICTI, 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 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 testing confirmed a mutation resulting in 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

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, previous therapies tried.

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
For Initial approval: Trial of 2 different drug classes prior to Aimovig approval. Drug classes include: Beta blockers (ex. Metoprolol, Propranolol, and Timolol), Antidepressants (ex. Amitriptyline, Nortriptyline, and Venlafaxine), Anticonvulsants (ex. Valproate and Topiramate), and Calcium Channel Blockers (ex. Verapamil). Other Criteria for Initial Approval: The member must have a diagnosis of Chronic migraine or Episodic migraine, as indicated by 4 or more attacks per month. Criteria for continuation approval: Prescriber confirms that the member demonstrates improvement after initial trial.

PART B PREREQUISITE
N/A

AJOVY

MEDICATION(S)
AJOVY AUTOINJECTOR, AJOVY 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, previous therapies tried

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Chronic or episodic migraine: Initial 3 months, Continuation: 1 year

OTHER CRITERIA
For chronic or episodic migraine initiation of therapy: Trial of 2 different drug classes prior to approval. Drug classes include: Beta blockers (ex. Metoprolol, Propranolol, Timolol), Antidepressants (ex. Amitriptyline, Nortriptyline, and Venlafaxine), Anticonvulsants (ex. Valproate and Topiramate), and Calcium Channel Blockers (ex. Verapamil) AND The member must have a diagnosis of migraine, as indicated by 4 or more attacks per month. For continuation of therapy: Prescriber confirms that the member demonstrates improvement after initial trial.

PART B PREREQUISITE
N/A

AKEEGA

MEDICATION(S)
AKEEGA

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

ALECENSA

MEDICATION(S)
ALECENSA

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

ALPHA 1 PROTEINASE INHIBITORS

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

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

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 has a baseline (pretreatment) AAT serum concentration of less than 80 mg/dL or 11 micromol/L.

PART B PREREQUISITE
N/A

ALUNBRIG

MEDICATION(S)
ALUNBRIG

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

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
1 year

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

AMPYRA

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: 3 months. 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

ANABOLIC STEROIDS

MEDICATION(S)
OXANDROLONE 10 MG TABLET, OXANDROLONE 2.5 MG TABLET

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

OFF LABEL USES
Members with Turner's Syndrome or Ullrich-Turner Syndrome (oxandrolone only), management of protein catabolism w/burns or burn injury (oxandrolone only), AIDS wasting and cachexia.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
One year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ANKTIVA

MEDICATION(S)
ANKTIVA

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

ANTICONVULSANT THERAPY

MEDICATION(S)
APTIOM, 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, EPRONTIA, EQUETRO, FYCOMPA, METHSUXIMIDE, MOTPOLY XR, RUFINAMIDE, SPRITAM, VIGAFYDE, XCOPRI, ZONISADE

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
Carbamazepine, Epitol, Divalproex, ethosuximide, felbamate, gabapentin, lamotrigine, levetiracetam, oxcarbazepine, phenytoin, primidone, Roweepra, tiagabine, topiramate, valproic acid, and zonisamide oral products 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

ANTIFUNGALS (IV)

MEDICATION(S)
VORICONAZOLE 200 MG VIAL

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

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. 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 epoeitin 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

ARCALYST

MEDICATION(S)
ARCALYST

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
CAPS, Pericarditis - 12 years or greater.

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

COVERAGE DURATION
CAPS-Lifetime. DIRA: initial 6 months, cont 3 years. Pericarditis: initial 3 months, cont 1 year.

OTHER CRITERIA
Must be up to date and have received all recommended vaccines, or must receive all recommended vaccinations prior to initiation of therapy. Initial tx DIRA: Approve if the patient weighs at least 10 kg, genetic test confirms a mutation in the IL1RN gene and the patient has demonstrated a clinical benefit with anakinra subcutaneous injection. DIRA continuation-approve if the patient has responded to therapy. Initial tx pericarditis: the patient has recurrent pericarditis AND for the current episode, the patient is receiving standard treatment or standard treatment is contraindicated. Pericarditis continuation - approve if the patient has had a clinical response to Arcalyst.

PART B PREREQUISITE

N/A

ARIKAYCE

MEDICATION(S)
ARIKAYCE

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

OFF LABEL USES
Cystic fibrosis pseudomonas aeruginosa infection

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. Cystic fibrosis-prescribed by or in consultation with a pulmonologist or physician who specializes in the treatment of cystic fibrosis

COVERAGE DURATION
1 year

OTHER CRITERIA
MAC Lung disease: Initial-approve if the patient has NOT achieved negative sputum cultures for MAC within the past 3 months after completion of a 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. Cystic fibrosis-patient has pseudomonas aeruginosa in culture of the airway.

PART B PREREQUISITE

N/A

ATYPICAL ANTIPSYCHOTICS

MEDICATION(S)
ASENAPINE MALEATE, CAPLYTA, CLOZAPINE ODT, FANAPT, OLANZAPINE-FLUOXETINE HCL, 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 Fanapt will be authorized if using for acute treatment of manic or mixed episodes associated with bipolar I disorder. 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

AUGTYRO

MEDICATION(S)
AUGTYRO

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

AURYXIA

MEDICATION(S)
AURYXIA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Iron deficiency anemia in CKD not on dialysis

REQUIRED MEDICAL INFORMATION
Diagnosis of hyperphosphatemia. Patient has dialysis-dependent CKD.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

AUSTEDO

MEDICATION(S)
AUSTEDO, AUSTEDO XR, AUSTEDO XR TITRATION KT(WK1-4)

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Impaired hepatic function, Concomitant use of monoamine oxidase inhibitors (minimum of 14 days should elapse after stopping MAOI and before starting Austedo), Concomitant use of reserpine (minimum of 20 days should elapse after stopping reserpine and before starting Austedo), Concomitant use of tetrabenazine, Current suicidality, Untreated or inadequately-treated depression, Non-Huntingtons Disease related Chorea

REQUIRED MEDICAL INFORMATION
Patient has a diagnosis of tardive dyskinesia or chorea (involuntary movements) associated with Huntingtons Disease.

AGE RESTRICTION
18 years of age or older

PRESCRIBER RESTRICTION
Chorea - prescribed by, or in consultation with, a neurologist. Tardive dyskinesia - prescribed by, or in consultation with, a psychiatrist or neurologist.

COVERAGE DURATION
1 year

OTHER CRITERIA
For chorea - diagnosis of Huntington's disease is confirmed by genetic testing AND patient has tried/failed or has intolerance to tetrabenazine.

PART B PREREQUISITE
N/A

AYVAKIT

MEDICATION(S)
AYVAKIT

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

BALVERSA

MEDICATION(S)
BALVERSA

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

BASAL INSULIN

MEDICATION(S)
BASAGLAR KWIKPEN U-100, BASAGLAR TEMPO PEN U-100, INSULIN DEGLUDEC, INSULIN DEGLUDEC PEN (U-100), INSULIN DEGLUDEC PEN (U-200), INSULIN GLARGINE, INSULIN GLARGINE MAX SOLOSTAR, INSULIN GLARGINE SOLOSTAR, INSULIN GLARGINE-YFGN, LEVEMIR, LEVEMIR FLEXPEN, LEVEMIR FLEXTOUCH, REZVOGLAR KWIKPEN, SEMGLEE (YFGN), SEMGLEE (YFGN) PEN, 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, Rezvoglar, Semglee, Semglee-YFGN, or insulin glargine-YFGN 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 the preferred product, Lantus (brand), for the given diagnosis, (B) The member has a documented contraindication to the Lantus (brand), (C) The member had an adverse reaction or would be reasonably expected to have an adverse reaction to Lantus (brand), OR (D) The member had an adverse reaction or would be reasonably expected to have an

adverse reaction to Lantus (brand) for the requested indication. For insulin degludec, Levemir and Tresiba, 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 one of the preferred products, Lantus or Toujeo, for the given diagnosis, (B) The member has a documented contraindication to one of the preferred products, Lantus or Toujeo, (C) The member had an adverse reaction or would be reasonably expected to have an adverse reaction to one of the preferred products, Lantus or Toujeo, OR (D) The member had an adverse reaction or would be reasonably expected to have an adverse reaction to one of the preferred products, Lantus or Toujeo for the requested indication.

PART B PREREQUISITE

N/A

BENLYSTA

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

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent Use with Other Biologics or Lupkynis.

REQUIRED MEDICAL INFORMATION
Diagnosis, medications that will be used in combination, autoantibody status

AGE RESTRICTION
SC-5 years and older (initial)

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, 3 yrs cont. Lupus Nephritis 6 mo. initial, 1 year cont.

OTHER CRITERIA
Lupus Nephritis - Initial: approve if the patient has autoantibody-positive SLE (i.e., positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA]). Continuation: approve if the patient has responded to the requested medication. SLE -Initial: The patient has autoantibody-positive SLE (i.e., positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA]) AND 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]) unless the patient is determined to be intolerant due to a significant toxicity, as determined by the prescribing physician. Continuation: 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]) unless the patient is determined to be intolerant due to a significant toxicity, as determined by the prescribing physician AND the patient has responded to Benlysta as determined by the prescriber.

PART B PREREQUISITE

N/A

BESREMI

MEDICATION(S)
BESREMI

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

BIMZELX

MEDICATION(S)
BIMZELX, BIMZELX AUTOINJECTOR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)

REQUIRED MEDICAL INFORMATION
The member must have a confirmed diagnosis of moderate to severe Plaque Psoriasis, defined as a minimum body surface area involvement of greater than or equal to 5 percent, or by involvement of the hands, feet, facial, or genital regions, by which, despite involvement of a smaller BSA, the disease may interfere significantly with activities of daily life

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a dermatologist

COVERAGE DURATION
Lifetime

OTHER CRITERIA
Approve if the patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Skyrizi, Stelara (SC), Otezla, or Cosentyx. Note: If the patient does not meet this requirement, a trial of a non-preferred adalimumab product will also count. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074), Simlandi, adalimumab-adaz, adalimumab-fkjp and Yusimry.

PART B PREREQUISITE
N/A

BOSENTAN

MEDICATION(S)
BOSENTAN

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
1 year

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

BOSULIF

MEDICATION(S)
BOSULIF

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

BRAFTOVI

MEDICATION(S)
BRAFTOVI

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

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
N/A

PART B PREREQUISITE
N/A

BYLVAY

MEDICATION(S)
BYLVAY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
PFIC: 3 months and older (initial therapy) ALGS: 12 months and older (initial therapy)

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hepatologist, gastroenterologist, or a physician who specializes in progressive familial intrahepatic cholestasis for PFIC or Alagille syndrome for ALGS (initial and continuation)

COVERAGE DURATION
Initial-6 months, continuation-1 year

OTHER CRITERIA
Progressive Familial Intrahepatic Cholestasis, Initial therapy-approve if the patient meets the following (i, ii, iii, and iv): i. Patient has moderate-to-severe pruritus, according to prescriber AND ii. Diagnosis of progressive familial intrahepatic cholestasis type 1 or type 2 was confirmed by genetic testing AND iii. Patient does not have any of the following (a, b, or c): a) Cirrhosis OR b) Portal hypertension OR c) History of a hepatic decompensation event AND Note: Examples of a hepatic decompensation event include variceal hemorrhage, ascites, and hepatic encephalopathy. iv. Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory. Progressive Familial Intrahepatic Cholestasis, continuation-approve if the patient has had a response to therapy and does not have any of the following (a, b, or c): a) Cirrhosis OR b) Portal hypertension

OR c) History of a hepatic decompensation event. Note: Examples of a hepatic decompensation event include variceal hemorrhage, ascites, and hepatic encephalopathy.
Alagille Syndrome, Initial therapy, approve if the patient meets all of the following (i, ii, iii, iv and v): i. Patient has moderate-to-severe pruritis, according to the prescriber AND ii. Diagnosis of Alagille syndrome was confirmed by genetic testing demonstrating a JAG1 or NOTCH2 deletion or mutation AND iii. Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory AND iv. Patient has tried at least two systemic medications for Alagille syndrome, unless contraindicated (examples include cholestyramine, naltrexone, rifampicin, sertraline, ursodiol) AND v. Patient does NOT have any of the following (a, b or c): a) Cirrhosis b) Portal hypertension c) History of a hepatic decompensation event Note: Examples of a hepatic decompensation event include variceal hemorrhage, ascites, and hepatic encephalopathy. Alagille Syndrome, Continuation Therapy, approve if the patient has had a response to therapy and does not have any of the following (a, b, or c): a) Cirrhosis OR b) Portal hypertension OR c) History of a hepatic decompensation event Note: Examples of a hepatic decompensation event include variceal hemorrhage, ascites, and hepatic encephalopathy.

PART B PREREQUISITE
N/A

CABOMETYX

MEDICATION(S)
CABOMETYX

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

CALQUENCE

MEDICATION(S)
CALQUENCE

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

CAMZYOS

MEDICATION(S)
CAMZYOS

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 a cardiologist

COVERAGE DURATION
Initial: 8 months, continuation: 1 year

OTHER CRITERIA
For Obstructive Hypertrophic Cardiomyopathy: 1. Initial Therapy. Approve if the pt meets ALL of the following criteria (a, b, c and d): a Pt meets both of the following (i and ii): i. Pt has at least one symptom associated with obstructive hypertrophic cardiomyopathy (examples include shortness of breath, chest pain, lightheadedness, fainting, fatigue, and reduced ability to perform physical exercise) AND ii.Pt has NYHA Class II or III symptoms of heart failure (Note: Class II signifies mild symptoms with moderate physical activity and some exercise limitations whereas Class III denotes noticeable symptoms with minimal physical activity and patients are only comfortable at rest), b. Pt with left ventricular hypertrophy meets one of the following (i or ii): i. Pt has maximal left ventricular wall thickness greater than or equal to 15 mm OR ii. Pt has familial hypertrophic cardiomyopathy with a maximal left ventricular wall thickness greater than or equal to 13 mm, c. Pt has a peak left ventricular outflow tract gradient greater than or equal to 50 mmHg (at rest or after provocation [Valsalva

maneuver or post exercise]), d. Pt has LVEF greater than or equal to 55 percent 2. Pt is Currently Receiving Camzyos. Approve if the pt meets ALL of the following criteria: a. Pt has been established on therapy for at least 8 months b. Pt meets both of the following (i and ii): i. Currently or prior to starting therapy, pt has or has experienced at least one symptom associated with obstructive hypertrophic cardiomyopathy (examples include shortness of breath, chest pain, lightheadedness, fainting, fatigue, and reduced ability to perform physical exercise) AND ii. Currently or prior to starting therapy, pt is in or was in NYHA Class II or III heart failure (Note: Class II signifies mild symptoms with moderate physical activity and some exercise limitations whereas Class III denotes noticeable symptoms with minimal physical activity and patients are only comfortable at rest), c.Pt has a current LVEF greater than or equal to 50 percent, d. Pt meets at least one of the following (i or ii): i. Pt experienced a beneficial clinical response when assessed by at least one objective measure (Note: Examples include improved peak oxygen consumption/mixed venous oxygen tension, decreases in left ventricular outflow tract gradient, reductions in N-terminal pro-B-type natriuretic peptide levels, decreased high-sensitivity cardiac troponin I levels, reduced ventricular mass index, and/or a reduction in maximum left atrial volume index) OR ii. Pt experienced stabilization or improvement in at least one symptom related to obstructive hypertrophic cardiomyopathy (Note: Examples of symptoms include shortness of breath, chest pain, lightheadedness, fainting, fatigue, ability to perform physical exercise, and/or favorable changes in the Kansas City Cardiomyopathy Questionnaire-23 (KCCQ-23) Clinical Summary Score (CSS) or Hypertrophic Cardiomyopathy Symptom Questionnaire (HCMSQ).

PART B PREREQUISITE

N/A

CAPRELSA

MEDICATION(S)
CAPRELSA

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

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

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

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

CHOLBAM

MEDICATION(S)
CHOLBAM

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with Chenodal

REQUIRED MEDICAL INFORMATION
Diagnosis as confirmed FAB-MS or genetic testing, LFTs

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a hepatologist, metabolic specialist, or GI.

COVERAGE DURATION
Initial: 3 months, Continuation: 1 year

OTHER CRITERIA
Bile acid synthesis disorders due to single enzyme defects: 1.Initial: Diagnosis is based on abnormal urinary bile acid as confirmed by Fast Atom Bombardment ionization – Mass Spectrometry (FAB-MS) analysis or molecular genetic testing consistent with the diagnosis, 2. Continuation: Patient has responded to initial Cholbam treatment with an improvement in LFTs and does not have complete biliary obstruction. Bile acid synthesis disorders due to peroxisomal disorders (PD), including Zellweger Spectrum disorders 1.Initial: Diagnosis of PD with an abnormal urinary bile acid analysis by FAB-MS or molecular genetic testing consistent with the diagnosis AND has liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption (e.g. rickets). 2. Continuation: Patient has responded to initial therapy based on improvement of liver function (e.g. AST or ALT) AND does not have complete biliary obstruction.

PART B PREREQUISITE

N/A

CIALIS

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

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Erectile Dysfunction. Concomitant use of nitrates.

REQUIRED MEDICAL INFORMATION
The member must have a diagnosis of benign prostatic hyperplasia.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial duration 3 months. If BPH symptoms improve (AUA-SI score decrease), approve for 1 year.

OTHER CRITERIA
The daily dose is prescribed as 2.5 mg or 5 mg once daily. The member must have symptoms of at least moderate severity that are bothersome, as defined by the American Urological Association Symptom Index (AUA-SI) greater than or equal to 8. Must have tried and failed or be intolerant of or contraindicated to two other drugs, one each from any two of the following different therapeutic classes: Alpha-1 adrenergic blockers (terazosin, doxazosin, tamsulosin, alfuzosin, silodosin) tried for a minimum of one month at the maximum tolerated dose, 5-alpha reductase inhibitors (finasteride, dutasteride) tried for a minimum of four months at the maximum tolerated dose, combination alpha-1 adrenergic blocker/5-alpha reductase inhibitors (dutasteride/tamsulosin) tried for a minimum of four months at the maximum tolerated dose.

PART B PREREQUISITE

N/A

CIBINQO

MEDICATION(S)
CIBINQO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with a biologic, targeted synthetic disease-modifying antirheumatic drug (DMARD), Anti-Interleukin monoclonal antibody, Xolair, potent immunosuppressants (e.g. azathioprine, cyclosporine) or other Janus Kinase inhibitors.

REQUIRED MEDICAL INFORMATION
Diagnosis, medication trials

AGE RESTRICTION
12 years and older

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

COVERAGE DURATION
1 year

OTHER CRITERIA
Refractory, moderate-to-severe atopic dermatitis: Initial Therapy. Approve if patient meets both of the following (i and ii): i. Patient has atopic dermatitis involvement estimated to be greater than or equal to 10% of the body surface area (BSA) according to the prescribing physician AND ii. Patient meets both of the following (1 and 2): 1. History of failure, contraindication, or intolerance to one of the following therapeutic classes of topical therapies (document drug, date of trial, and/or contraindication to medication (a, b, or c) a. Medium to very-high potency topical corticosteroid for 2 weeks, b. Topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)] for 6 weeks c. Eucrisa (crisaborole) AND 2. One of the following (a or b): a. Phototherapy (UVB or PUVA) has failed to achieve and maintain remission of low or mild disease activity state OR b. Systemic treatment [e.g.,

oral corticosteroid, intramuscular corticosteroid, oral cyclosporine, oral azathioprine, oral methotrexate, or oral mycophenolate mofetil].

PART B PREREQUISITE

N/A

CIMZIA

MEDICATION(S)
CIMZIA 200 MG VIAL KIT, CIMZIA 2X200 MG/ML SYRINGE KIT, CIMZIA 2X200 MG/ML(X3)START KT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.

REQUIRED MEDICAL INFORMATION
For Rheumatoid Arthritis, the member must have a confirmed diagnosis of moderate to severe Rheumatoid Arthritis and the disease must be active. For Crohn's Disease, the member must have a confirmed diagnosis of moderate to severe Crohn's Disease. For Anklyosing Spondylitis, the member must have a confirmed diagnosis of Ankylosing Spondylitis as defined by presence of active disease for at least 4 weeks defined by any disease specific functional scoring tool (i.e. a BASDAI Index of at least 4, Health Assessment Questionnaire (HAQ), Modified Health Assessment Questionnaire (MHAQ), etc...) and an expert opinion based on clinical features, acute phase reactants and imaging modalities. For Psoriatic Arthritis, the member must have a confirmed diagnosis of Psoriatic Arthritis. For Plaque Psoriasis (PP), the member has a confirmed diagnosis of moderate to severe plaque psoriasis (defined as a minimum body surface area involvement of greater than or equal to 5% or by involvement of the hands, facial, or genital regions, by which despite involvement of a small BSA, the disease may interfere significantly with activities of daily life).

AGE RESTRICTION
Adults for CD and PP.

PRESCRIBER RESTRICTION
RA/AS-prescribed by or in consultation with a rheumatologist. CD-prescribed by or in consultation with a gastroenterologist or a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or dermatologist. PP-prescribed by or in consultation with a dermatologist. nr-axSpA-prescribed by or in consultation with a rheumatologist.

COVERAGE DURATION

For AS 12wk initial, w/pos response then 3 years. Other approved indications, 3 years.

OTHER CRITERIA

For RA, approve if the patient has tried two of the following: Enbrel, a preferred adalimumab product, Orencia, Rinvoq or Xeljanz/XR Note: If the patient does not meet this requirement, a trial of a non-preferred adalimumab product will also count. . For AS, approve if the patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Cosenytx, Rinvoq or Xeljanz/XR (Note: If the patient does not meet this requirement, a trial of a non-preferred adalimumab product will also count). For PsA, approve if the patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Cosentyx, Stelara, Otezla, Orencia, Rinvoq, Skyrizi or Xeljanz/XR (Note: If the patient does not meet this requirement, a trial of a non-preferred adalimumab product will also count). For CD, approve if patient has previously tried a preferred adalimumab product (Note: If the patient does not meet this requirement, a trial of a non-preferred adalimumab product will also count). For PP, approve if the patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Skyrizi, Stelara SC, Otezla, or Cosentyx (Note: If the patient does not meet this requirement, a trial of a non-preferred adalimumab product will also count). Non-radiographic axial spondylitis (nr-axSpA)-approve if the patient has objective signs of inflammation, defined as at least one of the following: C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory OR sacroiliitis reported on MRI. nr-axSpA continuation-approve if the patient has had a response as determined by the prescriber. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074), Simlandi, adalimumab-adaz, adalimumab-fkjp and Yusimry.

PART B PREREQUISITE

N/A

CLOMIPHENE

MEDICATION(S)
CLOMIPHENE CITRATE 50 MG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Infertility

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

COLUMVI

MEDICATION(S)
COLUMVI

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

COMETRIQ

MEDICATION(S)
COMETRIQ

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

COPAXONE

MEDICATION(S)
COPAXONE

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
Indefinite

OTHER CRITERIA
For Copaxone (brand name) coverage, 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 the preferred product, glatiramer (generic), for the given diagnosis, (B) The member has a documented contraindication to the glatiramer (generic), (C) The member had an adverse reaction or would be reasonably expected to have an adverse reaction to glatiramer (generic), OR (D) The member had an adverse reaction or would be reasonably expected to have an adverse reaction to glatiramer (generic) for the requested indication.

PART B PREREQUISITE
N/A

COPIKTRA

MEDICATION(S)
COPIKTRA

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

COSENTYX

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

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)

REQUIRED MEDICAL INFORMATION
For Plaque Psoriasis, the member must have a confirmed diagnosis of moderate to severe Plaque Psoriasis, and defined as a minimum body surface area involvement of greater than or equal to 5%, or by involvement of the hands, feet, facial, or genital regions, by which, despite involvement of a smaller BSA, the disease may interfere significantly with activities of daily life. For Psoriatic Arthritis, the member must have a confirmed diagnosis of active Psoriatic Arthritis. For Anklyosing Spondylitis, the member must have a confirmed diagnosis of Ankylosing Spondylitis as defined by presence of active disease for at least 4 weeks defined by any disease specific functional scoring tool (i.e. a BASDAI Index of at least 4, Health Assessment Questionnaire (HAQ), Modified Health Assessment Questionnaire (MHAQ), etc.) and an expert opinion based on clinical features, acute phase reactants and imaging modalities. For Hidradenitis Suppurativa, the member must have a confirmed diagnosis of moderate to severe Hidradenitis Suppurativa, defined as Hurley Stage II or III.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PP, HS-prescribed by or in consultation with a dermatologist. AS/spondylo/enthesitis-prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist.

COVERAGE DURATION

For AS/spondylo/HS 12wk initial, w/pos response then 3 years. Other approved indications, 3 years.

OTHER CRITERIA

For Plaque Psoriasis, approve if the patient meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. For axial forms of Psoriatic Arthritis, Cosentyx will be approved. For non axial forms of Ankylosing Spondylitis, the member must first try and fail any two of the following conventional therapies over a three month period: NSAIDs, intraarticular steroids, methotrexate, other DMARD agents. For non-radiographic axial spondyloarthritis, approve if the patient has objective signs of inflammation, defined as C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory or sacroiliitis reported on magnetic resonance imaging. For enthesitis-related arthritis approve. For HS, the pt must have tried and failed or had an inadequate response to one other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin).

PART B PREREQUISITE

N/A

COTELLIC

MEDICATION(S)
COTELLIC

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

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

DAURISMO

MEDICATION(S)
DAURISMO

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

DAYBUE

MEDICATION(S)
DAYBUE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, MECP2 gene mutation

AGE RESTRICTION
2 years of age and older

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a neurologist

COVERAGE DURATION
1 year

OTHER CRITERIA
Rett Syndrome – approve if patient meets A and B: A)Patient has a pathogenic mutation in the MECP2 gene AND B)Patient has classical/typical Rett syndrome, according to the Rett Syndrome Diagnostic Criteria

PART B PREREQUISITE
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

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 x 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

DICHLORPHENAMIDE

MEDICATION(S)
DICHLORPHENAMIDE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, prior medication trials, potassium levels

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial: 2 months, Continuation: 3 years

OTHER CRITERIA
Hypokalemic periodic paralysis (HypoPP) and related variants initial therapy: Members must meet all of the following (1, 2, 3, and 4): 1. HypoPP has been confirmed by one of the following (a, b or c): a. Serum potassium concentration of less than 3.5 mEq/L during a paralytic attack OR b. Family history of the condition OR c. Genetically confirmed skeletal muscle calcium or sodium channel mutation, 2. Member had improvements in paralysis attack symptoms with potassium intake, 3. Member has tried and failed oral acetazolamide therapy, 4. The prescribing physician has excluded other reasons for acquired hypokalemia (e.g. renal, adrenal, thyroid dysfunction, renal tubular acidosis, diuretic and laxative abuse). Hyperkalemia periodic paralysis (HyperPP) and related variants initial therapy: Members must meet all of the following (1, 2, and 3): 1. HyperPP has been confirmed by one of the following (a, b, c or d) a. An increase from baseline in serum potassium concentration of greater than or equal to 1.5 mEq/L during a paralytic attack OR b. Serum potassium concentration during a paralytic

attack greater than 5.0 mEq/L OR c. A family history of the condition OR d. Genetically confirmed skeletal muscle sodium channel mutation 2. Prescribing physician has excluded other reasons for acquired hyperkalemia (e.g. drug abuse, renal and adrenal dysfunction) 3. Member has tried and failed oral acetazolamide therapy. HypoPP, HyperPP and related variants continuation of therapy: Patient has responded to dichlorphenamide (e.g. decrease in the frequency or severity of paralytic attacks) as determined by the prescribing physician.

PART B PREREQUISITE

N/A

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

DIFICID

MEDICATION(S)
DIFICID

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
Ten days.

OTHER CRITERIA
Must first try and fail or have recurrence of disease after two courses of vancomycin in the past 90 days. If members are allergic to vancomycin, Dificid will be approved. If members are continuing therapy started during a hospitalization, Dificid will be approved.

PART B PREREQUISITE
N/A

DOPTELET

MEDICATION(S)
DOPTELET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, platelet count

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Thrombo w/chronic liver disease-7 days. Chronic ITP-Initial - 3months, Cont - 3 years

OTHER CRITERIA
Thrombocytopenia with chronic liver disease-Approve if the patient has a current platelet count less than 50 x 10^9/L AND the patient is scheduled to undergo a procedure within 8 to 14 days after starting therapy. Chronic ITP-approve if the patient has a platelet count less than 30,000 microliters or less than 50,000 microliters and is at an increase risk of bleeding AND has tried one other therapy or has undergone splenectomy. Continuation: Approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications.

PART B PREREQUISITE
N/A

DOXEPIN TOPICAL

MEDICATION(S)
DOXEPIN 5% CREAM, PRUDOXIN

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

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, KOMBIGLYZE XR, ONGLYZA, SAXAGLIPTIN HCL, SAXAGLIPTIN-METFORMIN ER

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 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

DPP-4/SGLT2

MEDICATION(S)
QTERN, 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

DROXIDOPA

MEDICATION(S)
DROXIDOPA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
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) – initial - approve if the patient meets ALL of the following criteria: 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.

PART B PREREQUISITE
N/A

DUPIXENT

MEDICATION(S)
DUPIXENT PEN, DUPIXENT SYRINGE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with Xolair or another anti-interleukin monoclonal antibody

REQUIRED MEDICAL INFORMATION
Diagnosis, prescriber specialty, other medications tried and length of trials.

AGE RESTRICTION
For atopic dermatitis (AD), 6 months of age or older. For asthma, 6 years of age or older. For chronic rhinosinusitis with nasal polyposis (CRSwNP) - 18 years of age or older. Eosinophilic esophagitis-1 year of age or older. Prurigo nodularis - 18 years of age or older.

PRESCRIBER RESTRICTION
For Atopic Dermatitis or prurigo nodularis: The medication must be prescribed by or in consultation with an allergist, immunologist, or dermatologist. For Asthma, the medication is prescribed by or in consultation with an allergist, pulmonologist, or immunologist. For CRSwNP, the medication is prescribed by or in consultation with an allergist, immunologist, or otolaryngologist. Eosinophilic esophagitis (EE)-prescribed by or in consultation with an allergist or gastroenterologist.

COVERAGE DURATION
AD-1 year. Asthma-initial 6 mo, cont 3 yrs. CRSwNP, EE, prur nod: initial 6 months, cont 1 year.

OTHER CRITERIA
For AD:pt meets A, B, C: A.Has chronic AD, B.Involvement est to be 10% or more of BSA according to prescriber, C.Pt meets 1 and 2: 1. H/o failure, CI, or intolerance to 1 (a, b, c) a.Med to very-high potency topical corticosteroid (CS) for 2 wks, b.Topical calcineurin inhibitor [e.g., pimecrolimus, tacrolimus] for 6 wks or c.Eucrisa (crisaborole) AND 2.One of the following: a.Phototherapy (UVB or PUVA) has failed to achieve and maintain remission of low/mild dz activity OR b.Systemic tx [e.g., oral

CS, intramuscular CS, oral cyclosporine, oral azathioprine, oral MTX, or oral mycophenolate mofetil]. For asthma:meets following (A, B, C, D): A.Mod to severe asthma, eosinophilic phenotype or oral CS-dependent AND B.For eosinophilic phenotype, pt has peripheral blood eos count of 150 cells or more per microliter w/in previous 6 wks (prior to tx w/ Dupixent) AND C.For Initial therapy (a and b): a.Pt has received at least 3 mo of combo tx w/oral CS or inhaled CS (ICS) AND 1 of the following: inhaled LABA, inhaled LAMA, LTRA, or theophylline AND b.Asthma continues to be uncontrolled as defined by 1 of the following:2 or more asthma exacer requiring tx w/systemic CS in the past yr, 1 or more asthma exacer requiring hospitalization or tx in an ER in the past yr, FEV1 less than 80% predicted, FEV1/FVC less than 0.80, or asthma worsens upon tapering of oral CS AND D.For Cont:Responded to Dupixent as determined by the prescriber (ex., decr asthma exacer, decr asthma sx, decr hospitalizations/ED/urgent care/MD visits due to the asthma, decr req for oral CS), AND continues to receive oral or ICS. For CRSwNP initial:Currently receiving intranasal CS AND experiencing significant sx such as nasal obstruction, rhinorrhea, or decr/loss of smell according to the prescriber AND meets 1 of the following (i or ii): i.Received systemic CS w/in previous 2 yrs or has a CI to systemic CS or ii.Had prior surgery for nasal polyps. Cont-approve if continues to receive an intranasal CS AND responded to Dupixent as determined by the prescriber. EE initial-pt weighs 15kg or greater, diagnosis of EE confirmed by endoscopic biopsy showing 15 or more intraepithelial eosinophils per high-power field, doesn't have secondary cause of EE, and has received at least 8 wks of tx w/Rx-strength PPI. Cont-approve if received at least 6 mo of tx and has decr intraepithelial eosinophil count or decr dysphagia/pain upon swallowing or reduced freq/severity of food impaction. Prurigo nodularis Init:Pt has 20 or more nodular lesions and has experienced pruritus for at least 6 weeks AND Pt tried 1 high- or super-high-potency Rx topical CS. Cont-received at least 6 mo of tx w/ Dupixent and has experienced decr nodular lesion count, decr pruritis or decr nodular lesion size.

PART B PREREQUISITE

N/A

EGRIFTA

MEDICATION(S)
EGRIFTA SV

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
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

ELAHERE

MEDICATION(S)
ELAHERE

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

ELIGARD

MEDICATION(S)
ELIGARD, LEUPROLIDE DEPOT

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

ELREXFIO

MEDICATION(S)
ELREXFIO

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

ELZONRIS

MEDICATION(S)
ELZONRIS

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

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, previous therapies tried.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Chronic or episodic migraine: Init 3 months, Cont: 12 months. Episodic cluster (Emgality): 6 months.

OTHER CRITERIA
For chronic or episodic migraine initiation of therapy: Trial of 2 different drug classes prior to approval. Drug classes include: Beta blockers (ex. Metoprolol, Propranolol, Timolol), Antidepressants (ex. Amitriptyline, Nortriptyline, and Venlafaxine), Anticonvulsants (ex. Valproate and Topiramate), and Calcium Channel Blockers (ex. Verapamil). AND The member must have a diagnosis of migraine, as indicated by 4 or more attacks per month. For continuation of therapy: Prescriber confirms that the member demonstrates improvement after initial trial. For episodic cluster headache: approve if the patient has between one headache every other day and eight headaches per day.

PART B PREREQUISITE
N/A

EMPAVELI

MEDICATION(S)
EMPAVELI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with Soliris or Ultomiris

REQUIRED MEDICAL INFORMATION
Diagnosis, test results

AGE RESTRICTION
PNH–18 years and older

PRESCRIBER RESTRICTION
PNH–prescribed by or in consultation with a hematologist

COVERAGE DURATION
PNH–initial 4 months, continuation 1 year

OTHER CRITERIA
Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Paroxysmal Nocturnal Hemoglobinuria (PNH)-Initial therapy-Approve if diagnosis was confirmed by peripheral blood flow cytometry results showing the absence or deficiency of glycosylphosphatidylinositol (GPI)-anchored proteins on at least two cell lineages AND for a patient transitioning to Empaveli from Soliris (eculizumab intravenous infusion) or Ultomiris (ravulizumab intravenous infusion), the prescriber attests that these medications will be discontinued within 4 weeks after starting Empaveli. Continuation-approve if the patient is continuing to derive benefit (e.g., stabilization of hemoglobin levels, decreased transfusion requirements or transfusion independence, reductions in hemolysis)

PART B PREREQUISITE

N/A

ENBREL

MEDICATION(S)
ENBREL, ENBREL MINI, ENBREL SURECLICK

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

OFF LABEL USES
Graft versus host disease, Behcet's disease, and Uveitis.

EXCLUSION CRITERIA
Concurrent use with biologic therapy or targeted synthetic DMARD.

REQUIRED MEDICAL INFORMATION
For Rheumatoid Arthritis the member must have a confirmed diagnosis of moderate to severe Rheumatoid Arthritis and the disease must be active. For Anklyosing Spondylitis, the member must have a confirmed diagnosis of Ankylosing Spondylitis as defined by presence of active disease for at least 4 weeks defined by any disease specific functional scoring tool (i.e. a BASDAI Index of at least 4, Health Assessment Questionnaire (HAQ), Modified Health Assessment Questionnaire (MHAQ), etc...) and an expert opinion based on clinical features, acute phase reactants and imaging modalities. For Psoriatic Arthritis, the member must have a confirmed diagnosis of Psoriatic Arthritis. For Plaque Psoriasis, the member must have a confirmed diagnosis of chronic and moderate to severe Plaque Psoriasis, and defined as a minimum body surface area involvement of greater than or equal to 5%, or by involvement of the hands, feet, facial, or genital regions, by which, despite involvement of a smaller BSA, the disease may interfere significantly with activities of daily life.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RA/AS/JIA/JRA prescribed by or in consult w/ a rheumatologist. PsA, prescribed by or in consult w/ a rheumatologist or a dermatologist. PP, prescribed by or in consult w/ a dermatologist or rheumatologist. GVHD, prescribed by on in consult w/ an oncologist, hematologist, or a transplant center physician. Behcet's disease, prescribed by or in consult w/ a rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist. Uveitis, ophthalmologist or rheumatologist.

COVERAGE DURATION

For AS 12wk initial, w/pos response then 3 years. Other approved indications, 3 years.

OTHER CRITERIA

For RA, pt has tried one conventional synthetic DMARD for at least 3 months (note: pts who already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). For JIA or JRA, approve if the pt has aggressive dz, as determined by the prescriber, or the pt has tried one other systemic therapy for this condition (eg, MTX, sulfasalazine, leflunomide, NSAID, biologic) or the pt will be started on Enbrel concurrently with MTX, sulfasalazine, or leflunomide or the pt has an absolute CI to MTX (eg, pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias), sulfasalazine, or leflunomide and non axial forms of PsA, must first try and fail MTX for at least two months, OR if the member has an absolute CI to MTX, then Enbrel will be approved. For axial forms of PsA, Enbrel will be approved. For non axial forms of Ankylosing Spondylitis, the member must first try and fail any two of the following conventional therapies over a three month period: NSAIDs, intraarticular steroids, methotrexate, other DMARD agents. For Plaque Psoriasis, approve if the patient meets one of the following conditions: 1) patient has tried at least one traditional systemic agent for at least 3 months for plaque psoriasis, unless intolerant (eg, MTX, cyclosporine, Soriatane, oral methoxsalen plus PUVA, (note: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) the patient has a CI to one oral agent for psoriasis such as MTX. For GVHD, Tried at least one conventional systemic treatment for GVHD. Behcet's, tried at least one conventional therapy (eg, systemic corticosteroids, immunosuppressives, interferon alpha, etc) or a preferred adalimumab product or infliximab (Note: If the patient does not meet this requirement, a trial of a non-preferred adalimumab product will also count). Uveitis, tried 1 of the following periocular, intraocular, or systemic CS, immunosuppressives, a pref adalimumab product or an infliximab product (Note: If the patient does not meet this requirement, a trial of a non-preferred adalimumab product will also count). Clinical criteria incorporated into the Enbrel 25 mg quantity limit edit: approve additional quantity (to allow for 50 mg twice weekly dosing) if one of the following is met: Patient has plaque psoriasis, OR Patient has RA/JIA/PsA/AS and is started and stabilized on 50 mg twice weekly dosing, OR Patient has RA and the dose is being increased to 50 mg twice weekly and patient has taken MTX in combination with Enbrel 50 mg once weekly for at least 2 months, unless MTX is CI or intolerant, OR Patient has JIA/PsA/AS and the dose is being increased to 50 mg twice weekly after taking 50 mg once weekly for at least 2 months. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074), Simlandi, adalimumab-adaz, adalimumab-fkjp and Yusimry.

PART B PREREQUISITE

N/A

ENDARI

MEDICATION(S)
ENDARI, L-GLUTAMINE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Endari 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

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

ENTYVIO SC

MEDICATION(S)
ENTYVIO PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with a biologic DMARD (e.g. infliximab, Cimzia, Stelara, adalimumab), Janus kinase inhibitor or Tysabri

REQUIRED MEDICAL INFORMATION
Trial of preferred products, Reauth: Objective measure or symptom improvement documentation

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a gastroenterologist

COVERAGE DURATION
Initial: 6 months, Continuation: 1 year

OTHER CRITERIA
Moderately to severely active Ulcerative Colitis - Initial therapy: Approve if the patient meets ALL of the following (i and ii): i. According to the prescriber, the patient is currently receiving Entyvio intravenous or will receive induction dosing with Entyvio intravenous within 2 months prior to initiating therapy with Entyvio subcutaneous AND ii. Patient has tried TWO of the following preferred products: a preferred adalimumab product, Stelara SC, Rinvoq, Simponi SC, Skyrizi or Xeljanz/XR tablets. Note: If the patient does not meet this requirement, a trial of a non-preferred adalimumab product will also count. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074), Simlandi, adalimumab-adaz, adalimumab-fkjp and Yusimry. Continuation therapy: Approve for 1 year if the patient meets BOTH of the following (i and ii): i. Patient has been established on Entyvio subcutaneous or intravenous for at least 5 months AND ii. Patient meets at least 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 the requested drug). Examples of assessment for inflammatory response include fecal markers (such as fecal calprotectin), serum markers (such as C-reactive protein), endoscopic assessment, and/or reduced doses of corticosteroids. OR 2. Compared with baseline (prior to initiating the requested drug), the patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or decreased rectal bleeding. 2. Moderately to severely active Crohn's disease a. Initial therapy: Approve if the patient meets ALL of the following (i and ii): i. According to the prescriber, the patient is currently receiving Entyvio intravenous or will receive induction dosing with Entyvio intravenous within 2 months prior to initiating therapy with Entyvio subcutaneous AND ii.Patient has tried TWO of the following preferred products: a preferred adalimumab product, Skyrizi SQ, Stelara SQ or Rinvoq b.Continuation therapy: Approve for 1 year if the patient meets BOTH of the following (i and ii): i. Patient has been established on Entyvio SQ or IV for at least 5 months AND ii.Patient meets at least one of the following (a or b): a. When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug). Note: Examples of objective measures include fecal markers (e.g., fecal lactoferrin, fecal calprotectin), serum markers (e.g., C-reactive protein), imaging studies (magnetic resonance enterography [MRE], computed tomography enterography [CTE]), endoscopic assessment, and/or reduced dose of corticosteroids OR b. Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or blood in stool.

PART B PREREQUISITE

N/A

EPCLUSA

MEDICATION(S)
EPCLUSA 150-37.5 MG PELLET PKT, EPCLUSA 200 MG-50 MG TABLET, EPCLUSA 200-50 MG PELLET PACK, 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

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

EPKINLY

MEDICATION(S)
EPKINLY

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

ERIVEDGE

MEDICATION(S)
ERIVEDGE

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

ERLEADA

MEDICATION(S)
ERLEADA

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

EVEKEO

MEDICATION(S)
AMPHETAMINE SULFATE, EVEKEO ODT

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

EVEROLIMUS

MEDICATION(S)
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

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

EVRYSDI

MEDICATION(S)
EVRYSDI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Pregnant patients, female patients not utilizing effective contraception during treatment and for 1 month after the last dose of Evrysdi

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a physician who specializes in the management of patients with spinal muscular atrophy and/or neuromuscular disorders (initial and continuation)

COVERAGE DURATION
Initial and continuation: 4 months

OTHER CRITERIA
Spinal Muscular Atrophy, Initial Treatment - Approve if the patient meets all of the following (a, b and c):a.Patient has baseline motor ability assessment that suggests spinal muscular atrophy (based on age, motor ability, and development) is provided from one of the following exams: (i, ii, iii, iv, v, vi, or vii) i. Bayley Scales of Infant and Toddler Development, Third Edition (BSID-III) [Item 22], ii. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), iii. Hammersmith Functional Motor Scale Expanded (HFMSE), iv. Hammersmith Infant Neurological Exam Part 2 (HINE-2), v. Motor Function Measure-32 Items (MFM-32), vi. Revised Upper Limb Module (RULM) test, OR vii. World Health Organization motor milestone scale AND b. Has had a genetic test confirming the diagnosis of spinal muscular atrophy with bi-allelic mutations in the survival motor neuron 1 (SMN1)

gene reported as at least one of the following: homozygous deletion, homozygous mutation, or compound heterozygous mutation [documentation required] AND c. The patient meets all of the following criteria (i, ii and iii): i. Has two to four survival motor neuron 2 (SMN2) gene copies [documentation required], ii. The patient has objective signs consistent with spinal muscular atrophy Types 1, 2, or 3 [documentation required], and iii. For patients who have received prior treatment with a survival motor neuron 2 (SMN2)-directed antisense oligonucleotide, the prescriber attests that further therapy with this product will be discontinued. Patients currently receiving Evrysdi approve if the patient meets all of the following (a, b and c): a. Patient meets all of the requirements for initial therapy, b. Patient has responded to Evrysdi, c. Patient continues to have benefit from ongoing Evrysdi therapy by the most recent (within the past 4 months) physician monitoring/assessment tool OR patient must have had a positive clinical response from pretreatment baseline (i.e., within the past 4 months) from one of the following exams: (i, ii, iii, iv, v, vi or vii): i. Bayley Scales of Infant and Toddler Development, Third Edition (BSID-III) [Item 22], ii. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), iii. Hammersmith Functional Motor Scale Expanded (HFMSE), iv. Hammersmith Infant Neurological Exam Part 2 (HINE-2), v. Motor Function Measure-32 Items (MFM-32), vi. Revised Upper Limb Module (RULM) test or vii. World Health Organization motor milestone scale.

PART B PREREQUISITE

N/A

EXKIVITY

MEDICATION(S)
EXKIVITY

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

FASENRA

MEDICATION(S)
FASENRA, FASENRA PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Member will not be using in combination with Xolair or another Anti-Interleukin monoclonal antibody

REQUIRED MEDICAL INFORMATION
Diagnosis. Previous therapy. Peripheral blood eosinophil count.

AGE RESTRICTION
6 years or older

PRESCRIBER RESTRICTION
The drug is being prescribed by or in consultation with an allergist, immunologist or pulmonologist.

COVERAGE DURATION
Initial 6 months. Continuation, indefinitely.

OTHER CRITERIA
The patient has a diagnosis of severe asthma, with an eosinophilic phenotype. The member must have peripheral blood eosinophil count greater than or equal to 150 cells per microliter, within the previous 6 weeks (prior to treatment with any anti-interleukin [IL-5] therapy). The member must have received at least 3 months of combination therapy with an inhaled corticosteroid AND one of the following: inhaled long acting beta agonist, inhaled long acting muscarinic antagonist, leukotriene receptor antagonist, theophylline. The patients asthma continues to be uncontrolled as defined by one of the following: Experienced one or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year, Experienced one or more asthma exacerbations requiring hospitalization or treatment in an emergency department in the previous year, Patient has a FEV1 less than 80 percent predicted, Patient has FEV1/FVC less than 0.80, Patients asthma worsens upon tapering of oral corticosteroid therapy. NOTE: An exception to the requirement for a trial of one additional asthma

controller/maintenance medication can be made if the patient has already received anti-IL-5 therapy (e.g., Cinqair, Fasenra, Nucala) used concomitantly with an ICS for at least 3 months. For continuation of therapy, if the member meets the following criteria, then therapy will be continued indefinitely: The patient has responded to Fasenra 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), AND The patient continues to receive therapy with an inhaled corticosteroid.

PART B PREREQUISITE

N/A

FILGRASTIM

MEDICATION(S)
NEUPOGEN, NIVESTYM, RELEUKO, 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

PART B PREREQUISITE
N/A

FILSPARI

MEDICATION(S)
FILSPARI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with any renin-angiotensin-aldosterone antagonists (e.g., angiotensin converting enzyme inhibitors [ACEIs] or angiotensin receptor blockers [ARBs]), endothelin receptor antagonists, or aliskiren

REQUIRED MEDICAL INFORMATION
Diagnosis, lab values (proteinuria and/or urine protein-to-creatinine ratio, eGFR)

AGE RESTRICTION
18 years of age or older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a nephrologist

COVERAGE DURATION
Initial – 9 months. Continuation – 1 year

OTHER CRITERIA
Primary Immunoglobulin A Nephropathy: 1. Initial Criteria – approve if patient meets all the following criteria: i. Diagnosis has been confirmed by biopsy 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 or equal to 1.0 g/day, OR (2) Urine protein-to-creatinine ratio greater than or equal to 1.5 g/g, AND b) Patient has received the maximum or maximally tolerated dose of ONE of the following for at least 30 days prior to starting Filspari [(1) or (2)]: (1) Angiotensin converting enzyme inhibitor (e.g. lisinopril, enalapril), OR (2) Angiotensin receptor blocker (e.g. losartan, valsartan), AND iii. Patient has an estimated glomerular filtration rate greater than or equal to 30 mL/min/1.73 m2 2. Continuation Criteria – approve if patient meets all the following criteria: i. Diagnosis has been

confirmed by biopsy ii.Patient has had a response to Filspari according to the prescriber (Note: Examples of a response are a reduction in urine protein-to-creatinine ratio from baseline, reduction in proteinuria from baseline) iii. Patient has an estimated glomerular filtration rate greater than or equal to 30 mL/min/1.73 m2

PART B PREREQUISITE

N/A

FILSUVEX

MEDICATION(S)
FILSUVEZ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Combination with Vyjuvek.

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
6 months of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a dermatologist or wound care specialist

COVERAGE DURATION
3 months

OTHER CRITERIA
Dystrophic epidermolysis bullosa (DEB)/Junctional epidermolysis bullosa (EB): 1.Initial therapy: Patient meets ALL of the following (a, b and c): a.Patient has at least one clinical feature of epidermolysis bullosa, b.Patient has one or more open wound(s) that will be treated (i.e., target wound[s]), c.Target wound(s) meet the following, according to the prescriber (i, ii, iii and iv): i.Target wound(s) is clean in appearance and does not appear to be infected, ii.Target wound(s) is 10 cm2 to 50 cm2, iii.Target wound(s) is greater than or equal to 21 days and less than 9 months old, iv.Squamous cell and/or basal cell carcinoma has been ruled out for the target wound(s). 2.Continuation of therapy: Patient meets ALL of the following (a, b and c): a.The target wound(s) remains open, b.The target wound(s) has decreased in size from baseline, c.For patients new to the plan, they will also need to have met initial criteria at time of treatment with the requested medication.

PART B PREREQUISITE

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

FIRAZYR

MEDICATION(S)
ICATIBANT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Icatibant will not be used in combination with other approved treatments for acute hereditary angioedema (HAE) attacks.

REQUIRED MEDICAL INFORMATION
Diagnosis of HAE and icatibant is being used for the treatment of acute HAE attacks.

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
Prescribed by an immunologist, allergist, otolaryngologist or rheumatologist

COVERAGE DURATION
1 year

OTHER CRITERIA
Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Treatment of Acute Attacks, Initial Therapy-the patient has HAE type I or type II as confirmed by the following diagnostic criteria (i and ii): i. the patient has low levels of functional C1-INH protein (less than 50% of normal) at baseline, as defined by the laboratory reference values AND ii. the patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values. Patients who have treated previous acute HAE attacks with icatibant-the patient has treated previous acute HAE type I or type II attacks with icatibant AND according to the prescribing physician, the patient 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

FIRDAPSE

MEDICATION(S)
FIRDAPSE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
History of seizures (initial therapy).

REQUIRED MEDICAL INFORMATION
Diagnosis, seizure history, lab and test results.

AGE RESTRICTION
6 years and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist or a neuromuscular specialist.

COVERAGE DURATION
For initiation of therapy: 3 months For continuation of therapy: 1 year

OTHER CRITERIA
Initial therapy: Diagnosis confirmed by at least one electrodiagnostic study (e.g., repetitive stimulation) OR anti-P/Q-type voltage-gated calcium channels (VGCC) antibody testing according to the prescribing physician. Continuation therapy: Patient continues to derive benefit (e.g., improved muscle strength, improvement in mobility) from Firdapse, according to the prescribing physician.

PART B PREREQUISITE
N/A

FIRMAGON

MEDICATION(S)
FIRMAGON

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

FOTIVDA

MEDICATION(S)
FOTIVDA

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

FRUZAQLA

MEDICATION(S)
FRUZAQLA

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

FULVESTRANT

MEDICATION(S)
FULVESTRANT

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

FYARRO

MEDICATION(S)
FYARRO

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

GALAFOLD

MEDICATION(S)
GALAFOLD

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use of enzyme replacement therapy (ERT). Severe renal impairment (eGFR less than 30 ml/min/1.73m2) or ESRD requiring dialysis.

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
16 years and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a geneticist, nephrologist, or a physician who specializes in the treatment of Fabry disease.

COVERAGE DURATION
3 years

OTHER CRITERIA
Approve if the patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data.

PART B PREREQUISITE
N/A

GATTEX

MEDICATION(S)
GATTEX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Members with biliary and/or pancreatic disease. Members with active gastrointestinal malignancy.

REQUIRED MEDICAL INFORMATION
Parenteral nutrition (PN) and/or intravenous (IV) fluid dependency.

AGE RESTRICTION
Member is 1 year of age or older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a gastroenterologist

COVERAGE DURATION
6 months initial, 12 months continuation.

OTHER CRITERIA
For initial authorization, chart notes supporting the use of parenteral nutrition/IV fluids for 12 months and current volume of parenteral support in liters per week. For continuation, the provider must provide medical records documenting tolerance and effectiveness of therapy. Effectiveness of therapy is defined as a decrease in parenteral nutrition/IV volume from baseline weekly requirement at start of Gattex treatment.

PART B PREREQUISITE
N/A

GAVRETO

MEDICATION(S)
GAVRETO

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

GAZYVA

MEDICATION(S)
GAZYVA

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

GILOTRIF

MEDICATION(S)
GILOTRIF

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

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. Bydureon, Byetta, Ozempic, Rybelsus, Trulicity, Victoza)

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Lifetime

OTHER CRITERIA
For Type 2 diabetes mellitus (T2DM), member must have a diagnosis of type 2 diabetes mellitus.

PART B PREREQUISITE
N/A

GLEOSTINE

MEDICATION(S)
GLEOSTINE

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

GLP-1 AGONIST

MEDICATION(S)
BYDUREON BCISE, BYETTA, 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, VICTOZA 2-PAK, VICTOZA 3-PAK

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. Bydureon, Byetta, Ozempic, Rybelsus, Trulicity, Victoza, Mounjaro)

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Lifetime

OTHER CRITERIA
For Type 2 diabetes mellitus (T2DM), member must have a diagnosis of type 2 diabetes mellitus.

PART B PREREQUISITE
N/A

GRANIX

MEDICATION(S)
GRANIX

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

GROWTH HORMONE

MEDICATION(S)
GENOTROPIN, HUMATROPE 12 MG CARTRIDGE, HUMATROPE 24 MG CARTRIDGE, HUMATROPE 6 MG CARTRIDGE, NORDITROPIN FLEXPRO, NUTROPIN AQ NUSPIN, OMNITROPE, SAIZEN, SAIZEN-SAIZENPREP, SEROSTIM, ZOMACTON

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

OFF LABEL USES
Short-bowel syndrome

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
HIV initial-1.wasting/cachexia due to malabsorption, opportunistic infx, depression and other causes which have been addressed prior to starting tx, 2.on antiretroviral or HAART or more than 30 days and will cont throughout Serostim tx, 3.not being used for alternations in body fat distribution (abdom girth, liopdystrophy, buffalo hump, excess abdm fat), AND 4. unintentional wt loss greater than 10 percent from baseline, wt less than 90 percent of lower limit of IBW, or BMI less than or equal to 20 kg/m2.HIV Cont tx -meets intial tx criteria.GHD in children/adoles initial must meet ONE of the following-1.had hypophysectomy,2.has congenital hypopit AND GH response to one preferred GH test of less than 10 ng/mL (preferred tests levodopa, insulin-induced hypoglycemia, arginine, clonidine, glucagon),3.panhypopit AND had GH response to one preferred GH test of less than 10 ng/mL, has 3 or more pit hormone def(ACTH, TSH, LH/FSH, or prolactin), or pit stalk agenesis, empty sella, sellar or supra-sellar mass lesion, or ectopic posterior bright spot on MRI or CT, 4. brain rad, had GH response to one preferred GH test of less than 10 ng/mL, AND meets one of these a. pretxgrowth rate (GR) is less than 7 cm/yr in children younger than 3 or b. or if 18 y/o or younger with growth velocity that is less than 10th percentile for age/gender on last 6 months of data, OR 5. had GH response to one preferred GH test of less than 10 ng/mL, ht less than the 10th percentile for age/gender, AND meets one of these a. pretx growth rate (GR) is less than 7 cm/yr in children younger than 3 or b. GR is less than 4 cm/yr in 3 y/o or older, c. or if 18 y/o or younger with growth velocity that is less than 10th percentile for age/gender on last 6 months of data. Additionally, pts older than 12 must also have open epiphyeses and pts older than 18 must also not attained midparental ht.

AGE RESTRICTION

ISS 5 y/o or older, SGA 2 y/o or older, SBS and HIV wasting/cachexia 18 y/o or older

PRESCRIBER RESTRICTION

GHD (Initial tx children or adolescents w/o hypophysectomy), GHD adults or transitional adolescents, Noonan (initial), Prader Willi (initial for child/adult and cont tx in adults), SHOX (initial), SGA (initial) - prescribed by or in consultation with an endocrinologist. CKD (initial) endocrinologist or nephrologist.

COVERAGE DURATION

ISS - 6 mos intial, 12 months cont tx, SBS 4 weeks, HIV 24 weeks, others 12 mos

OTHER CRITERIA

GHD initial in adults and adoles 1. endocrin must certify not being prescribed for anti-aging or to enhance athletic performance, 2. has either childhood onset or adult onset resulting from GHD alone, multiple hormone deficiency from pituitary dx, hypothalmic dz, pituitary surgery, cranial radiation tx, tumor treatment, TBI or subarachnoid hemorrhage, AND 3. meets one of the following - A. childhood onset has known mutations, embryonic lesions, congential defects or irreversible structural hypothalmic pituitary lesion/damage, B. 3 or more pituitary hormone def (ACTH, TSH, LH/FSH, or prolactin, IGF1), AND other causes of low serum IGF-1 have been excluded, C. Neg response to ONE preferred GH stim test (insulin peak response less than or equal to 5 mcg/L, Glucagon peak less than or equal to 3 mcg/L, if insulin and glucagon contraindicated then Arginine alone test with peak of less than or equal to 0.4 mcg/L, GHRH plus arginine peak of less than or equal to 11 mcg/L if BMI is less than 25, peak less than 8 mcg/L if BMI is more than 25 but less than 30, or peak less than 4 mcg/L if BMI if more than 30) AND if a transitional adoles must be off tx for at least one month before retesting. Cont tx - endocrin must certify not being prescribed for anti-aging or to enhance athletic performance. ISS initial - baseline ht less than the 1.2 percentile or a standard deviation score (SDS) less than -2.25 for age and gender, open epiphyses, does not have CDGP and height velocity is either growth rate (GR) is a. less than 4 cm/yr for pts older than 5 or b. growth velocity is less than 10th percentile for age/gender. Cont tx - prescriber confirms response to therapy. Additionally, pts older than 12 must also have open epiphyeses and pts older than 18 must also have not attained midparental height. CKD initial - CKD defined by abnormal CrCl. Noonan initial - baseline height less than 5th percentile. PW cont tx in adults or adolesents who don't meet child requir - physician certifies not being used for anti-aging or to enhance athletic performance. SHOX initial - SHOX def by chromo analysis, open epiphyses, height less than 3rd percentile for age/gender. SGA initial -baseline ht less than 5th percentile for age/gender and born SGA (birth weight/length that is more than 2 SD below mean for gestational age/gender and didn't have sufficient catch up growth by 2-4 y/o). Cont tx - prescriber confirms response to therapy. Additionally, pts older than 12 must also have open epiphyeses and pts older than 18 must also have not attained midparental height. Cont Tx for CKD, Noonan, PW in child/adoles, SHOX, and TS in members- prescriber confirms response to therapy. SBS initial pt receiving specialized nutritional

support. Cont tx - 2nd course if pt responded to tx with a decrease in the requirement for specialized nutritional support.

PART B PREREQUISITE

N/A

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).

REQUIRED MEDICAL INFORMATION
Diagnosis, lab results (C1-INH protein, C4 levels), reauth: 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) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] – Prophylaxis Initial Therapy: Approve if the patient meets all of the below:
1. The patient has HAE type I or type II as confirmed by the following diagnostic criteria (a and b): a. The patient has low levels of functional C1-INH protein at baseline, as defined by the laboratory reference values [documentation required] AND b. The patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values [documentation required].
Continuation of therapy: Patient meets both of the following (1 and 2):
1. Medical chart documentation of the number and severity of HAE attacks occurring in the previous 6 months
2. Patient has experienced a reduction in the number of HAE attacks from baseline

PART B PREREQUISITE

N/A

HARVONI

MEDICATION(S)
HARVONI 33.75-150 MG PELLET PK, HARVONI 45-200 MG PELLET 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

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
Non-24: Patient is totally blind with no perception of light

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
Initial - dx of Non-24 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. Cont - Approve if pt has received at least 6 months therapy with Hetlioz under the guidance of a physician who specializes in the treatment of sleep disorders AND has achieved adequate results with Hetlioz therapy according to the prescribing physician (e.g., entrainment, clinically meaningful or significant increases in nighttime sleep, clinically meaningful or significant decreases in daytime sleep). For SMS - approve.

PART B PREREQUISITE

N/A

HIGH RISK MEDICATION - FIRST GENERATION ANTIHISTAMINES

MEDICATION(S)
PROMETHAZINE 12.5 MG TABLET, PROMETHAZINE 25 MG TABLET, PROMETHAZINE 50 MG TABLET, 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

HUMIRA

MEDICATION(S)

ADALIMUMAB-ADAZ(CF), ADALIMUMAB-ADAZ(CF) PEN, ADALIMUMAB-FKJP(CF), ADALIMUMAB-FKJP(CF) PEN, HUMIRA 40 MG/0.8 ML SYRINGE (ONLY NDCS STARTING WITH 00074), HUMIRA PEN 40 MG/0.8 ML (ONLY NDCS STARTING WITH 00074), HUMIRA PEN CROHN-UC-HS 40 MG (ONLY NDCS STARTING WITH 00074), HUMIRA PEN PS-UV-ADOL HS 40 MG (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) 10 MG/0.1 ML SYRINGE (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) 20 MG/0.2 ML SYRINGE (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) 40 MG/0.4 ML SYR (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) PEDI CROHN 80 MG/0.8 ML (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) PEDI CROHN 80-40 MG (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) PEN 40 MG/0.4 ML (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) PEN 80 MG/0.8 ML (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) PEN CRHN-UC-HS 80 MG (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) PEN PEDI UC 80 MG (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) PEN PS-UV-AHS 80-40 (ONLY NDCS STARTING WITH 00074), SIMLANDI(CF) AUTOINJECTOR, YUSIMRY(CF) PEN

PA INDICATION INDICATOR

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

OFF LABEL USES

Sarcoidosis

EXCLUSION CRITERIA

Concurrent use with another biologic DMARD or targeted synthetic DMARD.

REQUIRED MEDICAL INFORMATION

For Rheumatoid Arthritis the member must have a confirmed diagnosis of moderate to severe Rheumatoid Arthritis and the disease must be active. For Juvenile Idiopathic Arthritis, the member must have a confirmed diagnosis of Juvenile Idiopathic Arthritis and the disease must be active. For Anklyosing Spondylitis, the member must have a confirmed diagnosis of Ankylosing Spondylitis as defined by presence of active disease for at least 4 weeks defined by any disease specific functional scoring tool (i.e. a BASDAI Index of at least 4, Health Assessment Questionnaire (HAQ), Modified Health Assessment Questionnaire (MHAQ), etc...) and an expert opinion based on clinical features, acute phase reactants and imaging modalities. For Psoriatic Arthritis, the member must have a confirmed diagnosis of Psoriatic Arthritis. For Plaque Psoriasis, the member must have a confirmed diagnosis of chronic and moderate to severe Plaque Psoriasis, and defined as a minimum body

surface area involvement of greater than or equal to 5%, or by involvement of the hands, feet, facial, or genital regions, by which, despite involvement of a smaller BSA, the disease may interfere significantly with activities of daily life. For Pediatric and Adult Crohn's Disease, the member must have a confirmed diagnosis of moderate to severe Crohn's Disease. For Ulcerative Colitis, the member must have a confirmed diagnosis of moderate to severe ulcerative colitis. For Hidradenitis Suppurativa, the member must have a confirmed diagnosis of moderate to severe Hidradenitis Suppurativa, defined as Hurley Stage II or III.

AGE RESTRICTION

CD-6 years or older UC-5 years or older

PRESCRIBER RESTRICTION

RA/JIA/JRA/AS-prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or dermatologist. PP-prescribed by or in consultation with a dermatologist or rheumatologist. UC/CD-prescribed by or in consultation with a gastroenterologist or a rheumatologist. HS-Dermatologist. UV-ophthalmologist or rheumatologist. Sarcoidosis pulmonologist, ophthalmologist, dermatologist or rheumatologist.

COVERAGE DURATION

AS 12wk initl,w/pos resp, 3 year. UC 8wk initl,w/remssn evidnce, 3 year. Othr aprvd indictn, 3 year.

OTHER CRITERIA

For RA, pt tried 1 conventional synthetic DMARD for at least 3 mo (note: pts who already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). For JIA and JRA, pt has tried another agent (e.g MTX, sulfasalazine, leflunomide, NSAID), or biologic DMARD (eg, etanercept, abatacept, infliximab, anakinra, tocilizumab) or will be starting on a preferred adalimumab concurrently with MTX, sulfasalazine, or leflunomide. Approve w/o trying another agent if pt has absolute CI to MTX, sulfasalazine, or leflunomide or if pt has aggressive disease. For non axial forms of PsA, must first t/f MTX for at least 3 mo, OR if the pt has an absolute CI to MTX, then a preferred adalimumab will be approved. Axial forms of PsA, a preferred adalimumab product will be approved. Non axial forms of AS, the pt must t/f any 2 of the following conventional therapies over a 3 mo period: NSAIDs, intraarticular steroids, MTX, other DMARD agents. PP, approve if the pt meets 1 of the following criteria: 1) pt has tried at least 1 traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 mo, unless intolerant (note: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) pt has a CI to MTX as determined by the prescriber. CD, tried corticosteroids (CSs) or if CSs are CI or if pt currently on CSs or pt has tried 1 other agent for CD (eg, azathioprine, 6-mercaptopurine, MTX, certolizumab, infliximab, ustekinumab, or vedolizumab) OR pt had ileocolonic resection OR enterocutaneous (perianal or

abdominal) or rectovaginal fistulas. For CD diagnosis, 1st line coverage will be provided if the pt had an ileocolonic resection OR enterocutaneous (perianal or abdominal) or rectovaginal fistulas. For UC, Pt has tried a systemic therapy (eg, 6-mercaptopurine, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a CS such as prednisone or methylprednisolone) for 2 mo or was intolerant to 1 of these agents, or pt has pouchitis and has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine (Rowasa) enema. For HS, the pt must have t/f or had an inadequate response to one other therapy (e.g., intralesional or oral CS, systemic antibiotics, isotretinoin, cyclosporine). For sarcoidosis-approve if pt has tried at least 1 corticosteroid AND at least one immunosuppressive agent (e.g. MTX, azathioprine, cyclosporine, Leukeran, leflunomide, cyclophosphamide, mycophenolate), an infliximab product or thalidomide. Clinical criteria incorporated into the adalimumab 40 mg quantity limit edit: Allow for approval of additional quantities to accommodate induction dosing. The allowable qty is dependent upon the induction dosing regimen for the applicable FDA-labeled indications as outlined in product labeling. Note: preferred adalimumabs include: Humira (NDCs starting with -00074), Simlandi, adalimumab-adaz, adalimumab-fkjp and Yusimry.

PART B PREREQUISITE

N/A

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

nodule (two or more), or ungula fibromas (two or more). Minor feature criteria involve 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 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 nodule (two or more), or ungula fibromas (two or more). Minor feature criteria involve 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

IBRANCE

MEDICATION(S)
IBRANCE

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

ICLUSIG

MEDICATION(S)
ICLUSIG

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

IDHIFA

MEDICATION(S)
IDHIFA

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

IDIOPATHIC PULMONARY FIBROSIS

MEDICATION(S)
OFEV, PIRFENIDONE

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 and older

PRESCRIBER RESTRICTION
IPF/Chronic fibrosing ILD-Prescribed by or in consultation with a pulmonologist. ILD associated with systemic sclerosis-prescribed by or in consultation with a pulmonologist or rheumatologist.

COVERAGE DURATION
Lifetime.

OTHER CRITERIA
For OFev and pirfenidone: IPF - must have FVC greater than or equal to 40 percent of the predicted value AND IPF must be diagnosed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or surgical lung biopsy demonstrating UIP. For Ofev only: Interstitial lung disease associated with systemic sclerosis-approve if the FVC is greater than or equal to 40 percent of the predicted value and the diagnosis is confirmed by high-resolution computed tomography. For Ofev only: Chronic fibrosing interstitial lung disease-approve if the forced vital capacity is greater than or equal to 45% of the predicted value AND according to the prescriber the patient has fibrosing lung disease impacting more than 10% of lung volume on high-resolution computed tomography AND according to the prescriber the patient has clinical signs of progression.

PART B PREREQUISITE

N/A

ILUMYA

MEDICATION(S)
ILUMYA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs).

REQUIRED MEDICAL INFORMATION
Diagnosis. Previous therapies.

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a dermatologist

COVERAGE DURATION
Initial: 4 months Continuation: 3 years

OTHER CRITERIA
For initiation of therapy, the patient meets all of the following indication specific requirements (A and B): A. The patient meets either of the following criteria: 1) At least 5 percent body surface area was affected by plaque psoriasis at the time of diagnosis, or 2) Crucial body areas (e.g. feet, hands, face, neck, groin, intertriginous areas) were affected by plaque psoriasis at the time of diagnosis. B. The patient meets the following criteria: Patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Skyrizi, Stelara SC, Otezla, or Cosentyx. Note: If the patient does not meet this requirement, a trial of a non-preferred adalimumab product will also count. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074), Simlandi, adalimumab-adaz, adalimumab-fkjp and Yusimry. For continuation of therapy: Patient had demonstrated a positive response to the medication.

PART B PREREQUISITE

N/A

IMATINIB

MEDICATION(S)
IMATINIB MESYLATE

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

IMBRUVICA

MEDICATION(S)
IMBRUVICA 140 MG CAPSULE, IMBRUVICA 280 MG TABLET, IMBRUVICA 420 MG TABLET, IMBRUVICA 560 MG TABLET, IMBRUVICA 70 MG CAPSULE, IMBRUVICA 70 MG/ML SUSPENSION

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

OFF LABEL USES
Central Nervous System Lymphoma (primary), Hairy Cell Leukemia, B-Cell lymphoma (e.g. gastric mucosa associated lymphoid tissue (MALT) lymphoma, nongastric MALT lymphoma, AIDS related, post-transplant lymphoproliferative disorder), marginal zone lymphoma, Mantle cell lymphoma

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 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). For B-cell lymphoma approve if the patient is using Imbruvica as second-line or subsequent therapy according to the prescribing physician. For Central Nervous System Lymphoma (primary) approve if relapsed or refractory. For Hairy Cell Leukemia approve if relapsed or refractory. Mantle Cell Lymphoma – approve if patient meets one of the following (a, b or c): a. Patient has tried one systemic regimen or is not a candidate for a systemic regimen (e.g., bendamustine,

rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, cytarabine, carboplatin, cisplatin, oxaliplatin, or lenalidomide) OR b.Imbruvica is being used in combination with rituximab prior to induction therapy (e.g., rituximab, cyclophosphamide, vincristine, doxorubicin, and dexamethasone) OR c. Imbruvica is being used as induction or maintenance therapy in combination with chemotherapy. Marginal Zone Lymphoma – approve if the patient has tried at least one systemic regimen (e.g., bendamustine, rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, or lenalidomide).

PART B PREREQUISITE

N/A

IMDELLTRA

MEDICATION(S)
IMDELLTRA

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

IMJUDO

MEDICATION(S)
IMJUDO

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

IMLYGIC

MEDICATION(S)
IMLYGIC

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

IMPAVIDO

MEDICATION(S)
IMPAVIDO

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

OFF LABEL USES
Ameba 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 Ameba 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 ameba related infections are Acanthamoeba keratitis, granulomatous amebic encephalitis (GAE), and primary amebic meningoencephalitis (PAM).

PART B PREREQUISITE
N/A

INGREZZA

MEDICATION(S)
INGREZZA, INGREZZA INITIATION PK(TARDIV), INGREZZA SPRINKLE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Non-Huntington’s related chorea

REQUIRED MEDICAL INFORMATION
Diagnosis, Reauth: AIMS or DISCUS score

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
TD - Prescribed by, or in consultation with, a neurologist or psychiatrist. Chorea HD – prescribed by or in consultation with a neurologist.

COVERAGE DURATION
Initial: 3 months, Continuation: 1 year

OTHER CRITERIA
Moderate to Severe Tardive dyskinesia: Initial use: TD diagnosis has been confirmed by all of the following (1, 2 and 3): 1. Patient has had a stable drug and dose medication exposure of one of the following (a, b or c): a. Typical or first generation antipsychotic agents (e.g. chlorpromazine, haloperidol, fluphenazine) b. Atypical or second-generation antipsychotic agents (e.g. clozapine, risperidone, olanzapine) c.Dopamine receptor-blocker used in treatment of nausea and gastroparesis (e.g. prochlorperazine, promethazine, metoclopramide) 2.Symptoms persist despite one of the following (a or b): a. Discontinuation or reduction in dose of offending agent(s) b.Discontinuation or reduction in dose of offending agent(s) is not possible 3. Patient has presence of involuntary athetoid or choreiform movements. Continued use: Patient has experienced an improvement or maintenance of symptoms while on Ingrezza based on reduction in abnormal involuntary movement scale (AIMS) or

Dyskinesia Identification System: Condensed User Scale (DISCUS) from baseline. Chorea associated with Huntington’s disease – approve if diagnosis is confirmed by genetic testing (for example, an expanded HTT CAG repeat sequence of at least 36).

PART B PREREQUISITE

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

INLYTA

MEDICATION(S)
INLYTA

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

INQOVI

MEDICATION(S)
INQOVI

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

INREBIC

MEDICATION(S)
INREBIC

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

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, 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, INSULIN LISPRO, INSULIN LISPRO JUNIOR KWIKPEN, INSULIN LISPRO KWIKPEN U-100, INSULIN LISPRO PROTAMINE MIX, 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 products 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

INTERMEZZO

MEDICATION(S)
ZOLPIDEM TART 1.75 MG TAB SL, ZOLPIDEM TART 3.5 MG TABLET SL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis is for as needed use for the treatment of insomnia when a middle of the night awakening is followed by difficulty returning to sleep (the insomnia must be characterized by difficulty returning to sleep after middle of the night awakening).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
One year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

INTRAROSA/OSPHENA

MEDICATION(S)
INTRAROSA, OSPHENA

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

IRESSA

MEDICATION(S)
GEFITINIB

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

ISTURISA

MEDICATION(S)
ISTURISA

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
Initial: 6 months, Continuation: 1 year

OTHER CRITERIA
Cushing’s disease – 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

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 tinia, 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
Twelve weeks.

OTHER CRITERIA
Tinea or Pityrisis 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 Candidiases 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

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

IVIG

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
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. 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

IWILFIN

MEDICATION(S)
IWILFIN

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

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

JAYPIRCA

MEDICATION(S)
JAYPIRCA

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

JEMPERLI

MEDICATION(S)
JEMPERLI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

JOENJA

MEDICATION(S)
JOENJA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
12 years of age and older

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, an immunologist, pulmonologist, gastroenterologist, hematologist, geneticist or an infectious diseases physician who treats patients with primary immune deficiencies

COVERAGE DURATION
Initial – 6 months, Continuation – 1 year

OTHER CRITERIA
Activated phosphoinositide 3-kinase delta syndrome (APDS), initial therapy – approve if the patient meets all of the following criteria (i, ii, and iii): i.Patient weighs greater than or equal to 45 kg ii.Patient has a genetic phosphoinositide 3-kinase delta mutation with a variant in PIK3CD and/or PIK3R1 genes, AND iii.Patient has at least one clinical finding or manifestations consistent with APDS (Note: examples of clinical findings or manifestations of APDS include recurrent sinopulmonary infections, recurrent herpesvirus infections, lymphadenopathy, hepatomegaly, splenomegaly, nodular lymphoid hyperplasia, autoimmunity, cytopenias, enteropathy, bronchiectasis, and organ dysfunction).
APDS, continuation – approve if the patient meets all of the following criteria (i, ii, iii, and iv): i.Patient has been established on therapy for at least 6 months (a patient who has received less than 6 months

of therapy or who is restarting therapy should be considered under initial therapy) ii.Patient weighs greater than or equal to 45 kg, AND iii.Patient has a genetic phosphoinositide 3-kinase delta mutation with a variant in PIK3CD and/or PIK3R1 genes, AND iv.Patient has had a positive clinical response in the signs and manifestations of APDS. (Note: Examples of positive clinical response in the signs and manifestations of APDS include reduction of: lymph node size, spleen size, immunoglobulin replacement therapy use, infection rate, or immunoglobulin M (IgM) levels.)

PART B PREREQUISITE

N/A

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 a failure of or 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

JYNARQUE

MEDICATION(S)
JYNARQUE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Patient is currently receiving Samsca (tolvaptan tablets). Patients with eGFR less than 25 ml/min. Patients with history, signs or symptoms of significant liver impairment or injury (does not apply to uncomplicated polycystic liver disease).

REQUIRED MEDICAL INFORMATION
Diagnosis, renal function, liver function

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a nephrologist

COVERAGE DURATION
1 year (initial and continuation)

OTHER CRITERIA
Initial: Approve if the patient has rapidly-progressing autosomal dominant polycystic kidney disease (ADPKD) (e.g., reduced or declining renal function, high or increasing total kidney volume [height adjusted]), according to the prescriber. Of note, generic tolvaptan is equivalent to generic Samsca and does not apply to this prior authorization. Continuation: Clinical documentation that current laboratory values for liver and kidney function remain within acceptable treatment ranges.

PART B PREREQUISITE
N/A

KALBITOR

MEDICATION(S)
KALBITOR

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 allergist/immunologist or a physician in the treatment of hereditary angioedema (HAE) or related disorders (initial and continuation)

COVERAGE DURATION
1 year

OTHER CRITERIA
HAE due to C1 inhibitor (C1-INH) Deficiency (Type I or Type II), Treatment of Acute Attacks, initial therapy – approve if patient has HAE type I or type II as confirmed by the following diagnostic criteria (a and b): a) Patient has low levels of functional C1-INH protein (less than 50 percent of normal) at baseline, as defined by the laboratory reference values [documentation required] AND b) Patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values [documentation required].

Patients who have treated previous acute HAE attacks with Kalbitor – approve if the patient has a diagnosis of HAE type I or II [documentation required] AND according to the prescriber, the patient has had a favorable clinical response with Kalbitor treatment.

PART B PREREQUISITE

N/A

KALYDECO

MEDICATION(S)
KALYDECO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Patients who are homozygous for the F508del mutation. Combination use with Orkambi, Trikafta or Symdeko.

REQUIRED MEDICAL INFORMATION
For patients new to therapy, CFTR gene mutation status required. Members already started on therapy prior to joining health plan with unconfirmed mutation status must confirm CFTR mutation status to continue.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
CFTR gene mutation cnfrmed,lifetime. If cont use from prior to joining plan and mutation unknwn, 3mo

OTHER CRITERIA
Patients new to therapy must have appropriate CFTR gene mutation. Patients continuing therapy from prior to joining health plan already started on therapy must confirm CFTR gene mutation to continue treatment.

PART B PREREQUISITE
N/A

KERENDIA

MEDICATION(S)
KERENDIA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with spironolactone or eplerenone

REQUIRED MEDICAL INFORMATION
Diagnosis, lab values (eGFR, UACR, potassium), medication trials

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Diabetic kidney disease, approve if the patient meets the following criteria (i, ii, iii, and iv):
i. Patient has a diagnosis of type 2 diabetes AND
ii. Patient meets one of the following (a or b):
a. Patient is currently receiving a maximally tolerated angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) OR
b. According to the prescriber, patient has a contraindication to ACE inhibitor or ARB therapy, AND
iii. Patient has tried/failed, has a contraindication or intolerance to one sodium-glucose cotransporter 2 (SGLT2) inhibitor (e.g. Jardiance, Farxiga)
iv. Patient meets all of the following (a, b, and c) despite use (if not intolerant or contraindicated) of ACEI/ARB and SGLT2:
a. Estimated glomerular filtration rate greater than or equal to 25 mL/min/1.73 m2 AND

b. Urine albumin-to-creatinine ratio greater than or equal to 30 mg/g AND
c. Serum potassium level less than or equal to 5.0 mEq/L.

PART B PREREQUISITE
N/A

KEVZARA

MEDICATION(S)
KEVZARA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.

REQUIRED MEDICAL INFORMATION
Diagnosis, prescriber specialty, other medications tried.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a rheumatologist

COVERAGE DURATION
3 years

OTHER CRITERIA
RA initial - approve if the patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Orencia (IV/SC), Rinvoq or Xeljanz/XR (Note: if the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the try TWO requirement: Cimzia, an infliximab product, golimumab SC/IV, Actemra, Rituxan, Kineret, or a non-preferred adalimumab product) OR if, according to the prescribing physician, the patient has heart failure or a previously treated lymphoproliferative disorder. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074), Simlandi, adalimumab-adaz, adalimumab-fkjp and Yusimry. Cont tx - pt must have had a response as determined by the prescriber. For polymyalgia rheumatic, initial – approve if the patient has tried one systemic corticosteroid. Continuation of therapy – patient must have had a response to therapy. For polyarticular juvenile idiopathic arthritis (pJIA), member must have confirmed diagnosis of juvenile idiopathic arthritis and disease must be active AND patient has tried

TWO of the following: Etanercept, Orencia, a preferred adalimumab product, Rinvoq, or Xeljanz. Note: previous trial(s) with the following drugs can count towards meeting the try TWO requirement: infliximab or a non-preferred adalimumab product.

PART B PREREQUISITE

N/A

KIMMTRAK

MEDICATION(S)
KIMMTRAK

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

KINERET

MEDICATION(S)
KINERET

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

OFF LABEL USES
Still's disease (SD). Systemic Juvenile Idiopathic Arthritis (SJIA).

EXCLUSION CRITERIA
Concurrent use with another biologic DMARD or targeted synthetic DMARD.

REQUIRED MEDICAL INFORMATION
For Rheumatoid Arthritis, the member must have a confirmed diagnosis of Rheumatoid Arthritis and the disease must be active. For Cryopyrin Associated Periodic Syndrome, the member must have a confirmed diagnosis of CAPS with subtype Neonatal-Onset Multisystem Inflammatory Disease (NOMID).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RA, SIJA and Still's disease-prescribed by or in consultation with a rheumatologist. CAPS-prescribed by or in consultation with a rheumatologist, geneticist, dermatologist, pediatrician. DIRA-prescribed by or in consultation with a rheumatologist, geneticist, dermatologist or physician specializing in tx of autoinflammatory disorders.

COVERAGE DURATION
RA/CAPS/SIJA/Still's - Lifetime. DIRA: initial - 3 months, continuation - 3 years.

OTHER CRITERIA
For Rheumatoid Arthritis, approve if the patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Orencia (IV/SC), Rinvoq or Xeljanz/XR. (Note: if the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the try TWO requirement: Actemra, Cimzia, infliximab, Kevzara, golimumab IV/SC, or a non-preferred adalimumab product). For Still's disease, Approve if the patient has tried a corticosteroid and has had an inadequate

response to one conventional synthetic disease-modifying antirheumatic drug (DMARD) or was intolerant to this therapy OR the patient has at least moderate to severe active systemic features of this condition, according to the prescriber OR the patient has active systemic features with concerns of progression to macrophage activation syndrome as determined by the prescriber. SIJA approve if the patient has tried one other systemic agent or the patient has at least moderate to severe active systemic features of this condition or the patient has active systemic features with an active joint count of one joint or greater or the patient has active systemic features with concerns of progression to macrophage activation syndrome. DIRA initial - approve if genetic testing has confirmed a mutation in the IL1RN gene. DIRA continuation - approve if the patient has responded to therapy as determined by the prescriber. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074), Simlandi, adalimumab-adaz, adalimumab-fkjp and Yusimry.

PART B PREREQUISITE

N/A

KISQALI

MEDICATION(S)
KISQALI, KISQALI FEMARA CO-PACK

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

KORLYM

MEDICATION(S)
KORLYM, MIFEPRISTONE 300 MG TABLET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Pregnancy.

REQUIRED MEDICAL INFORMATION
The member must have a confirmed diagnosis of endogenous Cushings syndrome, requiring control of hyperglycemia secondary to hypercortisolism, with Type 2 Diabetes Mellitus or glucose intolerance. Members must not be pregnant, as evidenced by a documented negative pregnancy test prior to the initiation of treatment. For continuation, the member must have experienced improvement, as attested by the prescriber.

AGE RESTRICTION
Aged 18 years or older.

PRESCRIBER RESTRICTION
Endocrinologist or specialist in treating Cushing's syndrome.

COVERAGE DURATION
Initial authorization 3 months. If improvement met, then lifetime.

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.

PART B PREREQUISITE
N/A

KOSELUGO

MEDICATION(S)
KOSELUGO

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

OFF LABEL USES
Astrocytoma.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
2 years and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist, oncologist, or a medical geneticist

COVERAGE DURATION
1 year

OTHER CRITERIA
For neurofibromatosis type 1, must have symptomatic, inoperable plexiform neurofibromas (PN).

PART B PREREQUISITE
N/A

KRAZATI

MEDICATION(S)
KRAZATI

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

KUVAN

MEDICATION(S)
SAPROPTERIN DIHYDROCHLORIDE

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

LAZCLUZE

MEDICATION(S)

LAZCLUZE

PENDING CMS APPROVAL

LENALIDOMIDE

MEDICATION(S)
LENALIDOMIDE

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

LENVIMA

MEDICATION(S)
LENVIMA

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

LEUKINE

MEDICATION(S)
LEUKINE

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

LITFULO

MEDICATION(S)
LITFULO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with an oral or topical Janus Kinase Inhibitor (JAKi), a biologic immunomodulator or other potent immunosuppressants (e.g., cyclosporine, azathioprine, methotrexate)

REQUIRED MEDICAL INFORMATION
Diagnosis of severe alopecia areata

AGE RESTRICTION
12 years and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a dermatologist

COVERAGE DURATION
Initial: 6 months, Continuation: 1 year

OTHER CRITERIA
Alopecia areata, initial therapy: approve if the patient: 1. Has a current episode of alopecia areata lasting for greater than or equal to 6 months without spontaneous re-growth 2. Has greater than or equal to 50 percent scalp hair loss 3. Does not have hair loss due to androgenetic alopecia, chemotherapy-induced hair loss or other causes of hair loss other than alopecia areata. Alopecia areata, continuation of therapy: approve if the patient meets the following: 1. Has been established on Litfulo for at least 6 months (less than 6 months or a restart, review under initial therapy) 2. Experienced a beneficial clinical response defined as improvement from baseline (prior to initiating Litfulo) in extent and density of scalp hair loss 3. The prescriber states the patient continues to require systemic therapy for treatment of alopecia areata.

PART B PREREQUISITE

N/A

LIVMARLI

MEDICATION(S)
LIVMARLI

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 a hepatologist, gastroenterologist, or a physician who specializes in Alagille syndrome or PFIC (initial and continuation)

COVERAGE DURATION
Initial-6 months, continuation-1 year

OTHER CRITERIA
Alagille Syndrome, initial-approve if the patient meets (i, ii and iii): i. Patient has moderate-to-severe pruritus, according to prescriber AND ii. Diagnosis of Alagille syndrome was confirmed by genetic testing demonstrating a JAG1 or NOTCH2 deletion or mutation AND iii. Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory. PFIC: Approve if patient meets all of the following (i, ii and iii): i. Patient has moderate-to-severe pruritis, according to prescriber AND ii.Diagnosis of PFIC was confirmed by genetic testing demonstrating a gene mutation affiliated with PFIC (including ATP8B1 gene, ABCB11 gene, ABCB4 gene, TJP2 gene, NR1H4 gene, and MYO5B gene) AND iii. Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory. Alagille Syndrome, PFIC, continuation-approve if the patient has had a response to therapy.

PART B PREREQUISITE

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

LONSURF

MEDICATION(S)
LONSURF

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

LOQTORZI

MEDICATION(S)
LOQTORZI

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

LORBRENA

MEDICATION(S)
LORBRENA

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

LUCEMYRA

MEDICATION(S)
LOFEXIDINE HCL, LUCEMYRA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, previous therapies tried.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 month

OTHER CRITERIA
The prescriber indicates that there was a documented trial and failure with clonidine (oral or topical patch) prior to Lucemyra approval.

PART B PREREQUISITE
N/A

LUMAKRAS

MEDICATION(S)
LUMAKRAS

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

LUMOXITI

MEDICATION(S)
LUMOXITI

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

LUNSUMIO

MEDICATION(S)
LUNSUMIO

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

LUPKYNIS

MEDICATION(S)
LUPKYNIS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with biologics or with cyclophosphamide

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older (initial and continuation)

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a nephrologist or rheumatologist (initial therapy and continuation)

COVERAGE DURATION
Initial and continuation - 1 year

OTHER CRITERIA
Lupus Nephritis, Initial therapy- Approve if the patient meets all of the following criteria (A, B, and C): A) Patient has autoantibody-positive systemic lupus erythematosus (SLE), defined as positive for antinuclear antibodies (ANA) and/or anti-double-stranded DNA (anti-dsDNA) antibody, B) Patient meets ONE of the following (a or b) a) Medication is being used concurrently with mycophenolate mofetil and a systemic corticosteroid OR b) Patient is not a candidate for mycophenolate mofetil and a systemic corticosteroid due to inadequate efficacy OR significant intolerance with these medications, C) Patient has an estimated glomerular filtration rate (eGFR) greater than 45 mL/min/m2. Lupus Nephritis, Continuation therapy- Approve if the patient meets all of the following criteria (A and B): A) Patient meets ONE of the following (a or b): a) Medication is being used concurrently with mycophenolate mofetil and a systemic corticosteroid OR b) Patient is not a candidate for mycophenolate mofetil and a systemic corticosteroid due to inadequate efficacy OR significant

intolerance with these medications, B) Patient has responded to therapy with the requested medication.

PART B PREREQUISITE

N/A

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

AGE RESTRICTION
Premenstrual disorders – 18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
1. Endometriosis: a. For initial therapy – member meet one of the following (i or ii): i. Has had surgical ablation to prevent recurrence OR ii.Trial/failure, contraindication or intolerance to one NSAID and one oral contraceptive. b. For continuation of therapy – member meets both of the following (i AND ii): i. Symptoms recur after one course, ii. Member meets one of the following (1, 2 or 3): 1. Use will be in combination with norethindrone 5 mg daily AND 2. Use will be in combination with an “add-back” sex hormone (e.g., estrogen, medroxyprogesterone), 3. Use will be in combination with a bone-sparing agent (e.g., bisphosphonate).
2. Uterine leiomyomata (fibroids): Use prior to surgery to reduce size of fibroids OR treatment of anemia
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 AND b. Patient has tried a selective serotonin reuptake inhibitor (SSRI) AND a combine oral contraception for treatment of premenstrual disorder.

PART B PREREQUISITE

N/A

LYNPARZA

MEDICATION(S)
LYNPARZA

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

LYTGOBI

MEDICATION(S)
LYTGOBI

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

MARGENZA

MEDICATION(S)
MARGENZA

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

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

MAYZENT

MEDICATION(S)
MAYZENT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with other disease-modifying agents used for multiple sclerosis.

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

MEKINIST

MEDICATION(S)
MEKINIST

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

MEKTOVI

MEDICATION(S)
MEKTOVI

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

MEMANTINE

MEDICATION(S)
MEMANTINE 5-10 MG TITRATION PK, 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

METHAMPHETAMINE

MEDICATION(S)
METHAMPHETAMINE HCL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Use in patients for weight loss.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

MULPLETA

MEDICATION(S)
MULPLETA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, platelet count, date of procedure

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
7 days

OTHER CRITERIA
Approve if the patient has a current platelet count less than 50 x 109/L AND the patient is scheduled to undergo a procedure within 8 to 14 days after starting Mulpleta therapy.

PART B PREREQUISITE
N/A

MYALEPT

MEDICATION(S)
MYALEPT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

MYCAPSSA

MEDICATION(S)
MYCAPSSA

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 the patient meets the following criteria (A and B): A.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 Note: Pre-treatment (baseline) refers to the IGF-1 level prior to the initiation of a somatostatin analog (e.g., Mycapssa [octreotide delayed-release capsules], an octreotide acetate injection product [e.g., Bynfezia Pen, Sandostatin {generics}, Sandostatin LAR Depot], Signifor LAR [pasireotide injection], Somatuline Depot [lanreotide injection], dopamine agonist [e.g., cabergoline, bromocriptine], or Somavert [pegvisomant injection]). Reference ranges for IGF-1 vary among laboratories. B.According to the prescriber, patient has responded to one octreotide acetate injection product or Somatuline Depot (lanreotide injection)

PART B PREREQUISITE

N/A

NASAL CORTICOSTEROIDS

MEDICATION(S)
AZELASTINE-FLUTICASONE, 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

NATPARA

MEDICATION(S)
NATPARA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Increased baseline risk for osteosarcoma.

REQUIRED MEDICAL INFORMATION
Baseline stores of 25-hydroxy vitamin D and serum calcium levels. Previous treatment.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist.

COVERAGE DURATION
Lifetime.

OTHER CRITERIA
Hypocalcemia secondary to hypoparathyroidism - Before starting Natpara, serum calcium concentration is greater than 7.5 mg/dL and 25-hydroxyvitamin D stores are sufficient per the prescribing physician.

PART B PREREQUISITE
N/A

NERLYNX

MEDICATION(S)
NERLYNX

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

NEXAVAR

MEDICATION(S)
SORAFENIB

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

NEXLETOL

MEDICATION(S)
NEXLETOL, NEXLIZET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
LDL-C and response to other agents, prior therapies tried

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Heterozygous Familial Hypercholesterolemia (HeFH) -approve if pt meets one of the following: patient has an untreated low-density lipoprotein cholesterol (LDL-C) level greater than or equal to 190 mg/dL (prior to treatment with antihyperlipidemic agents) OR patient has genetic confirmation of HeFH by mutations in the low-density lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9 or low-density lipoprotein receptor adaptor protein 1 gene OR patient has been diagnosed with HeFH meeting one of the following diagnostic criteria thresholds (a or b): a) The prescriber used the Dutch Lipid Network criteria and the patient has a score greater than 5 OR b) The prescriber used the Simon Broome criteria and the patient met the threshold for definite or possible familial hypercholesterolemia OR patient has clinical manifestations of HeFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma) AND Pt tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or

equal to 20 mg daily) AND ezetimibe concomitantly for greater than or equal to 8 weeks and LDL-C remains greater than or equal to 70 mg/dL unless the patient is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation. Atherosclerotic Cardiovascular Disease (ASCVD) -approve if pt meets all of the following: Pt has one of the following conditions: prior MI, history of ACS, diagnosis of angina (stable or unstable), history of stroke or TIA, PAD, undergone a coronary or other arterial revascularization procedure, AND Pt tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) AND ezetimibe concomitantly for greater than or equal to 8 weeks and LDL-C remains greater than or equal to 70 mg/dL unless the patient is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation. Primary Hyperlipidemia (not associated with HeFH or ASCVD): Approve if patient meets all of the following (a, b and c):a.The member has tried one high-intensity statin therapy (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily), unless member has been determined to be statin intolerant (as defined above) AND b. The member has tried ezetimibe for 8 weeks AND c.LDL remains 100 mg/dL or higher unless statin intolerant.

PART B PREREQUISITE

N/A

NGENLA

MEDICATION(S)
NGENLA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Use for athletic enhancement, anti-aging purposes or idiopathic short stature (ISS)

REQUIRED MEDICAL INFORMATION
Diagnosis, test results (e.g., growth hormone stim test results, growth rates, pituitary hormone levels, MRI/CT results)

AGE RESTRICTION
Greater than or equal to 3 years of age and less than 18 years old

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist (all dx except hypophysectomy)

COVERAGE DURATION
1 year

OTHER CRITERIA
GHD ped,init-1of(i,ii,iii,iv,or,v):i. Either(1or2):1-Two stim tests w/ levodopa,insulin-induced hypoglyc, arginine, clonidine, or glucagon w/ BOTH resp below lab norm OR 2- BOTH (a and b):a-One stim test below lab norm AND b-at least 1 GHD risk factor ii.Brain radiation/tumor resection AND (1or2):1-One stim test below lab norm OR 2-One other pit horm defic (ACTH,TSH,gonadotrop[LH, FSH are 1],prolactin), OR iii.congenital hypopit AND one of (1,2or3):1-one stim test resp below lab norm OR 2-one other pit horm def OR 3-Imaging triad ectopic posterior pit and pit hypoplasia w/ abn pit stalk. iv.Mult pit horm defic and 1 of (1or2):1-3+ pit horm def: somatrop,ACTH,TSH,gonadotrop,prolact, OR 2-one stim test below lab norm. v.Hypophysectomy. GHD ped, continuation of Ngenla or switching to Ngenla from another GH agent (after being established on either therapy for at least 10 months): Approve if the patient meets one of the following (A or B): A. Patient is less than 12 years of age and

provider attests patient has responded to treatment OR B. Patient is 12 years of age or greater and less than 18 years of age and meets both of the following (a and b): a. Provider attests patient has responded to treatment AND b. Patient’s epiphyses are open

PART B PREREQUISITE

N/A

NINLARO

MEDICATION(S)
NINLARO

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

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

NSAIDS

MEDICATION(S)
INDOMETHACIN 25 MG CAPSULE, INDOMETHACIN 50 MG CAPSULE, INDOMETHACIN ER

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

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
For gout, approve indomethacin as first line therapy without other previous drug trial criteria requirements. For other indications for indomethacin, the patient must try and fail at least two other FDA-approved products for the indication being treated. Prior to approval, 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

NUBEQA

MEDICATION(S)
NUBEQA

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

NUCALA

MEDICATION(S)
NUCALA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with Xolair or another Anti-Interleukin (IL) monoclonal antibody

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Asthma - 6 years of age. EGPA, polyps - 18 years of age and older. HES - 12 years and older.

PRESCRIBER RESTRICTION
Asthma/EGPA - prescribed by or in consultation with an allergist, immunologist, rheumatologist, or pulmonologist. HES-prescribed by or in consultation with an allergist, immunologist, hematologist, pulmonologist or rheumatologist. Polyps - prescribed by or in consultation with an allergist, immunologist, or otolaryngologist.

COVERAGE DURATION
Asthma/EGPA/Polyps: Initial 6 months. HES: Initial 8 months. Continuation all diagnoses - lifetime.

OTHER CRITERIA
Initial asthma - must have peripheral blood eosinophil count of greater than or equal to 150 cells per mcL within previous 6 weeks (prior to treatment with any anti-interleukin [IL]-5 therapy) AND Pt has received at least 3 mo of combo therapy with an ICS AND one of the following A. inhaled LABA, B. inhaled LAMA, C. Leukotriene receptor antagonist, or D. Theophylline. Pts asthma continues to be uncontrolled as defined by 1 of the following - pt experienced 2 or more asthma exacerbations requiring tx with systemic corticosteroids in the previous yr, pt experienced 1 or more asthma exacerbation requiring hospitalization or an ED visit in previous yr, pt has a FEV1 less than 80 percent predicted, Pt has an FEV1/FVC less than 0.80, or Pts asthma worsens upon tapering of oral

corticosteroid therapy. NOTE: An exception to the requirement for a trial of 1 additional asthma controller/maintenance med can be made if the pt has already received anti-IL-5 therapy. For cont asthma-The pt has responded to Nucala therapy as determined by the prescriber (e.g., decr asthma exacerbations, decr asthma sx, decr hospitalizations, ED/urgent care, or physician visits due to asthma, decr requirement for oral corticosteroid therapy) AND Pt continues to receive therapy with an ICS. For initial tx EGPA-pt has/had eosinophil level of greater than or equal to 150 cells per mcL within the previous 6 wks or within 6 wks prior to tx with any anti-interleukin (IL)-5 therapy AND the patient has active, non-severe disease. Cont of tx for EGPA-pt has responded to Nucala therapy as determined by the prescriber (e.g., reduced rate of relapse, corticosteroid dose reduction, reduced eosinophil level). HES initial-pt has had HES for greater than or equal to 6 mo AND has FIP1L1-PDGFRalpha-negative disease AND the pt does NOT have an identifiable non-hematologic secondary cause of HES AND prior to initiating tx with any anti-IL-5 therapy, pt has/had a blood eosinophil level of greater than or equal to 1,000 cells per mcL. Cont HES-approve if the pt has received at least 8 mo of tx with Nucala and pt has responded to Nucala therapy. Initial therapy nasal polyps-Pt has chronic rhinosinusitis with nasal polyposis as evidenced by direct examination, endoscopy or sinus CT scan AND Pt has experienced 2 or more of the following sx for at least 6 mo nasal congestion/obstruction/discharge and/or reduction/loss of smell AND Pt has received at least 3 months of tx with intranasal corticosteroid AND Pt will continue to receive tx with intranasal steroid concomitantly with Nucala AND pt meets one of the following (a, b or c): a) pt has received at least 1 course of tx with a systemic corticosteroid for 5 days or more within previous 2 yrs OR b) pt has contraindication to systemic corticosteroid tx OR c) Pt has had prior surgery for nasal polyps. Cont polyps-approve if the pt has received at least 6 mo of therapy, continues to receive tx with an intranasal steroid and has responded to tx.

PART B PREREQUISITE

N/A

NUEDEXTA

MEDICATION(S)
NUEDEXTA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, 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
Initial: 3 months, Continuation: 1 year.

OTHER CRITERIA
Pseudobulbar Affect - Diagnosis is confirmed by one 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.Patient has a brain injury or neurologic disease from one of the following: amyotrophic lateral sclerosis, multiple sclerosis, Parkinson’s disease, stroke or traumatic brain injury.

PART B PREREQUISITE
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
Initial: 3 months. Continuation: 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

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
Preventative treatment: Initial-3 months, Continuation-12 months. Acute treatment: 1 year

OTHER CRITERIA
Acute treatment: Approve if the patient has trialed and failed or has a contraindication [documentation required] to two different triptans (must be different active ingredients). Preventative treatment of episodic 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) and B) Patient has tried and failed two of the following drug classes prior to approval of Nurtec ODT: Beta blockers (ex. Metoprolol, Propranolol, and Timolol), Antidepressants (ex. Amitriptyline, Nortriptyline, and Venlafaxine), Anticonvulsants (ex. Valproate and Topiramate) or Calcium Channel Blockers (ex. Verapamil). For preventative treatment continuation: Prescriber confirms that the member demonstrates improvement after a 3-month trial of Nurtec ODT.

PART B PREREQUISITE

N/A

OCALIVA

MEDICATION(S)
OCALIVA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Patient does not have cirrhosis or has compensated cirrhosis without evidence of portal hypertension.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician

COVERAGE DURATION
New to therapy: 6 months. Continuing patients 3 years.

OTHER CRITERIA
Currently receiving therapy prior to joining health plan or started therapy in past 6 months or Diagnosis of primary biliary cholangitis (cirrhosis)(PBC) as defined by TWO of the following (a, b and/or c): a) ALP elevated above the upper limit of normal as defined by normal laboratory reference values, b) Positive anti-mitochondrial antibodies (AMAs) or other PBC-specific auto-antibodies, including sp100 or gp210, if AMA is negative and/or c) Histiologic evidence of PBC from a liver biopsy. Patient must also have not achieved an adequate response to an appropriate dosage of ursodiol for at least one year or is intolerant to ursodiol AND the requested medication must be used in combination therapy with ursodiol, unless intolerant to ursodiol. Continuation of therapy: approve if the patient has responded as determined by the prescribing physician (e.g. improved biochemical markers of PBC [e.g. ALP, bilirubin, GGT, AST, ALT levels]).

PART B PREREQUISITE

N/A

ODOMZO

MEDICATION(S)
ODOMZO

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

OGSIVEO

MEDICATION(S)
OGSIVEO

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

OJJAARA

MEDICATION(S)
OJJAARA

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

OLUMIANT

MEDICATION(S)
OLUMIANT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with other biologics, DMARDs, or other potent immunosuppressants. Exclude for indication of COVID-19 treatment in hospitalized patients (ie, non-D use).

REQUIRED MEDICAL INFORMATION
Diagnosis, previous medication use, concurrent medication

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
RA - Prescribed by or in consultation with a rheumatologist. Alopecia areata-prescribed by or in consultation with a dermatologist.

COVERAGE DURATION
Initial: 3 months Continuation of therapy: 3 years

OTHER CRITERIA
For Rheumatoid Arthritis- Initial: approve if the patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Orencia (IV/SC), Rinvoq or Xeljanz/XR. (NOTE: If the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the "try TWO" requirement: Actemra, Cimzia, infliximab, golimumab IV/SC, Kevzara or a non-preferred adalimumab product). Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074), Simlandi, adalimumab-adaz, adalimumab-fkjp and Yusimry. For continuation of therapy: Approve if the patient has had a positive response, as determined by the prescriber. For alopecia areata-Initial: approve if the patient has a current episode of alopecia areata lasting for greater than or equal to 6 months and has greater than or equal to 50 percent scalp hair loss and the patient does not

have hair loss due to androgenetic alopecia, chemotherapy-induced hair loss or other causes of hair loss other than alopecia areata. Continuation therapy-approve if the patient has experienced an improvement from baseline in extent and density of scalp hair loss and if the prescriber states the patient continues to require systemic therapy for the treatment of alopecia areata.

PART B PREREQUISITE

N/A

OMNIPOD

MEDICATION(S)
CEQUR SIMPLICITY 2U 3DAY PATCH, CEQUR SIMPLICITY INSERTER, OMNIPOD 5 G6 INTRO KIT (GEN 5), OMNIPOD 5 G6 PODS (GEN 5), OMNIPOD 5 G6-G7 INTRO KT(GEN5), OMNIPOD 5 G6-G7 PODS (GEN 5), OMNIPOD CLASSIC PODS (GEN 3), OMNIPOD DASH INTRO KIT (GEN 4), OMNIPOD DASH PODS (GEN 4), OMNIPOD GO PODS

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

OMVOH

MEDICATION(S)
OMVOH 100 MG/ML SYRINGE, OMVOH PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.

REQUIRED MEDICAL INFORMATION
The member must have a confirmed diagnosis of moderately to severely active ulcerative colitis. Trial of preferred products, Reauth: Objective measure or symptom improvement documentation

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a gastroenterologist

COVERAGE DURATION
Initial: 6 months, Continuation: 3 years

OTHER CRITERIA
1.Moderately to severely active Ulcerative Colitis
a.Initial therapy: Approve if the patient has tried TWO of the following preferred products: a preferred adalimumab product, Stelara SC, Rinvoq, Simponi SC, Skyrizi or Xeljanz/XR tablets. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074), Simlandi, adalimumab-adaz, adalimumab-fkjp and Yusimry. A trial with a non-preferred adalimumab would also count.
b.Continuation therapy: Approve if the patient meets BOTH of the following (i and ii):
i.Patient has been established on the requested medication for at least 6 months AND
ii.Patient meets at least 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 the requested drug). Examples of assessment for inflammatory

response include fecal markers (such as fecal calprotectin), serum markers (such as C-reactive protein), endoscopic assessment, and/or reduced doses of corticosteroids.
2.Compared with baseline (prior to initiating the requested drug), the patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or decreased rectal bleeding.

PART B PREREQUISITE
N/A

ONUREG

MEDICATION(S)
ONUREG

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

OPDIVO

MEDICATION(S)
OPDIVO

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

OPDUALAG

MEDICATION(S)
OPDUALAG

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

OPFOLDA

MEDICATION(S)
OPFOLDA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Use in combination with Lumizyme or Nexviazyme

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years of age or older

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

COVERAGE DURATION
1 year

OTHER CRITERIA
Acid alpha-glucosidase deficiency (Pompe Disease). Approve if the patient meets all of the following (a, b, c and d): a. Patient weighs 40 kg or greater, b. Medication will be used in combination with Pombiliti, c. Patient has not demonstrated an improvement in objective measures after receiving one of the following for at least one year (i or ii) (Note: examples of objective measures include forced vital capacity [FVC] and six-minute walk test [6MWT]): i. Lumizyme IV infusion (alglucosidase alfa) OR ii. Nexviazyme (avalglucosidase alfa-ngpt) intravenous infusion, d. Patient has late-onset acid alpha-glucosidase deficiency (late-onset Pompe disease) with diagnosis established by one of the following (i or ii): i. Patient has a laboratory test demonstrating deficient acid alpha-glucosidase activity in blood, fibroblasts, or muscle tissue, or ii. Patient has a molecular genetic test demonstrating acid alpha-glucosidase gene mutation.

PART B PREREQUISITE

N/A

OPHTHALMIC BETA BLOCKER

MEDICATION(S)
BETOPTIC S, TIMOLOL MALEATE 0.25% EYE DROP, TIMOLOL MALEATE 0.5% EYE DROP

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

OPHTHALMIC OTHER GLAUCOMA THERAPY

MEDICATION(S)
ALPHAGAN P 0.1% DROPS, 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

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

OPSUMIT

MEDICATION(S)
OPSUMIT

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 catheterization

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PAH-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 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

OPZELURA

MEDICATION(S)
OPZELURA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with a biologic or with other JAK inhibitors. Concurrent use with other potent immunosuppressants.

REQUIRED MEDICAL INFORMATION
Diagnosis, other medications tried

AGE RESTRICTION
12 years and older

PRESCRIBER RESTRICTION
AD-Prescribed by or in consultation with an allergist, immunologist or dermatologist. Nonsegmental vitiligo-prescribed by or in consultation with a dermatologist.

COVERAGE DURATION
AD-8 weeks. Vitiligo-6 months.

OTHER CRITERIA
Atopic Dermatitis, mild to moderate- Approve if the patient meets all of the following (A, B, C and D): A) Patient has mild to moderate atopic dermatitis, according to the prescriber, AND B) Patient has atopic dermatitis involvement estimated to affect less than or equal to 20% of the body surface area, AND C) Patient meets ONE of the following (i or ii): i. Patient meets ALL of the following criteria (a and b): a) Patient has tried at least one medium-, medium-high, high-, and or super-high-potency prescription topical corticosteroid AND Note: Concomitant use of a topical corticosteroid with a topical calcineurin inhibitor would meet the requirement. b) Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescriber OR ii. Patient is treating atopic dermatitis affecting one of the following areas: face, eyes, eyelids, skin folds, and or genitalia AND D) Patients meets ALL

of the following (i and ii): i. Patient has tried at least one topical calcineurin inhibitor, AND Note: Examples of topical calcineurin inhibitors include tacrolimus ointment (Protopic, generic) and pimecrolimus cream (Elidel, generic). Concomitant use of a topical calcineurin inhibitor with a topical corticosteroid would meet the requirement. ii. Inadequate efficacy was demonstrated with this topical calcineurin inhibitor, according to the prescriber. Vitiligo approve if the patient meets all of the following (A, B, and C): A) Patient has nonsegmental vitiligo B) Patient has vitiligo involvement estimated to affect less than or equal to 10 percent of the body surface area C) Patient meets ONE of the following (i or ii): i. Patient meets ALL of the following criteria (a, b and c): a. Patient has tried at least one high-, and/or super-high-potency prescription topical corticosteroid, AND b. The duration of this topical corticosteroid therapy was at least 12 weeks (Note: intermittent or continuous use of a topical corticosteroid for at least 12 weeks would meet the requirement), AND c. Inadequate efficacy was demonstrated with this topical corticosteroid therapy OR ii. Patient is treating vitiligo affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia.

PART B PREREQUISITE

N/A

ORENCIA

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

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.

REQUIRED MEDICAL INFORMATION
Diagnosis, concurrent medications, previous drugs tried.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RA and JIA/JRA-prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or dermatologist.

COVERAGE DURATION
Lifetime.

OTHER CRITERIA
For Rheumatoid Arthritis, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). For Juvenile Idiopathic Arthritis or Juvenile Rheumatoid Arthritis, must first try and fail methotrexate for at least 3 months, OR if the member has an absolute contraindication to methotrexate, then Orencia will be approved.

PART B PREREQUISITE
N/A

ORENITRAM

MEDICATION(S)
ORENITRAM ER, ORENITRAM MONTH 1 TITRATION KT, ORENITRAM MONTH 2 TITRATION KT, ORENITRAM MONTH 3 TITRATION KT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with other inhaled or parenteral prostacyclin agents used for pulmonary hypertension

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
1 year

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

ORGOVYX

MEDICATION(S)
ORGOVYX

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

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
For patients new to therapy, homozygous F508del mutation status in the CFTR gene required. Members already started on therapy prior to joining health plan with unconfirmed mutation status must confirm CFTR mutation status to continue.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
CFTR gene mutation cnfrmed,lifetime. If cont use from prior to joining plan and mutation unknwn, 3mo

OTHER CRITERIA
Patients new to therapy must have appropriate CFTR gene mutation. Patients continuing therapy from prior to joining health plan already started on therapy must confirm CFTR gene mutation to continue treatment.

PART B PREREQUISITE
N/A

ORLADEYO

MEDICATION(S)
ORLADEYO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant Use with Other HAE Prophylactic Therapies (e.g., Haegarda, Takhzyro).

REQUIRED MEDICAL INFORMATION
Diagnosis, lab results (C1-INH protein, C4 levels), reauth: number and severity of HAE attacks

AGE RESTRICTION
12 years and older (initial and continuation)

PRESCRIBER RESTRICTION
Prescribed by or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders. (initial and continuation)

COVERAGE DURATION
Initial: 6 months, Continuation: 1 year

OTHER CRITERIA
Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] – Prophylaxis
Initial Therapy: Approve if the patient meets all of the below:
1. The patient has HAE type I or type II as confirmed by the following diagnostic criteria (a and b): a. The patient has low levels of functional C1-INH protein at baseline, as defined by the laboratory reference values [documentation required] AND b.The patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values [documentation required].
Continuation of therapy: Patient meets both of the following (1 and 2):
1. Medical chart documentation of the number and severity of HAE attacks occurring in the previous 6 months

2. Patient has experienced a reduction in the number of HAE attacks from baseline

PART B PREREQUISITE

N/A

ORSERDU

MEDICATION(S)
ORSERDU

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

OTEZLA

MEDICATION(S)
OTEZLA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARD)

REQUIRED MEDICAL INFORMATION
For Psoriatic Arthritis, the member must have a confirmed diagnosis of active Psoriatic Arthritis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Rheumatologist, Dermatologist.

COVERAGE DURATION
Lifetime.

OTHER CRITERIA
For non axial forms of Psoriatic Arthritis, must first try and fail methotrexate for at least two months, OR if the member has an absolute contraindication to methotrexate, then Otezla will be approved. For axial forms of Psoriatic Arthritis, Otezla will be approved. For Plaque Psoriasis, the member must first try and fail over a three month period to one of the following: Methotrexate, Oral retinoids, cyclosporine, phototherapy. Behcet's-patient has oral ulcers or other mucocutaneous involvement AND patient has tried at least ONE other systemic therapy.

PART B PREREQUISITE
N/A

OXERVATE

MEDICATION(S)
OXERVATE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Treatment duration greater than 16 weeks per affected eye

REQUIRED MEDICAL INFORMATION
Diagnosis, Documentation of decreased or loss of corneal sensitivity and corneal epithelium changes, Documentation of treatment of underlying conditions if appropriate (e.g. herpetic eye disease, diabetes, dry eye, multiple sclerosis, etc.), discontinuation of ophthalmic steroids or avoidance of ophthalmic preservatives

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, an ophthalmologist

COVERAGE DURATION
2 months

OTHER CRITERIA
Initial Therapy in patients who have never received Oxervate: Approve if patient has diagnosis of neurotrophic keratitis. For Patients Who Have Previously Received Oxervate: approve if the patient meets the following criteria (i and ii): i. Patient has previously received 8 weeks or less of treatment per affected eye(s) AND ii. Patient has a recurrence of neurotrophic keratitis.

PART B PREREQUISITE
N/A

OXLUMO

MEDICATION(S)
OXLUMO

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 a nephrologist or urologist (initial therapy)

COVERAGE DURATION
Initial: 6 months. Continuation: 1 year.

OTHER CRITERIA
Primary Hyperoxaluria Type 1 Initial therapy-Approve if the patient meets i, ii, and iii: i. Patient has had a genetic test confirming the diagnosis of Primary Hyperoxaluria Type 1 via identification of an alanine:glyoxylate aminotransferase gene (AGXT) mutation AND ii. Patient has elevated urine oxalate excretion as demonstrated by ONE of the following (a or b): a) Patient has a urinary oxalate excretion greater than or equal to 0.7 mmol/24 hours/1.73 meters2 OR b) Patient has a urinary oxalate:creatinine ratio above the age-specific upper limit of normal AND iii. Patient has not previously received a liver transplant for primary hyperoxaluria Type 1. Primary Hyperoxaluria Type 1 Continuation therapy-approve if the patient is continuing to derive benefit from Oxlumo as determined by the most recent (i.e., within the past 6 months) objective measurement. Note: Examples of objective measurements of a response to Oxlumo therapy are reduced urinary oxalate excretion, decreased urinary oxalate:creatinine ratio, or reduced plasma oxalate levels from baseline (i.e., prior to Oxlumo therapy)

or improved or stabilized clinical signs/symptoms of Primary Hyperoxaluria Type 1 (e.g., nephrocalcinosis, formation of renal stones, renal impairment).

PART B PREREQUISITE

N/A

PANCREATIC ENZYMES

MEDICATION(S)
PANCREAZE, VIOKACE

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
Creon and Zenpep are 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

PANRETIN

MEDICATION(S)
PANRETIN

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

PARATHYROID HORMONE AGENTS

MEDICATION(S)
FORTEO, TERIPARATIDE, TYMLOS

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

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, ADCETRIS, 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, ALYMSYS, AMPHOTERICIN B 50 MG VIAL, AMPHOTERICIN B LIPOSOME, ANZEMET, APREPITANT, ARFORMOTEROL TARTRATE, ARSENIC TRIOXIDE, ARZERRA, ASPARLAS, ASTAGRAF XL, ATGAM, AVASTIN, AZACITIDINE, AZATHIOPRINE 100 MG TABLET, AZATHIOPRINE 50 MG TABLET, AZATHIOPRINE 75 MG TABLET, BAVENCIO, BCG (TICE STRAIN), BELEODAQ, BENDAMUSTINE HCL, BESPONSA, BLEOMYCIN SULFATE, BLINCYTO 35MCG VL W-STABILIZER, 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, BUDESONIDE 0.25 MG/2 ML SUSP, BUDESONIDE 0.5 MG/2 ML SUSP, BUDESONIDE 1 MG/2 ML INH SUSP, CARBOPLATIN, CARMUSTINE, CIDOFOVIR 375 MG/5 ML VIAL, CINACALCET HCL, CISPLATIN 100 MG/100 ML VIAL, CISPLATIN 200 MG/200 ML VIAL, CISPLATIN 50 MG VIAL, CISPLATIN 50 MG/50 ML VIAL, CLADRIBINE, CLINIMIX, CLINIMIX E, CLOFARABINE, COSMEGEN, 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, CYRAMZA, CYTARABINE, CYTOGAM, DACARBAZINE, DACTINOMYCIN, DANYELZA, DARZALEX, DARZALEX FASPRO, DAUNORUBICIN HCL, DECITABINE, DOCETAXEL 160 MG/16 ML VIAL, DOCETAXEL 160 MG/8 ML VIAL, DOCETAXEL 20 MG/2 ML VIAL, DOCETAXEL 20 MG/ML VIAL, DOCETAXEL 80 MG/4 ML VIAL, DOCETAXEL 80 MG/8 ML VIAL, DOXORUBICIN HCL, DOXORUBICIN HCL LIPOSOME, DRONABINOL, EMEND 125 MG POWDER PACKET, EMPLICITI, ENGERIX-B ADULT, ENGERIX-B PEDIATRIC-ADOLESCENT, ENHERTU, ENVARSUS XR, EPIRUBICIN 200 MG/100 ML VIAL, EPIRUBICIN 50 MG/25 ML VIAL, ERBITUX, ERIBULIN MESYLATE, ERWINASE, ETOPOSIDE 1,000 MG/50 ML VIAL, ETOPOSIDE 100 MG/5 ML VIAL, ETOPOSIDE 500 MG/25 ML VIAL, EVEROLIMUS 0.25 MG TABLET, EVEROLIMUS 0.5 MG TABLET, EVEROLIMUS 0.75 MG TABLET, EVEROLIMUS 1 MG TABLET, 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, FORMOTEROL 20 MCG/2 ML NEB VL, FOSCARNET

SODIUM, GANCICLOVIR SODIUM, GEMCITABINE HCL, GENGRAF, GRANISETRON HCL 1 MG TABLET, HALAVEN, HEPLISAV-B, HERCEPTIN 150 MG VIAL, HERCEPTIN HYLECTA, HERZUMA, IDARUBICIN HCL, IFOSFAMIDE, IMFINZI, INFUGEM, INTRALIPID, IPRATROPIUM BR 0.02% SOLN, IPRATROPIUM-ALBUTEROL, IRINOTECAN HCL, IXEMPRA, JEVTANA, JYNNEOS, JYNNEOS (NATIONAL STOCKPILE), KADCYLA, KANJINTI, KEMOPLAT, KEYTRUDA, KHAPZORY, KITABIS PAK, KYPROLIS, 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, LEVALBUTEROL CONCENTRATE, LEVALBUTEROL HCL, LEVOLEUCOVORIN CALCIUM, LIBTAYO, MARQIBO, MELPHALAN, MELPHALAN HCL, METHOTREXATE 1 GM VIAL, METHOTREXATE 2.5 MG TABLET, METHOTREXATE 250 MG/10 ML VIAL, METHOTREXATE 50 MG/2 ML VIAL, METHOTREXATE SODIUM, MITOMYCIN 20 MG VIAL, MITOMYCIN 40 MG VIAL, MITOMYCIN 5 MG VIAL, MITOXANTRONE HCL, MONJUVI, MVASI, MYCOPHENOLATE 200 MG/ML SUSP, MYCOPHENOLATE 250 MG CAPSULE, MYCOPHENOLATE 500 MG TABLET, MYCOPHENOLIC ACID, NELARABINE, NIPENT, OGIVRI, ONCASPAR, 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, ONIVYDE, ONTRUZANT, OXALIPLATIN, PACLITAXEL, PACLITAXEL PROTEIN-BOUND, PADCEV, 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, PENTAMIDINE 300 MG INHAL POWDR, PERJETA, PLENAMINE, PRALATREXATE, PREHEVBRIO, PREMASOL, PROGRAF 0.2 MG GRANULE PACKET, PROGRAF 1 MG GRANULE PACKET, PROLEUKIN, PROSOL, PULMOZYME, RECOMBIVAX HB, RIABNI, RITUXAN, RITUXAN HYCELA, ROMIDEPSIN, RUXIENCE, SANDIMMUNE 100 MG/ML SOLN, SIROLIMUS 0.5 MG TABLET, SIROLIMUS 1 MG TABLET, SIROLIMUS 1 MG/ML SOLUTION, SIROLIMUS 2 MG TABLET, SYLVANT, SYNDROS, 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), TECENTRIQ, TEMODAR 100 MG VIAL, TEMSIROLIMUS, THIOTEPA 100 MG VIAL, THIOTEPA 15 MG VIAL, TOBRAMYCIN 300 MG/4 ML AMPULE, TOBRAMYCIN 300 MG/5 ML AMPULE, TOPOTECAN HCL 4 MG VIAL, TOPOTECAN HCL 4 MG/4 ML VIAL, TRAVASOL, TRAZIMERA, TROPHAMINE, TRUXIMA, VALRUBICIN, VARUBI, VECTIBIX, VEGZELMA, VINBLASTINE SULFATE, VINCASAR PFS, VINCRISTINE SULFATE, VINORELBINE TARTRATE, VYXEOS, YERVOY, YONDELIS, YUPELRI, ZALTRAP, ZANOSAR, ZEPZELCA, ZIRABEV

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.

PCSK9 INHIBITORS

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

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use of Juxtapid, Kynamro or Leqvio. Concurrent use with Praluent.

REQUIRED MEDICAL INFORMATION
Prior therapies tried

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a Cardiologist/lipid/cardiometabolic specialist/endocrinologist.

COVERAGE DURATION
3 years

OTHER CRITERIA
For Heterozygous Familial Hypercholesterolemia and Clinical Atherosclerotic Cardiovascular Disease, the member must have tried and failed ONE high intensity statin (for example, atorvastatin greater than or equal to 40mg daily or rosuvastatin greater or equal to 20mg daily), unless a physician has diagnosed rhabdomyolysis or the member is determined to be statin intolerant. Statin intolerance is defined by experiencing statin related skeletal-related muscle symptoms while receiving two separate trials of statins and during both trials the skeletal-related symptoms resolved during drug discontinuation. The statin trials may be either a trial of two different statins or a rechallenge of the same statin at a lower dose. The member need not exceed two trials total to confirm intolerance. Additionally, for Clinical Atherosclerotic Cardiovascualar Disease, the treatment must be for secondary prevention, which requires a history of one of the following conditions: prior MI, history of acute coronary syndrome, diagnosis of angina, history of stroke or transient ischemic attack, peripheral

arterial disease, undergone a coronary or other arterial revascularization procedure. Homozygous Familial Hypercholesterolemia approve if: 1) has one of the following: a) genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus, OR b) untreated LDL greater than 500 mg/dL (prior to treatment), OR c) treated LDL greater than or equal to 300 mg/dL (after treatment but prior to agents such as Repatha, Kynamro or Juxtapid), OR d) has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma), AND 2) tried ONE high intensity statin (defined above) for 8 weeks or longer and LDL remains 70 mg/dL or higher unless statin intolerant (defined above). Allow approval for primary hyperlipidemia (not associated with ASCVD, HeFH or HoFH) with the following requirements (a. AND b.): a. The member tried one high-intensity statin therapy (defined above)(unless member is determined to be statin intolerant [defined above]) and ezetimibe for 8 weeks AND b. LDL remains 100 mg/dL or higher unless statin intolerant (defined above).

PART B PREREQUISITE

N/A

PEGFILGRASTIM

MEDICATION(S)
FULPHILA, FYLNETRA, NEULASTA, NEULASTA ONPRO, NYVEPRIA, STIMUFEND, UDENYCA, UDENYCA AUTOINJECTOR, UDENYCA ONBODY, ZIEXTENZO

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

PEMAZYRE

MEDICATION(S)
PEMAZYRE

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

PHESGO

MEDICATION(S)
PHESGO

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

PIQRAY

MEDICATION(S)
PIQRAY

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

POLIVY

MEDICATION(S)
POLIVY

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

POMALYST

MEDICATION(S)
POMALYST

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

PORTRAZZA

MEDICATION(S)
PORTRAZZA

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

POTELIGEO

MEDICATION(S)
POTELIGEO

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

PREVYMIS

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

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
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
4 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

PROCYSBI

MEDICATION(S)
PROCYSBI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use of Cystagon and Procysbi

REQUIRED MEDICAL INFORMATION
Diagnosis, genetic tests and lab results

AGE RESTRICTION
N/A

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

COVERAGE DURATION
1 year

OTHER CRITERIA
Cystinosis, nephropathic – approve if the member meets all of the following (1 and 2): 1. Prescriber confirms the diagnosis was confirmed by genetic testing confirming a mutation of the CTNS gene OR white blood cell cystine concentration above the upper limit of the normal reference range for the reporting laboratory AND 2. Member has tried and failed Cystagon.

PART B PREREQUISITE
N/A

PROMACTA

MEDICATION(S)
ALVAIZ, PROMACTA

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

OFF LABEL USES
Thrombocytopenia in myelodysplastic syndrome (MDS), Thrombocytopenia post-allogeneic transplantation

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chronic ITP is defined as greater than 6 months. For ITP, baseline platelet count must be less than 30,000/mm3, OR baseline platelet count must be 30,000-50,000/mm3 AND in the presence of a clinically significant previous bleeding episode OR at high risk of experiencing a clinically significant bleeding episode (for example, upcoming surgery, if the member is at high risk of falls, etc.). For continuation of therapy, a clinically positive response is either a platelet count with a positive increase to greater than 50,000/mm3 OR a clinically significant improvement in bleeding status if platelet count remains less than 50,000/mm3. If the platelet count does not increase after 4 weeks at maximum dose, then therapy will not be reauthorized. Diagnosis of Severe Aplastic Anemia, as defined based on the criteria of the International Aplastic Anemia Study Group (IAASG), requires that the member meet BOTH of the following criteria (1 and 2): (1.) Any two or three of the following peripheral blood criteria (Neutrophils less than 0.5 x 10 to the 9th/L AND/OR Platelets less than 20 x 10 to the 9th/L AND/OR Reticulocytes less than 1% corrected (percentage of actual hematocrit to normal hematocrit)) AND (2.) Any one of the following marrow criteria (Severe hypocellularity OR Moderate hypocellularity with hematopoietic cells representing less than 30% of residual cells). For MDS - platelet counts. For post-allogeneic thrombo: diagnosis, platelet count.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
For Hepatitis C related thrombocytopenia, must be prescribed by or in consultation with a gastroenterologist, hematologist, or infectious disease physician. MDS - prescribed by or in

consultation with hematologist or oncologist. Thrombocytopenia post-allogeneic transplant - prescribed by or in consultation with a hematologist, oncologist or stem cell transplant specialist.

COVERAGE DURATION

ITP, transplant thrombo 90 day init, w/pos clinical resp 1 yr. Hep C/MDS thrmbocytpna and AA-12mo.

OTHER CRITERIA

For chronic ITP must try and have insufficient response to (defined as the inability to achieve a platelet count of greater than 50,000/mm3) or be intolerant to both of the following: Corticosteroids AND one of either splenectomy, IVIG, or anti-D immunoglobulins. For Hepatitis C related thrombocytopenia, if currently on interferon based therapy, the member must have attempted and failed to improve platelet levels through interferon dose reduction. For aplastic anemia, the member will use the requested medication in combination with standard immunosuppressive therapy or had an insufficient response to immunosuppresive therapy. For MDS - approve if patient has low- to intermediate-risk MDS AND according to the prescriber the patient has clinically-significant thrombocytopenia (e.g. low platelet counts [pretreatment], is platelet transfusion-dependent, active bleeding, and/or a history of bleeding at low platelet counts.). For thrombocytopenia post-allogeneic transplantation: Initial therapy: Approve if patient meets both of the following (i and ii):
i. Patient has poor graft function, ii.Has a platelet count less than 50,000/mcL. Continuation therapy: Patient has demonstrated a beneficial clinical response.

PART B PREREQUISITE

N/A

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

PYRUKYND

MEDICATION(S)
PYRUKYND

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Patients with Pyruvate Kinase Deficiency homozygous for the c.1436G to A variant/mutation in the pyruvate kinase liver and red blood cell (PKLR) gene or patients with two non-missense variants/mutations (without the presence of other missense variant/mutation) in the PKLR gene.

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hematologist

COVERAGE DURATION
Initial: 6 months, Continuation: 1 year

OTHER CRITERIA
Hemolytic Anemia due to pyruvate kinase deficiency:Initial Therapy. Approve if the patient meets both of the following (i and ii): i.Patient meets both of the following (a and b): a.Presence of at least two variant/mutant alleles in the PKLR gene b.At least one of the variant/mutant alleles was a missense variant AND ii.Patient meets one of the following (a or b): a.Patient has a current hemoglobin level less than or equal to 10 g/dL or b.Patient is currently receiving red blood cell transfusions regularly, defined as at least 6 transfusions within the last year. Continuation of Therapy. Approve if the patient meets the following (i, ii, and iii): i.Patient meets both of the following (a and b): a.Presence of at least two variant/mutant alleles in the PKLR gene AND b.At least one of the variant/mutant alleles was a missense variant AND ii.Patient has current hemoglobin less than or equal to 12.0 g/dL AND

iii.According to the prescriber, the patient has experienced a benefit from therapy based on one of the following (a, b or c): a.Increase in or maintenance of hemoglobin levels OR b.Improvement in or maintenance of hemolysis laboratory parameters (e.g. indirect bilirubin, lactate dehydrogenase, and haptoglobin) OR c.Decrease in or maintenance of transfusion requirements

PART B PREREQUISITE

N/A

QINLOCK

MEDICATION(S)
QINLOCK

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

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 episodic migraine: For initial therapy: Approve if the patient meets (A, B and C): 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, Emgality, or Ajovy, C) Patient has tried and failed one of the following drug classes prior to approval of Qulipta: Beta blockers (ex. Metoprolol, Propranolol, and Timolol), Antidepressants (ex. Amitriptyline, Nortriptyline, and Venlafaxine), Anticonvulsants (ex. Valproate and Topiramate) or Calcium Channel Blockers (ex. Verapamil). For continuation of therapy: Prescriber confirms that the member demonstrates improvement after a 3-month trial.
Preventative treatment of chronic migraine - initial therapy: Approve if the patient meets the following (A and B):
A) Patient has a diagnosis of chronic migraine as indicated by 15 or more attacks per month, for 3 or

more months in a row, that include BOTH of the following: Headache Symptoms (as indicated by 2 or more of the following: unilateral location and/or pulsating quality and/or moderate to severe pain intensity and/or aggravation by or causing avoidance of routine physical activity) AND Associated Symptoms (as indicated by 1 or more of the following: Nausea/vomiting and/or photophobia). B) Patient has tried and failed two different drug classes prior to Qulipta approval: Beta blockers (ex. Metoprolol, propranolol, and timolol), antidepressants (ex. Amitriptyline, nortriptyline, venlafaxine), anticonvulsants (ex. Valproate and topiramate) and calcium channel blockers (ex. Verapamil). For continuation of therapy: Prescriber confirms that the member demonstrates improvement after a 3-month trial.

PART B PREREQUISITE

N/A

RADICAVA

MEDICATION(S)
RADICAVA ORS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, previous medication trials, ALSFRS-R score, FVC. For reauth: documentation that use of the drug has slowed the progression of ALS and function is improved relative to the expected natural course of the disease.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS.

COVERAGE DURATION
6 months

OTHER CRITERIA
ALS Initial treatment: Approve if patient meets ALL of the following (a, b, c, d, and e) a.According to the prescriber, the patient has a definite or probable diagnosis of ALS based on the application of the El Escorial or the revised Airlie House diagnostic criteria AND b.Patient has a score of two points or more on each item of the ALS Functional Rating Scale Revised (ALSFRS-R) as assessed and documented in the past 3 months [i.e. has retained most or all activities of daily living] AND c. Patient has a percent-predicted forced vital capacity (FVC) greater than or equal to 80 percent (i.e. has normal respiratory function) AND d. Patient has been diagnosed with ALS for less than or equal to 2 years AND e. Patient has received or is currently receiving riluzole (tablets, oral suspension or oral film). ALS Currently

receiving Radicava: 1. Approve if the patient meets both of the following (a and b): a. Member had met initial criteria requirements at time of medication being started AND b. According to the prescriber, the patient continues to benefit from therapy.

PART B PREREQUISITE

N/A

REGRANEX

MEDICATION(S)
REGRANEX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Treatment of pressure ulcers, venous stasis ulcers or ischemic diabetic ulcers

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
5 months

OTHER CRITERIA
Diabetic Neuropathic Ulcers – patient meets all of the following (1, 2, 3, and 4): 1. Treatment will be given in combination with ulcer would care (e.g., debridement, infection control, pressure relief) AND 2. Treatment is for lower extremity diabetic ulcers, AND 3. Ulcer extends into the subcutaneous tissue or beyond AND 4. Ulcer has adequate blood supply

PART B PREREQUISITE
N/A

RELYVRIO

MEDICATION(S)
RELYVRIO

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 a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS

COVERAGE DURATION
6 months

OTHER CRITERIA
ALS initial therapy Approve if the patient meets ALL of the following (a, b, c, d, e and f): a. The patient has a definite diagnosis of ALS based on the application of the revised El Escorial criteria, b. Patient does not have a tracheostomy, c. Patient has a percent-predicted slow vital capacity (SVC) greater than 60 percent based on gender, height and age, d. Onset of ALS symptoms began within the preceding 18 months, e. Patient meets one of the following (i, ii, iii): i. Patient has previously received a riluzole product, ii. Patient is currently receiving a riluzole product, iii.Patient will take Relyvrio concomitantly with a riluzole product, f. Patient will not use Relyvrio concomitantly with any other medications containing phenylbutyrate or taurursodiol, including over-the-counter supplements. ALS continuation therapy Approve if the patient meets ALL of the following (a and b): a. Patient will not use Relyvrio concomitantly with any other medications containing phenylbutyrate or taurursodiol including

over-the-counter supplements and b. Patient continues to benefit from therapy as attested by the prescriber.

PART B PREREQUISITE

N/A

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. 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

RETEVMO

MEDICATION(S)
RETEVMO

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

REVATIO

MEDICATION(S)
ALYQ, SILDENAFIL 20 MG TABLET, TADALAFIL 20 MG TABLET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Erectile dysfunction. Benign Prostatic hyperplasia.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Lifetime.

OTHER CRITERIA
N/A

PART B PREREQUISITE
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

REZLIDHIA

MEDICATION(S)
REZLIDHIA

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

REZUROCK

MEDICATION(S)
REZUROCK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
12 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
GVHD-Patient has chronic GVHD and has tried at least two prior lines of systemic therapy for GVHD.

PART B PREREQUISITE
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

RILUTEK

MEDICATION(S)
EXSERVAN, 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

RINVOQ

MEDICATION(S)
RINVOQ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with a biologic, targeted synthetic DMARD, other potent immunosuppressants, anti-interleukin monoclonal antibodies, janus kinase inhibitors or with Xolair.

REQUIRED MEDICAL INFORMATION
Diagnosis, concurrent medications, previous drugs tried

AGE RESTRICTION
RA/UC/CD/AS/nr-axSpA-18 years and older. AD-12 years and older. pJIA, PsA-2 years and older.

PRESCRIBER RESTRICTION
RA/AS/nr-axSpA/pJIA: Prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. AD-prescribed by or in consultation with an allergist, immunologist or dermatologist. UC/CD-prescribed by or in consultation with a gastroenterologist.

COVERAGE DURATION
3 years

OTHER CRITERIA
RA: approve if the patient has active psoriatic arthritis and has had an inadequate response with a 3 month trial of at least one tumor necrosis inhibitor or was unable to tolerate a 3 month trial. PsA- approve if the patient has active psoriatic arthritis and has had an inadequate response with a 3 month trial of at least one tumor necrosis inhibitor or was unable to tolerate a 3 month trial. AD- approve if the patient meets all of the following requirements (a, b, and c): a. Patient has atopic dermatitis involvement estimated to be equal to or greater than 10% of the body surface area (BSA) according to the prescribing physician AND b. Has refractory, moderate to severe atopic dermatitis AND c. Patient

meets all of the following treatment options (i AND ii): i. History of failure, contraindication, or intolerance to one of the following therapeutic classes of topical therapies (document drug, date of trial, and/or contraindication to medication (a, b, or c) a. Medium to very-high potency topical corticosteroid for 2 weeks, b. Topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)] for 6 weeks, c. Eucrisa (crisaborole) AND ii.One of the following (a or b): a. Phototherapy (UVB or PUVA) has failed to achieve and maintain remission of low or mild disease activity state OR b. Systemic treatment [e.g., oral corticosteroid, intramuscular corticosteroid, oral cyclosporine, oral azathioprine, oral methotrexate, or oral mycophenolate mofetil]. UC Approve if the patient has had a 3 month trial of at least one TNFi or was unable to tolerate a 3 month trial. CD - Approve if the patient has had a 3 month trial of at least one TNFi or was unable to tolerate a 3 month trial. AS - Approve if the patient has had a 3 month trial of at least one TNFi or was unable to tolerate a 3 month trial. nr-axSpA Approve if the patient meets both of the following (a and b): a. Patient has objective signs of inflammation, defined as C-reactive protein beyond the upper limit of normal for the reporting laboratory or sacroiliitis reported on magnetic resonance imaging. b. Patient has had a 3 month trial of at least one TNFi or was unable to tolerate a 3 month trial. pJIA: approve if the patient meets both of the following (a and b): a. Patient has a confirmed diagnosis of active polyarticular juvenile idiopathic arthritis, b. Patient has had a 3 month trial of at least one TNFi or was unable to tolerate a 3 month trial.

PART B PREREQUISITE

N/A

ROZLYTREK

MEDICATION(S)
ROZLYTREK

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

RUBRACA

MEDICATION(S)
RUBRACA

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

RYBREVANT

MEDICATION(S)
RYBREVANT

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

RYDAPT

MEDICATION(S)
RYDAPT

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

RYLAZE

MEDICATION(S)
RYLAZE

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

RYSTIGGO

MEDICATION(S)
RYSTIGGO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Use with other immunomodulatory biologic therapies

REQUIRED MEDICAL INFORMATION
Diagnosis, MG-ADL score

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist

COVERAGE DURATION
Initial: 6 months, Continuation: 1 year

OTHER CRITERIA
Initial Coverage: Approve if the patient meets all of the following: 1. Patient has confirmed anti-acetylcholine receptor antibody-positive generalized myasthenia gravis or confirmed anti-muscle tyrosine kinase antibody-positive generalized myasthenia gravis 2. Patient has Myasthenia Gravis Foundation of America class II to IV disease 3. Documentation of Myasthenia Gravis Activities of Daily Living (MG-ADL) total score of at least 3 for non-ocular symptoms AND a. Patient has had an inadequate response to initial therapy based on their antibodies: i. AChR+ disease: a minimum one-year trial of concurrent use with two or more immunosuppressive therapies (e.g. corticosteroids plus an immunosuppressant such as azathioprine, cyclosporine, mycophenolate, etc.) OR ii. MuSK+ disease: a minimum one-year trial with immunosuppressive therapy (e.g. corticosteroids, azathioprine, or mycophenolate) and rituximab OR 4. Patient has evidence of unresolved symptoms of generalized myasthenia gravis, for example: difficulty swallowing, difficulty breathing, or a functional disability

resulting in the discontinuation of physical ability (e.g. double vision, talking, impairment of mobility) 5. Treatment cycles are no more frequent than every 63 days from the start of the previous treatment cycle Continuation: Approve if the patient meets all of the following: 1. Documentation the patient has experienced a therapeutic response as defined by an improvement in the MG-ADL total score from baseline (prior to starting Rystiggo therapy) 2. Treatment cycles are no more frequent than every 63 days from the start of the previous treatment cycle

PART B PREREQUISITE

N/A

RYTELO

MEDICATION(S)
RYTELO

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

SAMSCA

MEDICATION(S)
TOLVAPTAN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Patients requiring urgent intervention to raise serum sodium acutely. Patients unable to sense or appropriately respond to thirst. Patients with hypovolemic hyponatremia. Concomitant use of strong CYP 3A inhibitors. Patients who are anuric. Liver disease.

REQUIRED MEDICAL INFORMATION
The diagnosis must be clinically significant hyponatreima, hypervolemic or euvolemic, defined as serum sodium less than 125meq/l or less marked hyponatremia, defined as serum sodium less than 135 mEq/L at baseline, and the patient must be symptomatic (symptoms may include nausea/vomiting, headache, confusion, lethargy, fatigue, loss of appetite, restlessness and irritability, muscle weakness, spasm, cramps, seizures, decreased consciousness, or coma), including patients with heart failure, cirrhosis, and SIADH.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
30 days.

OTHER CRITERIA
Therapy must be initiated or re-initiated in a hospital setting. The patient must have failed or resisted correction with one other means of treatment, such as loop diuretics, hypertonic saline, or salt tablets. The patient has been discontinued from any other possible cases of drug-induced hyponatremia or SIADH (such as carbamazepine, oxcarbazepine, chlorpropamide, fluoxetine, sertraline, vincristine,

vinblastine, cisplatin, cyclophosphamide, thiothixene, thioridazine, haloperidol, amitriptyline, MAO inhibitors, methotrexate, NSAIDs, interferon alpha and gamma, amiodarone, ciprofloxacin, and opiates).

PART B PREREQUISITE

N/A

SANDOSTATIN

MEDICATION(S)
OCTREOTIDE ACETATE, SANDOSTATIN LAR DEPOT

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

OFF LABEL USES
Pheochromocytoma/paraganglioma, Meningioma, Thyoma and thymic carcinoma

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, previous treatments/therapies

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
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

SARCLISA

MEDICATION(S)
SARCLISA

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

SCEMBLIX

MEDICATION(S)
SCEMBLIX

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

SCIG

MEDICATION(S)
CUTAQUIG, 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

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. PI – applies to all products: 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 – applies to all products except HyQvia: 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

SGLT-2

MEDICATION(S)
DAPAGLIFLOZIN, DAPAGLIFLOZIN-METFORMIN ER, FARXIGA, SEGLUROMET, STEGLATRO, XIGDUO XR

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, Jardiance, Synjardy and Synjardy 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

SIGNIFOR

MEDICATION(S)
SIGNIFOR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Medication history

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

SIGNIFOR LAR

MEDICATION(S)
SIGNIFOR LAR

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

OFF LABEL USES
Endogenous Cushing's Syndrome, awaiting surgery or therapeutic response after radiotherapy.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Medication history

AGE RESTRICTION
18 years and older (initial therapy)

PRESCRIBER RESTRICTION
Cushing's disease/syndrome: Prescribed by, or in consultation with, an endocrinologist or a physician that specializes in the treatment of Cushing's syndrome. Acromegaly: prescribed by, or in consultation with, an endocrinologist.

COVERAGE DURATION
Cushing's: initial – 4 months. Cont – 1 year. Patient awaiting surgery or response after radiotherapy – 4 months. Acromegaly – 1 year.

OTHER CRITERIA
For Cushing's disease/syndrome – Approve Signifor LAR 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/Signifor LAR and, according to the prescribing physician, the patient has had a response and continuation of therapy is needed to maintain response. For Acromegaly – approve Signifor LAR if the following criteria are met: 1) Patient has pre-treatment (baseline) insulin-like growth factor-1 (IGH-1) level above the upper limit of normal based on age and gender for the reporting laboratory AND 2) Patients meets one of the following (a, b or c): a) Has had an inadequate response to surgery and/or

radiotherapy OR b) Is not an appropriate candidate for surgery and/or radiotherapy OR c) The patient is experiencing negative effects due to tumor size (e.g. optic nerve compression).

PART B PREREQUISITE

N/A

SILIQ

MEDICATION(S)
SILIQ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).

REQUIRED MEDICAL INFORMATION
Diagnosis, prescriber specialty, other medications tried and length of trials.

AGE RESTRICTION
18 years of age or older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a dermatologist.

COVERAGE DURATION
Initial-4 months, Positive Response-Indefinite.

OTHER CRITERIA
The member meets all of the following indication specific requirements (A and B): A. The patient meets either of the following criteria: 1) At least 5 percent of the body surface area was affected by plaque psoriasis at the time of diagnosis, or 2) Crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) were affected by plaque psoriasis at the time of diagnosis. B. The patient meets the following criteria: 1) Patient has the patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Skyrizi, Stelara SC, Otezla, or Cosentyx. Note: If the patient does not meet this requirement, a trial of a non-preferred adalimumab product will also count. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074), Simlandi, adalimumab-adaz, adalimumab-fkjp and Yusimry.

PART B PREREQUISITE

N/A

SIMPONI

MEDICATION(S)
SIMPONI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.

REQUIRED MEDICAL INFORMATION
For Rheumatoid Arthritis, the member must have a confirmed diagnosis of moderate to severe Rheumatoid Arthritis and the disease must be active. For Anklyosing Spondylitis, the member must have a confirmed diagnosis of Ankylosing Spondylitis as defined by presence of active disease for at least 4 weeks defined by any disease specific functional scoring tool (i.e. a BASDAI Index of at least 4, Health Assessment Questionnaire (HAQ), Modified Health Assessment Questionnaire (MHAQ), etc...) and an expert opinion based on clinical features, acute phase reactants and imaging modalities. For Psoriatic Arthritis, the member must have a confirmed diagnosis of Psoriatic Arthritis. For Ulcerative Colitis, the member must have a confirmed diagnosis of moderate to severe ulcerative colitis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RA/AS-prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or dermatologist. UC-prescribed by or in consultation with a gastroenterologist or a rheumatologist.

COVERAGE DURATION
AS 12wk initl,w/pos resp, 3 year. UC 8wk initl,w/remssn evidnce, 3 year. Othr aprvd indictn, 3 year.

OTHER CRITERIA
For AS, approve if the patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Cosentyx, Rinvoq or Xeljanz/XR (Note: If the patient does not meet this requirement, a trial of a non-

preferred adalimumab product will also count). For PsA, approve if the patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Cosentyx, Stelara, Otezla. Orencia, Rinvoq, Skyrizi, Xeljanz/XR (Note: If the patient does not meet this requirement, a trial of a non-preferred adalimumab product will also count). For RA, approve if the patient has tried two of the following: Enbrel, a preferred adalimumab product, Orencia, Rinvoq or Xeljanz/XR (Note: If the patient does not meet this requirement, a trial of a non-preferred adalimumab product will also count). For UC, approve if the patient has had a trial with a preferred adalimumab product, Stelara SC, Rinvoq, Skyrizi or Xeljanz/XR tablets (Note: If the patient does not meet this requirement, a trial of a non-preferred adalimumab product will also count). Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074), Simlandi, adalimumab-adaz, adalimumab-fkjp and Yusimry.

PART B PREREQUISITE

N/A

SKYCLARYS

MEDICATION(S)
SKYCLARYS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

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, 3, and 4): 1.Patient has had a trinucleotide repeat expansion assay genetic test confirming the diagnosis of Friedreich's ataxia [documentation required] 2.Patient has all of the following in the past year (a, b and c) a.Patient has a B-type natriuretic peptide (BNP) less than or equal to 200 pg/mL [documentation required], AND b.Patient has a left ventricular ejection fraction greater than or equal to 40% [documentation required], AND c.Patient has a hemoglobin A1c (HbA1c) less than or equal to 11 percent [documentation required] 3.Patient has been assessed using the modified Friedreich's Ataxia Rating Scale and has a score greater than or equal to 20, but less than or equal to 80 [documentation required] 4. Patient is ambulatory. Continuation Therapy – approve if patient meets all of the following (1 and 2): 1. Patient has had a trinucleotide repeat expansion assay genetic test confirming the

diagnosis of Friedreich’s ataxia [documentation required] 2.Patient continues to benefit from therapy, as demonstrated by a slowed progression on the modified Friedreich’s Ataxia Rating Scale [documentation required]

PART B PREREQUISITE

N/A

SKYRIZI

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

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).

REQUIRED MEDICAL INFORMATION
Diagnosis, prescriber specialty, other medications tried and length of trials.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
PP-Prescribed by or in consultation with a dermatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. CD, UC-prescribed by or in consultation with a gastroenterologist or rheumatologist.

COVERAGE DURATION
PP-Initial: 4 months Continuation if positive response: 3 years. PsA: 3 years. CD, UC-3 years.

OTHER CRITERIA
PP Initial Therapy-The patient meets ONE of the following conditions (a or b): a) The patient has tried at least one traditional systemic agent for psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light [PUVA]) for at least 3 months, unless intolerant. NOTE: An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic (e.g., a preferred adalimumab product [Humira (NDCs starting with -00074), Simlandi adalimumab-adaz, adalimumab-fkjp and Yusimry], a non-preferred adalimumab product, a certolizumab pegol product [Cimzia], an etanercept product [Enbrel, Erelzi], an infliximab product [e.g., Remicade, Inflectra, Renflexis],

Cosentyx [secukinumab SC injection], Ilumya [tildrakizumab SC injection], Siliq [brodalumab SC injection], Stelara [ustekinumab SC injection], Taltz [ixekizumab SC injection], or Tremfya [guselkumab SC injection]). These patients who have already tried a biologic for psoriasis are not required to 'step back' and try a traditional systemic agent for psoriasis)b) The patient has a contraindication to methotrexate (MTX), as determined by the prescribing physician. Continuation Therapy - Patient must have responded, as determined by the prescriber. PsA-The patient must have diagnosis of active psoriatic arthritis and meet ONE of the following (i or ii): i. For non axial forms of Psoriatic Arthritis, must first try and fail methotrexate for at least two months, OR if the member has an absolute contraindication to methotrexate, then Skyrizi will be approved OR ii. For axial forms of Psoriatic Arthritis, Skyrizi will be approved. CD-Approve if the patient meets all of the following: Confirmed diagnosis of moderately to severely active Crohn's disease AND patient meets one of the following: Patient has tried or is currently taking corticosteroids, corticosteroids are contraindicated, patient has tried one other systemic therapy for CD (e.g. azathioprine, 6-mercaptopurine, methotrexate, certolizumab, infliximab, ustekinumab, or vedolizumab), patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas, or patient has had ileocolonic resection (to reduce the chance of CD recurrence). Ulcerative colitis: A) Approve if the patient meets one of the following (i or ii): i.Patient has tried a systemic therapy (e.g. 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, infliximab, golimumab SC, or a corticosteroid such as prednisone or methylprednisolone) for 2 months or was intolerant to one of these agents OR ii. Patient has pouchitis and has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine (Rowasa) enema.

PART B PREREQUISITE

N/A

SKYTROFA

MEDICATION(S)
SKYTROFA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Greater than or equal to 1 year of age and less than 18 years old

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist (all dx except hypophysectomy)

COVERAGE DURATION
1 year

OTHER CRITERIA
GHD in pediatric pt, initial-Approve if pt meets A and B:A)Pt tried short-acting somatropin and experi inadeq efficacy or sig intol AND B)Pt meets 1 of the following (i, ii, iii, iv, or v): i.Pt meets 1 of the following (1 or 2): (1)Pt had 2 GH stim tests with following:levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND both tests show an inadeq resp as defined by peak GH resp which is below normal range as determined lab OR (2)Pt meets BOTH of the following (a and b): (a)Pt had at least 1 GH stim test with following:levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND test shows an inadeq resp as defined by peak GH resp which is below normal range as determined by lab AND (b)Pt has at least 1 risk factor for GHD(e.g., ht for age curve has deviated downward across 2 major height percentiles, child's growth rate is less than the expected normal growth rate based on age and gender, low IGF-1 and/or IGFBP-3 levels) ii.Pt has undergone brain radi or tumor resection AND pt meets at least 1 of the following (1 or 2): (1)Pt has had 1 GH stim test with

the following:levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND test shows an inadeq resp defined by a peak GH resp which is below normal range as determined by lab OR (2) Pt has def in at least 1 other pituitary hormone (i.e., adrenocorticotropic hormone, TSH, gonadotropin [LH and/or FSH def are counted as 1 def], or prolactin) iii. Pt has congenital hypopituitarism AND meets 1 of following (1 or 2): (1)Pt had 1 GH stim test with following:levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND test shows an inadeq resp defined by peak GH response which is below normal range as determined by lab OR (2)Pt has a def in at least 1 other pit hormone (i.e., adrenocorticotropic hormone, TSH, gonadotropin [LH and/or FSH def are counted as 1 def], or prolactin) and/or the pt has imaging triad of ectopic posterior pituitary and pituitary hypoplasia with abnormal pituitary stalk iv. Pt has panhypopituitarism and meets one of the following (1, 2, or 3): (1) Pt has pituitary stalk agenesis, empty sella, sellar or supra-sellar mass lesion, or ectopic posterior pituitary bright spot on MRI or CT, OR (2) Pt has 3 or more of the following pit hormone deficiencies: somatropin, adrenocorticotropic hormone, TSH, gonadotropin (LH and/or FSH def are counted as 1 def), and prolactin, OR (3) Pt has had 1 GH stim test with the following:levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the test shows an inadeq resp defined by a peak GH response which is below normal range as determined by lab. v. Patient has had a hypophysectomy-approve. GHD in a pediatric pt, cont-approve if the pt is responding to therapy.

PART B PREREQUISITE

N/A

SODIUM OXYBATE PRODUCTS

MEDICATION(S)
LUMRYZ, SODIUM OXYBATE, XYWAV

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use of sodium oxybate, Xywav, Wakix, Sunosi, modafinil and/or armodafinil

REQUIRED MEDICAL INFORMATION
Previous therapies

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by a sleep specialist physician or a Neurologist

COVERAGE DURATION
12 months

OTHER CRITERIA
For Excessive Daytime Sleepiness (EDS) in patients with narcolepsy-approve if the patient has tried two CNS stimulants (e.g., methylphenidate, dextroamphetamine), modafinil, or armodafinil and narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). Cataplexy treatment in patients with narcolepsy-approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). For Xywav only: Idiopathic hypersomnia approve if the patient's diagnosis has been confirmed using polysomnography and a multiple sleep latency test.

PART B PREREQUISITE
N/A

SOGROYA

MEDICATION(S)
SOGROYA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
For GHD in adult or transition adult: Use as anti-aging therapy, to enhance athletic ability, or for body building

REQUIRED MEDICAL INFORMATION
Diagnosis, test results (e.g., growth hormone stim test results)

AGE RESTRICTION
Greater than or equal to 2.5 year of age

PRESCRIBER RESTRICTION
Prescribed by or in consulation with an endocrinologist (all dx except hypophysectomy)

COVERAGE DURATION
1 year

OTHER CRITERIA
GHD child/adol,init-1of(i,ii,iii,iv,or,v):i. Either(1or2):1-Two stim tests w/ levodopa,insulin-induced hypoglyc, arginine, clonidine, or glucagon w/ BOTH resp below lab norm OR 2- BOTH (a and b):a-One stim test below lab norm AND b-at least 1 GHD risk factor ii.Brain radiation/tumor resection AND (1or2):1-One stim test below lab norm OR 2-One other pit horm defic (ACTH,TSH,gonadotrop[LH, FSH are 1],prolactin), OR iii.congenital hypopit AND one of (1,2or3):1-one stim test resp below lab norm OR 2-one other pit horm def OR 3-Imaging triad ectopic posterior pit and pit hypoplasia w/ abn pit stalk. iv.Mult pit horm defic and 1 of (1or2):1-3+ pit horm def: somatrop,ACTH,TSH,gonadotrop,prolact, OR 2-one stim test below lab norm. v.Hypophysectomy. GHD child/adol, cont-pt respond to tx. GHD Adult/Transition Adol-ALL of (A,B,C,andD):A)endo certify not for anti-aging/athletic ability/body building,AND B)GHD that is 1 of:Child onset OR Adult onset from 1 of:GHD alone or mult horm def

(hypopit) from pit dz, hypothalam dz, pit surgery, cranial radiation tx, tumor tx, TBI, or subarach hem, AND C)one of (i,ii,or iii): i.Known perinatal insults OR congenital/genetic defects, OR ii.ALL of: 3+ pit horm def: ACTH, TSH, gonadotropin defic, prolactin, AND IGF-1 below lab norm, AND Other causes of low IGF-1 excluded, OR iii. 1 of (a or b):a-Adult-Neg resp to stim test (1,2,3,4,5,or6):Note: arginine test peak less/eq to 0.4mcg/L, meets neg resp stim test. 1-Insulin tol test (3 GH levels in atleast 60min [not incl time zero], w/adeq hypoglycemia) peak less/equal to 5mcg/L, OR 2-Glucagon stim test (GST) (3 GH levels in at least 180min[not incl time 0]) peak less/eq to 3mcg/L AND BMI less than 25, OR 3-GST peak less/eq to 3mcg/L AND BMI gr/eq to 25 and less/eq to 30 w/ hi pretest prob of GHD, OR 4-GST peak less/eq to 1mcg/L AND BMI gr/eq to and less/eq to 30 w/low pretest prob of GHD, OR 5-GST peak less/eq to 1mcg/L AND BMI gr than 30, OR 6-Macrilen test (4 GH levels in atleast 90min[not incl time 0]) peak less than 2.8ng/mL AND BMI gr/eq to 40. OR b-Transition adol-BOTH of (1and2): Note: Macrilen peak less than 2.8ng/mL meets neg resp to stim.1-Pt off GH tx for at least month before retest AND 2-one of:(i,ii,iii,iv,v,or,vi): i-Insulin tol test peak less/eq to 5mcg/L, OR ii.GST peak less/eq to 3mcg/L AND BMI less than 25, OR iii. GST peak less/eq to 3mcg/L AND BMI gr/eq to 25 and less/eq to 30 w/hi pretest prob of GHD, OR iv-GST peak less/eq to 1mcg/L AND BMI gr/eq to 25 and less/eq to 30 w/ low pretest prob of GHD, OR v-GST peak less/eq to 1mcg/L AND BMI greater than 30, OR vi-If both insulin tol test AND GST contraind, arginine test can be used (3 GH levels in at least 120min[not incl time 0]) peak less/eq to 0.4mcg/L.

PART B PREREQUISITE

N/A

SOHONOS

MEDICATION(S)
SOHONOS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Female: 8 years or older, Male: 10 years or older (Female/Male are defined as an individual with the biological traits of a female/male, regardless of the individual's gender identity or gender expression)

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist, rheumatologist, orthopedist or physician who specializes in bone disease.

COVERAGE DURATION
1 year

OTHER CRITERIA
Fibrodysplasia ossificans progressive 1. Initial: Approve if the patient meets A and B: A) Patient has had a genetic test confirming a mutation in Activin A Type 1 Receptor (ACVR1)R206H consistent with a diagnosis of fibrodysplasia ossificans progressive, AND B) Patient has heterotopic ossification as confirmed by radiologic testing Note: Examples of radiologic testing are x-ray, computed tomography (CT), magnetic resonance imaging (MRI), or positron emission tomography (PET) scan. 2. Continuation: Approve if the patient meets the current criteria and the medication is providing clinical benefit, as attested by the provider.

PART B PREREQUISITE

N/A

SOMATULINE

MEDICATION(S)
LANREOTIDE 120 MG/0.5 ML SYRNG, SOMATULINE DEPOT

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

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

SOTYKTU

MEDICATION(S)
SOTYKTU

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with other biologics or with targeted synthetic disease-modifying antirheumatic drugs (DMARDs), Concurrent use with other potent immunosuppressants, including methotrexate

REQUIRED MEDICAL INFORMATION
For Plaque Psoriasis, the member must have a confirmed diagnosis of moderate to severe Plaque Psoriasis and defined as a minimum body surface area involvement of greater than or equal to 5%, or by involvement of the hands, feet, facial, or genital regions, by which, despite involvement of a smaller BSA, the disease may interfere significantly with activities of daily life.

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a dermatologist

COVERAGE DURATION
Lifetime

OTHER CRITERIA
For Plaque Psoriasis, the member must have tried TWO of the following: Enbrel, a preferred adalimumab product, Skyrizi, Stelara SC, Otezla or Cosentyx. Note: If the patient does not meet this requirement, a trial of a non-preferred adalimumab product will also count. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074), Simlandi, adalimumab-adaz, adalimumab-fkjp and Yusimry.

PART B PREREQUISITE

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

SPRYCEL

MEDICATION(S)
SPRYCEL

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

STELARA

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

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Ustekinumab should not be given in combination with a Biologic DMARD or Targeted Synthesis DMARD.

REQUIRED MEDICAL INFORMATION
The member must have a confirmed diagnosis of moderate to severe Plaque Psoriasis, defined as a minimum body surface area involvement of greater than or equal to 5%, or by involvement of the hands, feet, facial, or genital regions, by which, despite involvement of a smaller BSA, the disease may interfere significantly with activities of daily life. For Psoriatic Arthritis, the member must have a confirmed diagnosis of Psoriatic Arthritis.

AGE RESTRICTION
Adults-CD. PsA and PP-6 years and older

PRESCRIBER RESTRICTION
PP-prescribed by or in consultation with a dermatologist. PsA-prescribed by on in consultation with a rheumatologist or dermatologist. CD/UC-prescribed by or in consultation with a gastroenterologist or a rheumatologist.

COVERAGE DURATION
Lifetime.

OTHER CRITERIA
For Plaque Psoriasis, patient must have tried and failed over a three month period a trial of one of the following: methotrexate, an oral retinoid, cyclosporine, or phototherapy. For non axial forms of Psoriatic Arthritis, must first try and fail methotrexate for at least two months, OR if the member has an absolute contraindication to methotrexate, then Stelara will be approved. For axial forms of Psoriatic Arthritis,

Stelara will be approved. For Crohn's Disease-induction therapy, approve if the patient meets ONE of the following criteria: 1) patient has tried or is currently taking a corticosteroid, or corticosteroids are contraindicated, OR 2) patient has tried one other agent for CD (eg, azathioprine, 6-MP, MTX, certolizumab, vedolizumab, a preferred adalimumb product, infliximab. Note: If the patient does not meet this requirement, a trial of a non-preferred adalimumab product will also count), OR 3) patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR 4) Patient had ileocolonic resection (to reduce the chance of Crohns disease recurrence). For Crohn's Disease-non-induction therapy, approve the SC formulation if the patient meets ONE of the following criteria: 1) patient has tried or is currently taking a corticosteroid, or corticosteroids are contraindicated, OR 2) patient has tried one other agent for CD, OR 3) patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR 4) Patient had ileocolonic resection (to reduce the chance of Crohns disease recurrence). For Ulcerative Colitis - approve. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074), Simlandi, adalimumab-adaz, adalimumab-fkjp and Yusimry.

PART B PREREQUISITE

N/A

STIVARGA

MEDICATION(S)
STIVARGA

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

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

SUNOSI

MEDICATION(S)
SUNOSI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent treatment with monoamine oxidase inhibitor (MAOI) or use of an MAOI with the preceding 14 days. Concurrent use with Xyrem, Xywav and/or Wakix.

REQUIRED MEDICAL INFORMATION
Diagnosis, medications that will be used in combination, prior therapies

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist, sleep specialist, or pulmonologist

COVERAGE DURATION
1 year

OTHER CRITERIA
A. For Narcolepsy-One of the following (1 and 2): 1. The member tried and failed or has a contraindication to two first line products: Amphetamine/dextroamphetamine (amphetamine salt combinations), Dexmethylphenidate, Dextroamphetamine, Methamphetamine, Methylphenidate (or their branded products: Adderall, Adderall XR, Focalin, Focalin XR, Dexedrine Spansules, Procentra, Zenzedi, Desoxyn, Methylin, Concerta, Daytrana, Metadate CD, Metadate ER, Quillivant, Ritalin, Ritalin LA, Ritalin SR) OR Member has a history of substance abuse AND 2. Patient has been evaluated using polysomnography and a multiple sleep latency test (MSLT) and the diagnosis of narcolepsy has been confirmed. Excessive sleepiness associated with OSA - APPROVE if patient has tried generic modafinil or armodafinil.

PART B PREREQUISITE

N/A

SUTENT

MEDICATION(S)
SUNITINIB MALATE

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

SYMDEKO

MEDICATION(S)
SYMDEKO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant therapy with Orkambi, Kalydeco or Trikafta

REQUIRED MEDICAL INFORMATION
Cystic fibrosis diagnosis. Homozygous for F508 del mutation or Tezacaftor/Ivacaftor-responsive mutation in CFTR gene.

AGE RESTRICTION
6 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Lifetime.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

TABRECTA

MEDICATION(S)
TABRECTA

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

TAFAMIDIS

MEDICATION(S)
VYNDAMAX, VYNDAQEL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with Onpattro or Tegsedi. Concurrent use of Vyndaqel and Vyndamax.

REQUIRED MEDICAL INFORMATION
Diagnosis, genetic tests

AGE RESTRICTION
18 years and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis.

COVERAGE DURATION
1 year.

OTHER CRITERIA
For cardiomyopathy of Wild-Type or Hereditary Transthyretin Amyloidosis: approve if the patient meets all of the following: A. The patient has genetic testing to identify a transthyretin (TTR) mutation (e.g., Val122Ile mutation, Thr60Ala mutation) or wild-type amyloidosis AND B. The diagnosis was confirmed by one of the following (i or ii): i. A technetium pyrophosphate scan (i.e., nuclear scintigraphy) OR ii. Amyloid deposits are identified on cardiac biopsy AND C. Diagnostic cardiac imaging (e.g., echocardiogram, cardiac magnetic imaging) has demonstrated cardiac involvement (e.g., increased thickness of the ventricular wall or interventricular septum)

PART B PREREQUISITE
N/A

TAFINLAR

MEDICATION(S)
TAFINLAR

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

TAGRISSO

MEDICATION(S)
TAGRISSO

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

TAKHZYRO

MEDICATION(S)
TAKHZYRO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with other HAE prophylactic therapies (e.g. Haegarda, Orladeyo)

REQUIRED MEDICAL INFORMATION
Diagnosis. Lab values (C1-INH protein, C4 levels), reauth: number and severity of HAE attacks

AGE RESTRICTION
2 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an allergist/immunologist or a physician that specializes in the treatment of hereditary angioedema (HAE) or related disorders (initial and continuation).

COVERAGE DURATION
Initial: 6 months, Continuation: 1 year

OTHER CRITERIA
Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] – Prophylaxis
Initial Therapy: Approve if the patient meets all of the below: 1. The patient has HAE type I or type II as confirmed by the following diagnostic criteria (a and b): a. The patient has low levels of functional C1-INH protein at baseline, as defined by the laboratory reference values [documentation required] AND b. The patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values [documentation required].
Continuation of therapy: Patient meets both of the following (1 and 2):
1. Medical chart documentation of the number and severity of HAE attacks occurring in the previous 6 months

2. Patient has experienced a reduction in the number of HAE attacks from baseline

PART B PREREQUISITE

N/A

TALTZ

MEDICATION(S)
TALTZ AUTOINJECTOR, TALTZ AUTOINJECTOR (2 PACK), TALTZ AUTOINJECTOR (3 PACK), TALTZ SYRINGE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).

REQUIRED MEDICAL INFORMATION
The member must have a confirmed diagnosis of moderate to severe Plaque Psoriasis, defined as a minimum body surface area involvement of greater than or equal to 5%, or by involvement of the hands, feet, facial, or genital regions, by which, despite involvement of a smaller BSA, the disease may interfere significantly with activities of daily life. The member must have a confirmed diagnosis of active Psoriatic Arthritis. The member must have a confirmed diagnosis of active non-radiographic axial spondyloarthritis (nr-asXpA).

AGE RESTRICTION
Plaque psoriasis 6 years and older (initial therapy). All other diagnoses - 18 years of age and older.

PRESCRIBER RESTRICTION
PP-prescribed by or in consultation with a dermatologist. PsA-Prescribed by or in consultation with a rheumatologist or a dermatologist.

COVERAGE DURATION
Lifetime.

OTHER CRITERIA
For Plaque Psoriasis, approve if the patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Skyrizi, Stelara (SC), Otezla, of Cosentyx (Note: If the patient does not meet this requirement, a trial of a non-preferred adalimumab product will also count). For Psoriatic Arthritis,

approve if the patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Stelara SC, Otezla, Orencia, Xeljanz/XR, Cosentyx, Rinvoq or Skyrizi (Note: If the patient does not meet this requirement, a trial of a non-preferred adalimumab product will also count). For AS, approve if the patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Cosentyx, Rinvoq or Xeljanz/XR (Note: If the patient does not meet this requirement, a trial of a non-preferred adalimumab product will also count). For nr-asXpA, approve if the patient has tried TWO of the following: Cimzia, Cosentyx, or Rinvoq. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074), Simlandi, adalimumab-adaz, adalimumab-fkjp and Yusimry.

PART B PREREQUISITE

N/A

TALVEY

MEDICATION(S)
TALVEY

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

TALZENNA

MEDICATION(S)
TALZENNA

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

TARCEVA

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

TARGRETIN - ORAL

MEDICATION(S)
BEXAROTENE 75 MG CAPSULE

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

TARGRETIN TOPICAL

MEDICATION(S)
BEXAROTENE 1% GEL

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

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 0.75 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

TASIGNA

MEDICATION(S)
TASIGNA

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

TAVALISSE

MEDICATION(S)
TAVALISSE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, previous therapies tried. Pre-treatment platelet count of less than 50,000/microL.

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hematologist.

COVERAGE DURATION
Initial - 4 months. Continuation - 3 years.

OTHER CRITERIA
For initiation of therapy: Member must have an FDA-approved indication for Tavalisse with pre-treatment platelet count of less than 50,000/microL. Allow initial approval if the patient has tried two other therapies or the patient has undergone splenectomy. For continuation of therapy: Platelet count must increase to a level sufficient to avoid clinically important bleeding after 12 weeks of Tavalisse therapy.

PART B PREREQUISITE
N/A

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

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 Wegeners 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 or b): a) 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]. b) 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

TAZAROTENE

MEDICATION(S)
TAZAROTENE 0.05% GEL, 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

TAZVERIK

MEDICATION(S)
TAZVERIK

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

TECVAYLI

MEDICATION(S)
TECVAYLI

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

TEGSEDI

MEDICATION(S)
TEGSEDI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with Onpattro or a tafamidis product

REQUIRED MEDICAL INFORMATION
Diagnosis, genetic testing, biopsy results. PND, FAP or NIS score.

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist, geneticist, or a physician who specializes in the treatment of amyloidosis.

COVERAGE DURATION
1 year

OTHER CRITERIA
Initial: Approve if the patient meets all of the following (1, 2, 3 and 4):
1.Patient has a documented transthyretin (TTR) mutation verified by genetic testing
2.Patient has documentation of biopsy proven amyloid deposits
3.Patient has symptomatic polyneuropathy (e.g., reduced motor strength/coordination, impaired sensation [e.g., pain, temperate, vibration, touch]).
4.Patient meets one of the following (a, b or c): a. Baseline polyneuropathy disability (PND) score less than or equal to IIIb, b. Baseline familial amyloidotic polyneuropathy (FAP) stage 1 or 2, c. Baseline neuropathy impairment score (NIS) between 10 and 130
Continuation: Approve if the patient meets all of the following:
1.Patient has demonstrated a benefit from therapy (e.g. improved neurological impairment, slowing of

disease progression, quality of life assessment)
2.Patient meets one of the following (a, b or c): a. Patient continues to have a PND score less than or equal to IIIb, b. Patient continues to have a FAP stage 1 or 2, c. Patient continues to have a NIS between 10 and 130

PART B PREREQUISITE
N/A

TEPMETKO

MEDICATION(S)
TEPMETKO

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

TERIFLUNOMIDE

MEDICATION(S)
TERIFLUNOMIDE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
MS, patient must have a relapsing form of MS (RRMS, SPMS with relapses, or PRMS), clinically-isolated syndrome, or active secondary progressive disease with evidence of new brain lesions.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist or MS specialist.

COVERAGE DURATION
Lifetime.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

TESTOSTERONE

MEDICATION(S)
ANDRODERM, JATENZO, 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, TLANDO

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

TEVIMBRA

MEDICATION(S)

TEVIMBRA

PENDING CMS APPROVAL

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
Prescribed by or in consultation with an allergist, immunologist, or pulmonologist

COVERAGE DURATION
Initial: 6 months, Continuation: 3 years

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).

PART B PREREQUISITE

N/A

THALOMID

MEDICATION(S)
THALOMID

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, Kaposis sarcoma, Castlemans 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

TIBSOVO

MEDICATION(S)
TIBSOVO

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

TIOPRONIN

MEDICATION(S)
THIOLA EC, TIOPRONIN 100 MG TABLET, TIOPRONIN DR 100 MG TABLET, TIOPRONIN DR 300 MG TABLET

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

TIVDAK

MEDICATION(S)
TIVDAK

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

TOPICAL ALPHA-ADRENERGIC AGENTS FOR ROSACEA

MEDICATION(S)
BRIMONIDINE 0.33% GEL PUMP, RHOFADE

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

TOPICAL RETINOID PRODUCTS

MEDICATION(S)
ADAPALENE 0.1% CREAM, ADAPALENE 0.3% GEL, AKLIEF, ALTRENO, CLINDAMYCIN PHOS-TRETINOIN, TRETINOIN 0.01% GEL, TRETINOIN 0.025% CREAM, TRETINOIN 0.025% GEL, TRETINOIN 0.05% CREAM, TRETINOIN 0.05% GEL, TRETINOIN 0.1% CREAM, TRETINOIN MICROSPHERE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Coverage is not provided for cosmetic use.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

TRANSMUCOSAL IR FENTANYL DRUGS

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

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 12 months.

OTHER CRITERIA
For breakthrough pain in patients with cancer if patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting OR patient is unable to take 2 other short-acting narcotics (eg, oxycodone, morphine sulfate, hydromorphone, etc) secondary to allergy or severe adverse events AND patient is on or will be on a long-acting narcotic (eg, Duragesic), or the patient is on intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotics (eg, morphine sulfate, hydromorphone, fentanyl citrate).

PART B PREREQUISITE
N/A

TRELSTAR

MEDICATION(S)
TRELSTAR

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

TREMFYA

MEDICATION(S)
TREMFYA 100 MG/ML INJECTOR, TREMFYA 100 MG/ML SYRINGE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).

REQUIRED MEDICAL INFORMATION
Diagnosis, prescriber specialty, other medications tried and length of trials.

AGE RESTRICTION
18 years of age or older.

PRESCRIBER RESTRICTION
Plaque psoriasis - prescribed by or in consultation with a dermatologist. Psoriatic arthritis prescribed by or in consultation with a dermatologist or rheumatologist.

COVERAGE DURATION
Initial-4 months, Positive Response-3 years

OTHER CRITERIA
For plaque psoriasis: The member meets all of the following indication specific requirements (A and B): A. The patient meets either of the following criteria: 1) At least 5 percent of the body surface area was affected by plaque psoriasis at the time of diagnosis, or 2) Crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) were affected by plaque psoriasis at the time of diagnosis. B.The patient meets the following criteria: 1) patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Skyrizi, Stelara SC, Otezla or Cosentyx. Note: If the patient does not meet this requirement, a trial of a non-preferred adalimumab product will also count. For psoriatic arthritis: Approve if the patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Skyrizi, Stelara SC, Otezla, Cosentyx, Xeljanz/XR, or Rinvoq. Note: If the patient does not meet this

requirement, a trial of a non-preferred adalimumab product will also count. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074), Simlandi, adalimumab-adaz, adalimumab-fkjp and Yusimry.

PART B PREREQUISITE

N/A

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, specific CFTR gene mutations, concurrent medications.

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
CF - approve if the patient has at least one copy of the F508del mutation in the cystic fibrosis conductance regulator gene.

PART B PREREQUISITE
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

TRIPTAN THERAPY

MEDICATION(S)
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

TRODELVY

MEDICATION(S)
TRODELVY

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

TRUQAP

MEDICATION(S)
TRUQAP

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

TUKYSA

MEDICATION(S)
TUKYSA

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

TURALIO

MEDICATION(S)
TURALIO

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

TYKERB

MEDICATION(S)
LAPATINIB

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

TYVASO

MEDICATION(S)
TYVASO, TYVASO DPI, TYVASO INSTITUTIONAL START KIT, TYVASO REFILL KIT, TYVASO STARTER KIT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with other oral or parenteral prostacyclin agents used for pulmonary hypertension

REQUIRED MEDICAL INFORMATION
Diagnosis as confirmed by appropriate test

AGE RESTRICTION
N/A

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: 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, 2. Individual has WHO functional class II, III or IV symptoms. Pulmonary Hypertension associated with Interstitial Lung Disease (PH-ILD) WHO Group 3 (this involves diagnoses such as idiopathic interstitial pneumonia, combined pulmonary fibrosis and emphysema, WHO Group 3 connective disease and chronic hypersensitivity pneumonitis): Patient meets all of the following (1, 2 and 3): 1.Patient has had right heart catheterization to confirm

diagnosis 2. Patient has connective tissue disease with a baseline FVC less than 70 percent AND 3. Patient has evidence of diffuse parenchymal lung disease on computed tomography of the chest.

PART B PREREQUISITE

N/A

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

UPTRAVI

MEDICATION(S)
UPTRAVI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Confirmation of right heart catheterization, medication history as referenced in other criteria

AGE RESTRICTION
N/A

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: Patient meets the following (1, 2 and 3): 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. AND 3. Meet one of the following (i or ii): i. Tried one or is currently taking one oral therapy for 30 days, unless patient has experienced treatment failure, intolerance, or oral therapy is contraindicated: PDE5 inhibitor (e.g., sildenafil, Revatio), endothelin receptor antagonist (ERA) [e.g., Tracleer, Letairis or Opsumit], or Adempas OR ii.Receiving or has received in the past one prostacyclin therapy for PAH (e.g., Orenitram, Ventavis, or epoprostenol injection).

PART B PREREQUISITE

N/A

VALCHLOR

MEDICATION(S)
VALCHLOR

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

VANFLYTA

MEDICATION(S)
VANFLYTA

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

VELSIPITY

MEDICATION(S)
VELSIPITY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.

REQUIRED MEDICAL INFORMATION
The member must have a confirmed diagnosis of moderately to severely active ulcerative colitis. Trial of preferred products, Reauth: Objective measure or symptom improvement documentation

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a gastroenterologist

COVERAGE DURATION
Initial: 6 months, Continuation: 3 years

OTHER CRITERIA
1.Moderately to severely active Ulcerative Colitis
a.Initial therapy: Approve if the patient has tried TWO of the following preferred products: a preferred adalimumab product, Stelara SC, Rinvoq, Simponi SC, Skyrizi or Xeljanz/XR tablets. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074), Simlandi, adalimumab-adaz, adalimumab-fkjp and Yusimry. A trial with a non-preferred adalimumab would also count.
b.Continuation therapy: Approve if the patient meets BOTH of the following (i and ii):
i.Patient has been established on the requested medication for at least 6 months AND
ii.Patient meets at least 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 the requested drug). Examples of assessment for inflammatory

response include fecal markers (such as fecal calprotectin), serum markers (such as C-reactive protein), endoscopic assessment, and/or reduced doses of corticosteroids.
2.Compared with baseline (prior to initiating the requested drug), the patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or decreased rectal bleeding.

PART B PREREQUISITE
N/A

VENCLEXTA

MEDICATION(S)
VENCLEXTA, VENCLEXTA STARTING PACK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

VENTAVIS

MEDICATION(S)
VENTAVIS

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
1 year

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 AND c. Pulmonary vascular resistance (PVR) greater than 3 Wood units. 2. Individual has WHO functional class III or IV symptoms. Part B vs D determination will be made based on location of administration.

PART B PREREQUISITE
N/A

VEOPOZ

MEDICATION(S)
VEOPOZ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with other complement inhibitors

REQUIRED MEDICAL INFORMATION
Diagnosis (including genetic test confirming CD55 loss-of-function mutation), serum albumin, reauth: response to therapy (as described in other criteria)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by a physician with expertise in managing CHAPLE disease

COVERAGE DURATION
Initial: 3 months, Continuation: 1 year

OTHER CRITERIA
CD55-Deficient Protein-Losing Enteropathy (CHAPLE Disease [Complement Hyperactivation, Angiopathic thrombosis, and Protein-Losing Enteropathy])-Approve if the patient meets 1 or 2: 1.Initial Therapy-Approve if the patient meets all of the following (a, b and c): a.Patient has had a genetic test confirming the diagnosis of CHAPLE disease with a biallelic CD55 loss-of-function mutation [documentation required], AND b.Patient meets both of the following (i and ii): i.Patient has a serum albumin level less than or equal to 3.2 g/dL [documentation required], AND ii.The patient has active disease and is experiencing one or more of the following signs or symptoms within the last 6 months: abdominal pain, diarrhea, peripheral edema, or facial edema. AND c.Patient meets all of the following (i, ii, and iii):
i.Patient does not have a history of meningococcal infection, AND ii.Patient has received or is in

compliance with updated meningococcal vaccinations according to the most current Advisory Committee on Immunization Practices recommendations, AND iii.Patient has received or is in compliance with updated vaccinations for the prevention of Streptococcus pneumonia and Haemophilus influenza type b infections according to the most current Advisory Committee on Immunization Practices guidelines. 2.Patient Currently Receiving Veopoz-Approve if the patient meets all of the following (a and b): a.Patient has had a genetic test confirming the diagnosis of CHAPLE disease with a biallelic CD55 loss-of-function mutation [documentation required], AND b.Patient had experienced a response to therapy as demonstrated by both of the following [documentation required]. i.Provider attests that the patient has demonstrated a positive clinical response to therapy [documentation required] Note: Examples of a positive clinical response include decreases in the frequency of problematic abdominal pain, bowel movement frequency, facial edema severity, and peripheral edema severity, reduced frequency in hospitalizations, increase in growth percentiles (e.g., body weight-for age and/or stature-for-age percentiles), and/or reduced use of corticosteroids. ii.Normalization of serum albumin levels [documentation required].

PART B PREREQUISITE

N/A

VEOZAH

MEDICATION(S)
VEOZAH

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Use in patients with cirrhosis, severe renal impairment (eGFR less than 30 ml/min/1.73m2) or end-stage renal disease, concomitant use with CYP1A2 inhibitors (e.g. allopurinol, acyclovir, fluvoxamine, mexiletine, cimeditine)

REQUIRED MEDICAL INFORMATION
Continuation of therapy: documentation of a positive clinical response to therapy (e.g. decreased frequency and severity of vasomotor symptoms from baseline)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Vasomotor symptoms due to menopause - Initial: Member meets all of the following (1, 2 and 3): 1.History of failure (following minimum 1-month trial), contraindication or intolerance to a hormonal therapy (e.g., estradiol, Premarin, Prempro) 2.History of failure (following minimum 1-month trial), contraindication or intolerance to a non-hormonal therapy (e.g., selective serotonin reuptake inhibitors [SSRIs], serotonin and norepinephrine reuptake inhibitors [SNRIs], gabapentin, clonidine) 3.Diagnosis of moderate to severe vasomotor symptoms due to menopause

PART B PREREQUISITE

N/A

VERZENIO

MEDICATION(S)
VERZENIO

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

VIJOICE

MEDICATION(S)
VIJOICE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Patient has laboratory confirmation of PIK3CA mutation

AGE RESTRICTION
2 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Patient has severe or life-threatening clinical manifestations of PROS, as assessed by the treating physician, that necessitates use of systemic treatment.

PART B PREREQUISITE
N/A

VITRAKVI

MEDICATION(S)
VITRAKVI

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

VIZIMPRO

MEDICATION(S)
VIZIMPRO

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

VONJO

MEDICATION(S)
VONJO

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

VORANIGO

MEDICATION(S)

VORANIGO

PENDING CMS APPROVAL

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

VOTRIENT

MEDICATION(S)
PAZOPANIB HCL, VOTRIENT

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

VOXZOGO

MEDICATION(S)
VOXZOGO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent treatment with growth hormone (e.g., somatropin), long acting growth hormone (e.g., lonapegsomatropin), or insulin-like growth factor-1 (IGF-1) (e.g., Increlex).

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Less than 18 years old (initial and continuation)

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist (initial and continuation)

COVERAGE DURATION
1 year

OTHER CRITERIA
Achondroplasia-Initial Therapy-New to treatment or Patient Has Been on Voxzogo less than 1 Year. Approve if the patient meets ALL of the following (i, ii, iii, and iv): i. The diagnosis of achondroplasia has been confirmed by genetic testing with an identifiable mutation in the fibroblast growth factor receptor type 3 (FGFR3) gene, AND ii. Patient meets both of the following (a and b): a) Patients epiphyses are open, AND b) There is evidence of annualized growth velocity greater than or equal to 1.5 cm/year, AND iii. Patient will not have limb-lengthening surgery during treatment with Voxzogo, AND iv. The prescriber has confirmed the patient is able to drink approximately 240 to 300 mL of fluid in the hour prior to Voxzogo administration. Continuation of therapy-Patient Has Been Receiving Voxzogo for greater than or equal to 1 Year. Approve if the patient meets ALL of the following (i, ii, iii, iv, and v): i. The diagnosis of achondroplasia has been confirmed by genetic testing with an identifiable

mutation in the fibroblast growth factor receptor type 3 (FGFR3) gene, AND ii. Patient meets both of the following (a and b): a) Patients epiphyses are open, AND b) There is evidence of annualized growth velocity greater than or equal to 1.5 cm/year, AND iii. Patient will not have limb-lengthening surgery during treatment with Voxzogo, AND iv. The prescriber has confirmed the patient is able to drink approximately 240 to 300 mL of fluid in the hour prior to Voxzogo administration, AND Patients most recent annualized growth velocity continues to be above their baseline annualized growth velocity value (i.e., before the patient started on Voxzogo).

PART B PREREQUISITE

N/A

VTAMA

MEDICATION(S)
VTAMA

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, a dermatologist

COVERAGE DURATION
1 year

OTHER CRITERIA
Plaque psoriasis: Patients meets all of the following criteria (1, 2 and 3):
1. Patient has psoriasis involvement estimated to affect less than or equal to 20 percent of the body surface area
2. Patient meets one of the following criteria (a or b): a. Patient meets all of the following criteria (i and ii):
i. Patient has tried at least one medium-, medium-high, high-, and/or super-high potency prescription topical corticosteroid, ii. Inadequate efficacy was demonstrated with this topical corticosteroid, according to the prescriber, b. Patient is treating psoriasis affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia
3. Patient meets all of the following criteria (a and b): a. Patient has tried at least one topical vitamin D analog (e.g. calcipotriene cream, ointment or foam, calcitriol ointment), b. Inadequate efficacy was

demonstrated with the topical Vitamin D analog

PART B PREREQUISITE

N/A

VYVGART HYTRULO

MEDICATION(S)
VYVGART HYTRULO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with Soliris or Ultomiris

REQUIRED MEDICAL INFORMATION
Diagnosis, Reauth: Medical Records demonstrating positive clinical response from baseline (specifics listed in other criteria under continuation of therapy area)

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a neurologist

COVERAGE DURATION
Initial – 6 months, Continuation – 1 year

OTHER CRITERIA
1.Generalized Myasthenia Gravis a.Initial Therapy: Approve if patient meets the following (i, ii, iii, iv, v and vi): i.Patient has confirmed anti-acetylcholine receptor antibody positive generalized myasthenia gravis ii.Patient meets Myasthenia Gravis Foundation of America classification of II to IV iii.Patient meets Myasthenia Gravis Activities of Daily Living (MG-ADL) score of 5 or greater iv.Patient meets one of the following (1 or 2): 1.Patient received or is currently receiving pyridostigmine: OR 2.Patient has had inadequate efficacy, a contraindication, or significant intolerance to pyridostigmine v.Patient has evidence of unresolved symptoms of generalized myasthenia gravis (Note: examples of unresolved symptoms include difficulty swallowing, difficulty breathing, or a functional disability resulting in the discontinuation of physical activity (e.g., double vision, talking, impairment of mobility vi.Treatment cycles are no more frequent than every 50 days from the start of the previous treatment cycle

b.Continuation of therapy: Approve if the patient meets both of the following (i and ii): i.Patient continues to derive benefit from the medication as demonstrated by meeting all of the following: 1.Improvement and/or maintenance of at least a 2 point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline 2.Reduction in signs/symptoms of MG 3.Maintenance, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting Vyvgart (IV or SQ). Please Note: Add on, dose escalation of IST, or additional rescue therapy from baseline to treat MG or exacerbation of symptoms while on therapy will be considered treatment failure. ii.Treatment cycles are no more frequent than every 50 days from the start of the previous treatment cycle

PART B PREREQUISITE

N/A

WEGOVY

MEDICATION(S)
WEGOVY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Patients with personal or family history of medullary thyroid carcinoma or in patients with multiple endocrine neoplasia syndrome type 2, patients with type 1 or type 2 diabetes mellitus, A1c 6.5% or greater, Patients with NYHA Class IV heart failure, ESRD, intermittent dialysis or peritoneal dialysis, history of chronic pancreatitis, concomitant use with a DPP-4 inhibitor, concomitant use with any GLP-1 containing product

REQUIRED MEDICAL INFORMATION
Diagnosis, Body Mass Index (BMI), History of established cardiovascular disease (CVD), A1c

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
None

COVERAGE DURATION
1 year

OTHER CRITERIA
Patient must meet all of the following criteria (1 AND 2): 1. Current BMI of 27 kg/m2 or greater 2.History of established cardiovascular disease as defined by one or more of the following (a, b or c): a. Prior myocardial infarction b. Prior stroke (ischemic or hemorrhagic) c. Symptomatic peripheral arterial disease as defined by one or more of the following: i. Intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest), ii. Peripheral arterial revascularization procedure, iii.Amputation due to atherosclerotic disease.

PART B PREREQUISITE

N/A

WELIREG

MEDICATION(S)
WELIREG

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

XALKORI

MEDICATION(S)
XALKORI

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

XELJANZ

MEDICATION(S)
XELJANZ, XELJANZ XR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with a biologic for an inflammatory condition (eg, tocilizumab, anakinra, abatacept, rituximab, certolizumab pegol, etanercept, adalimumab, infliximab, golimumab). Concurrent use with potent immunosuppressants [eg, azathioprine, tacrolimus, cyclosporine, mycophenolate mofetil] that are not methotrexate (MTX).

REQUIRED MEDICAL INFORMATION
For Rheumatoid Arthritis, the member must have a confirmed diagnosis of moderate to severe Rheumatoid Arthritis and the disease must be active. For Psoriatic Arthritis, the member must have a confirmed diagnosis of active Psoriatic Arthritis. For Ulcerative Colitis, the member must have a confirmed diagnosis of moderate to severe ulcerative colitis and the disease must be active. For ankylosing spondylitis, patient must have a confirmed diagnosis of active ankylosing spondylitis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RA, JIA/JRA, AS-prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. UC-prescribed by or in consultation with a gastroenterologist.

COVERAGE DURATION
Lifetime.

OTHER CRITERIA
For RA/PsA, approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor (TNFi) or was unable to tolerate a 3 month trial. UC - Approve Xeljanz/XR

tablets if the patient has tried at least ONE TNFi for ulcerative colitis. For JIA/JRA (this includes juvenile spondyloarthropathy/active sacroiliac arthritis) - approve Xeljanz immediate release tablets or oral solution if patient meets one of the following (a or b): a) had a 3 month trial of at least one TNFi or was unable to tolerate a 3 month trial OR b) The patient has aggressive disease. For AS, approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least one TNFi or was unable to tolerate a 3 month trial.

PART B PREREQUISITE

N/A

XENAZINE

MEDICATION(S)
TETRABENAZINE

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

OFF LABEL USES
Tardive dyskinesia (TD). Tourette syndrome and related tic disorders. Hyperkinetic dystonia. Hemiballism.

EXCLUSION CRITERIA
Impaired hepatic function, Concomitant use of MAOIs or Reserpine, Non-Huntington's related chorea.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
18 years of age or older

PRESCRIBER RESTRICTION
For treatment of chorea associated with Huntington's disease, Tourette syndrome or related tic disorders, 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
Authorization will be for 1 year.

OTHER CRITERIA
Chorea associated with Huntington’s disease – approve if the diagnosis of Huntington’s Disease is confirmed by genetic testing.

PART B PREREQUISITE
N/A

XERMELO

MEDICATION(S)
XERMELO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial – 4 months, continuation - 1 year

OTHER CRITERIA
Initiation of therapy - Patient meets all of the following criteria (1, 2 and 3):
1.Patient has diagnosis of carcinoid syndrome diarrhea
2.Patient is symptomatic with at least four bowel movements per day despite treatment with a somatostatin analogue (e.g., octreotide, lanreotide, pasireotide) for at least 3 months
3.Requested medication will be used in combination with a somatostatin analog
Continuation of therapy – Patient meets all of the following criteria (1, 2 and 3):
1.Patient has met initial therapy criteria
2.Provider confirms patient has experienced improvement on medication following at least 3 months of therapy when given in combination with somatostatin analogue therapy
3.Patient will continue to use the medication in combination with a somatostatin analog

PART B PREREQUISITE

N/A

XGEVA

MEDICATION(S)
XGEVA

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

XIFAXAN

MEDICATION(S)
XIFAXAN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

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

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Hepatic encephalopathy: 1 year, IBS-D: 14 days, Travelers' diarrhea: 3 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.

PART B PREREQUISITE
N/A

XOLAIR

MEDICATION(S)
XOLAIR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with an interleukin (IL) antagonist monoclonal antibody

REQUIRED MEDICAL INFORMATION
Moderate to severe persistent asthma or nasal polyps, baseline IgE level of at least 30 IU/mL. For asthma, patient has a baseline positive skin test or in vitro testing (ie, a blood test for allergen-specific IgE antibodies such as an enzyme-linked immunoabsorbant assay (eg, immunoCAP, ELISA) or the RAST) for 1 or more perennial aeroallergens (eg, house dust mite, animal dander [dog, cat], cockroach, feathers, mold spores) and/or for 1 or more seasonal aeroallergens (grass, pollen, weeds). CIU - must have urticaria for more than 6 weeks (prior to treatment with Xolair), with symptoms present more than 3 days/wk despite daily non-sedating H1-antihistamine therapy (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine). Ige-mediated food allergy: Baseline IgE, skin prick test, in vitro test for IgE.

AGE RESTRICTION
Moderate to severe persistent asthma-6 years and older. CIU-12 years and older. Nasal polyps - 18 years and older. IgE-mediated food allergy - 1 year or older.

PRESCRIBER RESTRICTION
Moderate to severe persistent asthma if prescribed by, or in consultation with an allergist, immunologist, or pulmonologist. CIU if prescribed by or in consultation with an allergist, immunologist, or dermatologist. Nasal polyps if prescribed by or in consultation with an allergist, immunologist or otolaryngologist. IgE-mediated food allergy: prescribed by or in consultation with an allergist or immunologist.

COVERAGE DURATION
Asthma/CIU Initial: 4 mo. Nasal polyps initial: 6 mo. Food allergy: 1 yr. Cont tx all dx: 12 months.

OTHER CRITERIA

Moderate to severe persistent asthma approve if pt meets criteria 1 and 2: 1) pt has received at least 3 months of combination therapy with an inhaled corticosteroid and at least one the following: long-acting beta-agonist (LABA), long-acting muscarinic antagonist (LAMA), leukotriene receptor antagonist, or theophylline, and 2) patient's asthma is uncontrolled or was uncontrolled prior to receiving any Xolair or anti-IL-4/13 therapy (Dupixent) therapy as defined by ONE of the following (a, b, c, d, or e): a) The patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year OR b) The patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year OR c) Patient has a forced expiratory volume in 1 second (FEV1) less than 80% predicted OR d) Patient has an FEV1/forced vital capacity (FVC) less than 0.80 OR e) The patient's asthma worsens upon tapering of oral corticosteroid therapy NOTE: An exception to the requirement for a trial of one additional asthma controller/maintenance medication can be made if the patient has already received anti-IL-4/13 therapy (Dupixent) used concomitantly with an ICS for at least 3 months. For continued Tx for asthma - patient has responded to therapy as determined by the prescribing physician and continues to receive therapy with one inhaled corticosteroid or inhaled corticosteroid containing combination product. For CIU cont tx - must have responded to therapy as determined by the prescribing physician. For Nasal polyps (a, b AND c): a) Patient is experiencing significant rhinosinusitis symptoms such as nasal obstruction, rhinorrhea, or reduction/loss of smell AND b) patient is currently receiving therapy with intranasal corticosteroid AND c) patient has received treatment with a systemic corticosteroid for chronic rhinosinusitis with nasal polyps within the previous 2 years OR has a contraindication to systemic corticosteroid therapy OR patient has had prior surgery for nasal polyps. Nasal polyps cont tx: Approve if patient continues to receive therapy with an intranasal corticosteroid and has responded to therapy. IgE-mediated food allergy (a, b, c and d): a. Baseline IgE greater than or equal to 30 IU/ml, b. Pos skin prick test to 1 or more foods and positive in vitro test for IgE to 1 or more foods, c. H/o allergic rxn that met all of the following: pt demonstrated s/s of a sign systemic allergic rxn, rxn occurred w/in a short period of time following a known ingestion of food, prescriber deemed rxn significant enough to require a Rx for an epinephrine auto-injector, d. Pt has been prescribed an epinephrine auto-injector.

PART B PREREQUISITE

N/A

XOSPATA

MEDICATION(S)
XOSPATA

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

XPOVIO

MEDICATION(S)
XPOVIO

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

XTANDI

MEDICATION(S)
XTANDI

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

ZEJULA

MEDICATION(S)
ZEJULA

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

ZELBORAF

MEDICATION(S)
ZELBORAF

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

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

ZEPOSIA

MEDICATION(S)
ZEPOSIA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
UC Concurrent Use with a Biologic or with a Targeted Synthetic Disease-modifying Antirheumatic Drug (DMARD) for Ulcerative Colitis

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
UC 18 years and older

PRESCRIBER RESTRICTION
UC Prescribed by or in consultation with a gastroenterologist

COVERAGE DURATION
1 year

OTHER CRITERIA
UC Patients new to therapy are required to try a preferred adalimumab product (a trial of Simponi SC, Skyrizi, infliximab or a non-preferred adalimumab product would also count) AND Stelara (a trial of Entyvio or Stelara IV would also count). Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074), Simlandi, adalimumab-adaz, adalimumab-fkjp and Yusimry. MS - approve.

PART B PREREQUISITE
N/A

ZOKINVY

MEDICATION(S)
ZOKINVY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, lab results

AGE RESTRICTION
12 months and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a geneticist or cardiologist

COVERAGE DURATION
1 year

OTHER CRITERIA
Hutchinson-Gilford Progeria Syndrome, approve if the patient meets (A and B): A) Patient has a body surface area greater than or equal to 0.39 m2, B) Genetic testing demonstrates a confirmed pathogenic mutation in the LMNA gene consistent with Hutchinson-Gilford Progeria Syndrome. Progeroid laminopathies, approve if the patient meets (A and B): A) Patient has a body surface area greater than or equal to 0.39 m2, B) Patient has Heterozygous LMNA mutation with progerin-like protein accumulation or Homozygous or compound heterozygous ZMPSTE24 mutations.

PART B PREREQUISITE
N/A

ZOLADEX

MEDICATION(S)
ZOLADEX

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

ZOLINZA

MEDICATION(S)
ZOLINZA

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

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

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 – approve if the patient has a molecularly confirmed pathogenic or likely pathogenic mutation in the CDKL5 gene.

PART B PREREQUISITE
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
Depression score or documentation of severe depression (as referenced in other criteria)

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. Meets one of the following criteria (a, b, c, or d): a.HAMD score greater than or equal to 24 (severe depression) b.MADRS score greater than or equal to 35 (severe depression) c.PHQ-9 score greater than or equal to 20 (severe depression) d.If member does not have severe depression as demonstrated by one of the depression scores (a, b or c), documentation of severe depression as evidenced by a psychiatrist clinical interview 3. No more than 12 months have passed since member has given birth

PART B PREREQUISITE

N/A

ZYDELIG

MEDICATION(S)
ZYDELIG

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

ZYKADIA

MEDICATION(S)
ZYKADIA

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

ZYNLONTA

MEDICATION(S)
ZYNLONTA

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

ZYNYZ

MEDICATION(S)
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