Network Health Insurance Corporation

Network Health Cares (PPO D-SNP)

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
For all diagnoses: If patient is new to plan, meets initial criteria at time they had started the medication. Documented dose and frequency are within the FDA approved dosing and frequency. RA: diagnosis and disease severity per ACR criteria, score from objective measure/tool at baseline and continuation (e.g. CDAI, Disease Activity Score with 28-joint counts (ESR or CRP), PAS or PAS-II, RAPID3, SDAI. pJIA: diagnosis and disease severity, score from objective measure/tool at baseline and continuation. sJIA: diagnosis and disease severity, score from objective measure/tool at baseline and continuation. Provider has assessed baseline disease severity utilizing an objective measure/tool such as systemic juvenile arthritis disease activity score (sJADAS) or American College of Rheumatology pediatric (ACR pedi) 30 criteria. GCA: diagnosis, pre-requisite medication trial, reauthorization: positive response. Diagnosis of large vessel arteritis that has at some point been verified with biopsy or with imaging of the large vessels (MRI, PET-CT, or CT angiography. Patient has active disease and an elevated C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR). SSc-ILD: Diagnosis, pulmonary function tests, reauth: positive response.

AGE RESTRICTION
sJIA/pJIA: 2 years and older. All other indications: 18 years and older.

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
Initial: 6 months, Continuation: 1 year

OTHER CRITERIA

PENDING CMS APPROVAL

PART B PREREQUISITE

N/A

ACTIMMUNE

MEDICATION(S)
ACTIMMUNE

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

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, pre-requisite treatments, BSA and/or SCORAD index value

AGE RESTRICTION
12 years of age and older

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

COVERAGE DURATION
Initial – 6 months, Continuation - 1 year

OTHER CRITERIA
PENDING CMS APPROVAL

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
PENDING CMS APPROVAL

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)
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

ALOSETRON

MEDICATION(S)
ALOSETRON HCL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Exclude if patient is biologically male

REQUIRED MEDICAL INFORMATION
Diagnosis, Reauth: positive clinical response

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial: 6 months, continuation: 1 year

OTHER CRITERIA
Severe diarrhea-predominant Irritable bowel syndrome (IBS): 1.Initial: Approve if the patient meets the following (a, b, c and d):
a. Patient has experienced chronic IBS symptoms for 6 months or longer, b. Patient had anatomic or biochemical abnormalities of the gastrointestinal track excluded, c. Patient has tried and failed one anti-diarrheal agent (e.g. loperamide), d. Patient has tried and failed one antispasmodic agent (e.g. dicyclomine). 2. Continuation: Approve if the patient meets the following (a, b and c):
a. If patient is new to plan, meets initial criteria at time they had started the medication, b. Documented dose and frequency are within the FDA approved dosing and frequency, c. Patient is experiencing a positive clinical response to therapy

PART B PREREQUISITE

N/A

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

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
Concurrent use a biologic drug or targeted synthetic drug

REQUIRED MEDICAL INFORMATION
Diagnosis, Reauth: documentation of positive clinical response

AGE RESTRICTION
CAPS, Pericarditis - 12 years or greater.

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

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

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

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

PART B PREREQUISITE

N/A

ARIKAYCE

MEDICATION(S)
ARIKAYCE

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

OFF LABEL USES
PENDING CMS APPROVAL

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 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

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 starting Austedo), Concomitant use of reserpine (minimum of 20 days should elapse after stopping reserpine and before starting Austedo), Concomitant use of tetrabenazine or Ingrezza, current suicidality, untreated or inadequately treated depression, Non-Huntington’s disease related chorea

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

AGE RESTRICTION
18 years of age or older

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

COVERAGE DURATION
HD: 1 year, TD – initial 4 months, continuation 1 year.

OTHER CRITERIA
PENDING CMS APPROVAL

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, 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
PENDING CMS APPROVAL

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
PENDING CMS APPROVAL

REQUIRED MEDICAL INFORMATION
Diagnosis, ANA or anti-dsDNA level, SLE: SELENA-SLEDAI score, LN: biopsy proven lupus nephritis, eGFR, uPCR

AGE RESTRICTION
PENDING CMS APPROVAL

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

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

OTHER CRITERIA
PENDING CMS APPROVAL

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
Diagnosis, PASI score, reauth: positive response

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a dermatologist

COVERAGE DURATION
Initial: 6 months, Continuation 1 year

OTHER CRITERIA
PENDING CMS APPROVAL

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 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

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

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

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

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, pre-requisite treatments, BSA and/or SCORAD index value

AGE RESTRICTION
12 years and older

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

COVERAGE DURATION
Initial – 6 months, Continuation - 1 year

OTHER CRITERIA
PENDING CMS APPROVAL

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
PENDING CMS APPROVAL

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
RA/AS-prescribed by or in consultation with a rheumatologist. CD-prescribed by or in consultation with a gastroenterologist. 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
Initial 6 months, continuation 1 year

OTHER CRITERIA
RA-Init-approve if pt has tried 2 of the following: Enbrel, a pref adalimumab product, Orencia, Rinvoq or Xeljanz/XR. Cont-approve if patient is responding positively to tx based on improvement in objective measurement/tool as compared to baseline. AS:Initial–approve if pt has TF 2 of the following: Enbrel, a pref adalimumab product, Cosentyx, Rinvoq or Xeljanz/Xeljanz XR. Cont–See required medical information for detail. PsA:Init-approve if pt a and b:a.Patiet is currently experiencing one of the following (i, ii, iii, iv or v): i.Actively inflamed joints, ii.Dactylitis, iii.Enthesitis, iv.Axial disease, v. Active skin and/or nail involvement, b.Has active mod/severe PsA and pt has tried 2 of the following: Enbrel, a

pref adalimumab product, Stelara SC, Otezla, Orencia, Xeljanz/XR, Cosentyx, Rinvoq or Skyrizi.Cont-approve if documentation of pos clinical response to tx as evidenced by improvement in any of the following from baseline (a, b, c, d, or e): a.Number of swollen joints, b.Number of tender joints,c.Dactylitis, d.Enthesitis, e.Axial disease. CD-Init:Approve if pt meets i, ii and iii: i. Documented dx of mod/severe CD, ii. Pt is currently experiencing one of the following:a.Frequent diarrhea and abdominal pain, b.At least 10 percent weight loss, c.Complication such as obstruction, fever, abdominal mass, d.Abnormal labs (e.g. CRP), e.CD Activity Index (CDAI) greater than 20, iii.Pt has tried 2 of the following pref products: a pref adalimumab product, Skyrizi SQ, Stelara SQ or Rinvoq. b.Cont:Approve if pt meets i and ii: i.Pt has been established on the requested med for at least 5 mo, ii. Pt has documentation of positive clinical response to tx as evidenced by meeting 1 or 2: a.Improvement in intestinal inflammation (e.g. mucosal healing, improvement of labs [PLT counts, ESR, CRP)] from baseline, b.Reversal of high fecal output state. PP:Init:Approve if pt has tried 2 of the following: Enbrel, a pref adalimumab product, Skyrizi, Stelara (SC), Otezla, or Cosentyx. Cont:Approve if pt has evidence of a pos response based on meeting a, b or c: a.Achieved/maintained clear/minimal disease, b.A decr in PASI score compared to baseline, c.Documented dose/frequency are w/in the FDA approved Dosing/Frequency. nr-axSpA:Init-approve if the patient has TF both of the following: Cosentyx and Rinvoq. Cont:Approve if pt experienced a pos clinical response to tx based on at least one of the following (1, 2, 3 or 4):1.Dz activity (e.g. pain, fatigue, inflammation, stiffness),2.Lab values (CRP),3.Axial status (e.g. lumbar spine motion, chest expansion),4.Total active (swollen and tender) joint count.Note: pref adalimumabs include: Humira (NDCs starting with -00074) and Simlandi.

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
PP: Diagnosis, PASI score, reauth: positive response. PsA: Diagnosis, pre-requisite medication trials, reauth: positive clinical response. AS: Diagnosis, pre-requisite medication trials, objective measure at initiation and continuation (examples outlined in other criteria). Nr-axSpA: Diagnosis, pre-requisite medication trials, objective signs of inflammation, reauth: positive clinical response. HS: Diagnosis, pre-requisite medication trials, objective measure at continuation (examples outlined in other criteria). Enthesitis-related arthritis: Diagnosis, pre-requisite medication trials, reauth: improvement in signs and symptoms. For all diagnoses: Documented Dose and Frequency are within the FDA approved Dosing and Frequency. If patient is new to plan, meets initial criteria at time they had started the medication.

AGE RESTRICTION
PP: 6 years and older. PsA: 2 years and older. Enthesitis-related arthritis: 4 years and older. AS, nr-axSpa, HS: 18 and older.

PRESCRIBER RESTRICTION
PP, HS: prescribed by or in consultation with a dermatologist. AS, non-radiographic axial spondyloarthritis or enthesitis related arthritis-prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist.

COVERAGE DURATION
Initial 6 months, continuation 1 year

OTHER CRITERIA

PENDING CMS APPROVAL

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

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

DIABETIC SUPPLIES

MEDICATION(S)

BD INSULIN SYRINGE, CURITY GAUZE PADS, EASY COMFORT 0.5 ML 30GX1/2", EASY COMFORT SYR 1 ML 30GX1/2", EASY TOUCH INSULIN SYR 1 ML, EASY TOUCH SYR 0.5ML 27G12.7MM, EASY TOUCH SYR 0.5ML 28G12.7MM, EASY TOUCH SYR 0.5ML 29G12.7MM, EASY TOUCH SYR 1 ML 27G 12.7MM, EASY TOUCH SYR 1 ML 28G 12.7MM, EASY TOUCH SYR 1 ML 29G 12.7MM, EASY TOUCH PEN NEEDLE 32GX1/4", EASY TOUCH PEN NEEDLE 32GX3/16, EASY-TOUCH INSULIN SYRINGE, CVS COTTON GAUZE 2"X2", STERILE GAUZE PADS 2"X 2", CVS GAUZE PADS 2"X2", GAUZE PAD, STERILE 2"X2", CVS GAUZE PAD 2"X2" STERILE, CVS GAUZE PADS 2" X 2", EQL GAUZE PADS 2"X2", GAUZE PADS 2" X 2 " STERILE, GAUZE PADS NON-STERILE 2X2, GAUZE PADS STERILE 2X2, GAUZE PADS & DRESSINGS - PADS 2 X 2, HM INSULIN SYRINGE, INCONTROL PEN NEEDLE 4MM 32G, INCONTROL PEN NEEDLE 6MM 31G, INCONTROL PEN NEEDLE 8MM 31G, COMFORT POINT PEN NDL 31GX1/4", INSULIN PEN NEEDLE, AIMSCO INS SYR 0.3 ML 29GX1/2", AIMSCO INS SYR 0.3 ML 30GX5/16, AIMSCO INS SYR 0.5 ML 29GX1/2", AIMSCO INS SYR 1 ML 29GX1/2", AIMSCO INS SYR 1 ML 30GX5/16", AIMSCO INSULIN 0.3 ML SYRINGE, AIMSCO INSULIN 0.3 ML SYRNGE, AIMSCO INSULIN 0.5 ML SYRINGE, AIMSCO INSULIN 0.5 ML SYRNGE, AIMSCO INSULIN 1 ML SYRINGE, AIMSCO SYRING 0.3 ML 31GX5/16", AIMSCO SYRING 0.5 ML 30GX5/16", AIMSCO SYRING 0.5 ML 31GX5/16", B-D INSULIN U100-1 ML SYRNG, B-D INSULIN U100-1 ML SYRNGE, B-D INSULIN U40-1 ML SYRINGE, BD INS SYR 0.3 ML 8MMX31G(1/2), BD INS SYR UF 0.3ML 12.7MMX30G, BD INS SYR UF 0.5ML 12.7MMX30G, BD INS SYRN UF 1 ML 12.7MMX30G, BD INS SYRN UF 1 ML 30G 12.7MM, BD INS SYRNG UF 0.3 ML 8MMX31G, BD INS SYRNG UF 0.5 ML 8MMX31G, BD INSULIN SYR 0.3 ML 31GX5/16, BD INSULIN SYR 0.5 ML 28GX1/2", BD INSULIN SYR 0.5 ML 30GX1/2", BD INSULIN SYR 0.5ML 31GX5/16", BD INSULIN SYR 1 ML 27GX5/8", BD INSULIN SYR 1 ML 28GX1/2", BD INSULIN SYR 1 ML 30GX1/2", BD INSULIN SYR 1 ML 31GX5/16", BD INSULIN SYR UF 1 ML 8MMX31G, BD INSULIN U100-1 ML SYRNGE, BL INSULIN 0.3 ML SYRINGE, BL INSULIN 0.5 ML SYRINGE, BL INSULIN 1 ML SYRINGE, BL INSULIN SYRINGE 0.3 ML, BL INSULIN SYRINGE 0.5 ML, BL INSULIN SYRINGE 1 ML, BROOKS INSULIN 0.3 ML SYRN, BROOKS INSULIN 1/2 ML SYRN, BROOKS INSULIN SYRINGE 1 ML, CA INS SYR 0.3 ML 30GX5/16", CA INS SYR 0.3 ML 31GX5/16", CA INS SYR 0.5 ML 30GX5/16", CA INS SYR 0.5 ML 31GX5/16", CA INSULIN SYR 0.3 ML 29GX1/2", CA INSULIN SYR 0.5 ML 29GX1/2", CA INSULIN SYR 1 ML 29GX1/2", CA INSULIN SYR 1 ML 30GX5/16", CA INSULIN SYR 1 ML 31GX5/16", CAREONE INS SYR 1 ML 30GX5/16", CAREONE SYR 0.3 ML 30GX1/2", CAREONE SYR 0.3 ML 31GX5/16", CAREONE SYR 0.5 ML 30GX1/2", CAREONE SYR 0.5 ML 31GX5/16", CAREONE SYR 1 ML 30GX1/2", CAREONE SYR 1 ML 31GX5/16", CVS INSULIN SYR 1 ML 29GX1/2", CVS SYRINGE 1/2 ML, CVS SYRINGE 3/10 ML, D&K INSULIN SYRINGE 0.3 ML, D&K INSULIN SYRINGE 0.5 ML, D&K INSULIN SYRINGE

1 ML, DG INSULIN SYR 29G-3/10 ML, DG INSULIN SYRINGE 28G-0.5 ML, DG INSULIN SYRINGE 28G-1 ML, DG INSULIN SYRINGE 29G-0.5 ML, ECK INSULIN 1 ML SYRINGE, ECK INSULIN 1/2 ML SYRINGE, ECK INSULIN 3/10 ML SRYINGE, ECK INSULIN 3/10 ML SYRINGE, EQL INS SYR 0.3 ML 29GX1/2", EQL INS SYR 0.3 ML 30GX5/16", EQL INS SYR 0.5 ML 29GX1/2", EQL INS SYR 0.5 ML 30GX5/16", EQL INSUL SYR 0.3 ML 31GX5/16", EQL INSUL SYR 0.5 ML 31GX5/16", EQL INSULIN SYR 1 ML 29GX1/2", EQL INSULIN SYR 1 ML 30GX5/16", EQL INSULIN SYR 1 ML 31GX5/16", EXEL INS SYR U100 1 ML 28GX1/2, EXEL INSUL SYR 0.5 ML 28GX1/2", FIFTY50 INS 0.3 ML 31GX5/16", FIFTY50 INS 0.5 ML 31GX5/16", FIFTY50 INS SYR 1 ML 31GX5/16", FIRST CHOICE SYRINGE 0.3 ML, FIRST CHOICE SYRINGE 0.5 ML, FIRST CHOICE SYRINGE 1 ML, FP INSULIN 0.3 ML SYRINGE, FP INSULIN 0.5 ML SYRINGE, FP INSULIN 1 ML SYRINGE, FP INSULIN SYRINGE 0.3 ML, FP INSULIN SYRINGE 0.5 ML, FP INSULIN SYRINGE 1 ML, GNP INS SYRINGE 1 ML 28G 1/2", GNP INSUL SYR 0.5 ML 31GX5/16", HCA INSULIN SYRINGE 0.3 ML, HCA INSULIN SYRINGE 0.5 ML, HCA INSULIN SYRINGE 1 ML, HM INSULIN SYRINGE 0.3 ML, HM INSULIN SYRINGE 0.5 ML, HM INSULIN SYRINGE 1 ML, INS SYR U100 0.5 ML 29GX1/2", INSULIN 1 ML SYRINGE, INSULIN 1/2 ML SYRINGE, INSULIN 3/10 ML SYRINGE, INSULIN SYR 1 ML HARD PACK, INSULIN SYRIN 0.3 ML 29GX1/2", INSULIN SYRIN 0.3 ML 30GX1/2", INSULIN SYRIN 0.3 ML 30GX5/16", INSULIN SYRIN 0.3 ML 31GX5/16", INSULIN SYRIN 0.5 ML 28GX1/2", INSULIN SYRIN 0.5 ML 29GX1/2", INSULIN SYRIN 0.5 ML 30G 5/16", INSULIN SYRIN 0.5 ML 30GX5/16", INSULIN SYRIN 0.5 ML 31G 5/16", INSULIN SYRIN 0.5 ML 31GX5/16", INSULIN SYRING 0.5 ML 28G 1/2", INSULIN SYRING 0.5 ML 29G 1/2", INSULIN SYRING 0.5 ML 29GX1/2", INSULIN SYRINGE 0.3 ML, INSULIN SYRINGE 0.5 ML, INSULIN SYRINGE 1 ML, INSULIN SYRINGE 1 ML 27G 1/2", INSULIN SYRINGE 1 ML 27GX1/2", INSULIN SYRINGE 1 ML 28G 1/2", INSULIN SYRINGE 1 ML 28GX1/2", INSULIN SYRINGE 1 ML 29G 1/2", INSULIN SYRINGE 1 ML 29GX1/2", INSULIN SYRINGE 1 ML 30G 1/2", INSULIN SYRINGE 1 ML 30GX1/2", INSULIN SYRINGE 1 ML 30GX5/16", INSULIN SYRINGE 1 ML 31G 5/16", INSULIN SYRINGE 1 ML 31GX5/16", INSULIN SYRINGE 1/2 ML, INSULIN SYRINGE 28GX0.5 ML, INSULIN SYRINGE 28GX1 ML, INSULIN SYRINGE 29G-0.3 ML, INSULIN SYRINGE 29G-0.5 ML, INSULIN SYRINGE 3/10 ML, INSULIN SYRINGE U-100, INSULIN SYRINGE U100 0.5 ML, INSULIN SYRINGE U100 1 ML, INSULIN SYRINGE U100 1/2 ML, KMART VALU PLUS SYR 3/10 ML, KMART VALU PLUS SYRINGE 1 ML, KRO INS SYRIN 0.3 ML 30GX5/16", KRO INS SYRIN 0.3 ML 31GX5/16", KRO INS SYRIN 0.5 ML 30GX5/16", KRO INS SYRIN 0.5 ML 31GX5/16", KRO INS SYRING 0.5 ML 29GX1/2", KRO INS SYRINGE 1 ML 29GX1/2", KRO INS SYRINGE 1 ML 30GX5/16", KRO INS SYRINGE 1 ML 31GX5/16", KROGER 0.5 ML INSULIN SYRINGE, KROGER 1 ML INSULIN SYRINGE, KROGER INS SYR 1 ML 29GX1/2", KROGER INS SYRINGE 0.5 ML, KROGER INS SYRINGE 3/10 ML, KROGER INSULIN SYRINGE 0.3 ML, KROGER INSULIN SYRINGE 0.3M, LEADER INS SYR 0.3 ML 29GX1/2", LEADER INS SYR 0.5 ML, LEADER INS SYR 0.5 ML 28GX1/2", LEADER INS SYR 0.5 ML 29GX1/2", LEADER INS SYR 0.5 ML 30GX1/2", LEADER INS SYR 1 ML, LEADER INS SYR 1 ML 28GX1/2", LEADER INS SYR 1 ML

29GX1/2", LEADER INS SYR 1 ML 30GX1/2", LEADER INS SYR 1 ML 31GX5/16", LEADER INS SYR 3/10 ML, LEADER INSULIN SYRINGE 0.3 ML, LEADER INSULIN SYRINGE 0.5 ML, LEADER INSULIN SYRINGE 1 ML, LEADER SYRING 0.3 ML 31GX5/16", LEADER SYRING 0.5 ML 31GX5/16", LONGS INS SYR 0.5 ML 29GX1/2", LONGS INS SYR 1 ML 29GX1/2", LONGS INSULIN SYRINGE 0.3 ML, LONGS INSULIN SYRINGE 0.5 ML, LONGS INSULIN SYRINGE 1 ML, MAJOR INSULIN SYRINGE 0.3 ML, MAJOR INSULIN SYRINGE 0.5 ML, MAJOR INSULIN SYRINGE 1 ML, MEDIC DRUG INSULIN SYR 0.3 ML, MS INS SYR 0.5 ML 29GX1/2", MS INS SYR 1 ML 29GX1/2", MS INS SYRINGE 1 ML 30GX1/2", MS INSUL SYR 0.3 ML 31GX5/16", MS INSUL SYR 0.5 ML 30GX1/2", MS INSUL SYR 0.5 ML 31GX5/16", MS INSULIN SYR 0.3 ML 29GX1/2", MS INSULIN SYR 1 ML 31GX5/16", MS INSULIN SYRINGE 0.3 ML, MS INSULIN SYRINGE 0.5 ML, MS INSULIN SYRINGE 1 ML, MS INSULIN SYRINGE 3/10 ML, PV INS SYRIN 1 ML 29GX1/2", PV INSUL SYR 0.3 ML 31GX5/16", PV INSUL SYR 0.5 ML 31GX5/16", PV INSULIN SYR 1 ML 31GX5/16", PV INSULIN SYRINGE 0.5 ML, QC INSUL SYR 0.5 ML 31GX5/16", QC INSULIN SYR 1 ML 31GX5/16", QC INSULIN SYRINGE 0.3 ML, QC INSULIN SYRINGE 0.5 ML, QC INSULIN SYRINGE 1 ML, RELI-ON INSULIN 0.3 ML SYR, RELI-ON INSULIN 0.5 ML SYR, RELI-ON INSULIN 1 ML SYR, RELION INSULIN SYR 0.3 ML, RELION INSULIN SYR 0.5 ML, RELION INSULIN SYRINGE 1 ML, SB INS SYR 0.5 ML 29GX1/2", SB INS SYR 0.5 ML 30GX5/16", SB INS SYR 1 ML 29GX1/2", SB INS SYRINGE 1 ML 30GX5/16", SB INSULIN SYR 1 ML 31GX5/16", SB INSULIN SYRINGE 0.3 ML, SB INSULIN SYRINGE 0.5 ML, SB INSULIN SYRINGE 1 ML, SB INSULN SYR 0.5 ML 30GX5/16", SCHNUCKS SYR 0.5 ML 29GX1/2", SCHNUCKS SYR 0.5 ML 30GX5/16", SM INS SYR 0.5 ML 29GX1/2", SM INS SYR 0.5 ML 30GX5/16", SM INS SYR 1 ML 29GX1/2", SM INS SYRING 0.3 ML 30GX5/16", SM INS SYRINGE 1 ML 28GX1/2", SM INS SYRINGE 1 ML 30GX5/16", SM INSUL SYR 0.3 ML 31GX5/16", SM INSUL SYR 0.5 ML 31GX5/16", SM INSULIN SYR 0.3 ML 29GX1/2", SM INSULIN SYR 0.5 ML 28GX1/2", SM INSULIN SYR 1 ML 31GX5/16", SUNMARK INSULIN SYRINGE 0.3 ML, SUNMARK INSULIN SYRINGE 0.5 ML, SUNMARK INSULIN SYRINGE 1 ML, VALUEPLUS SYR 0.3 ML 29GX1/2", VH INS SYR 0.5 ML 29GX1/2", VH INS SYR 1 ML 29GX1/2", WD MEDIC INSULIN SYR 0.3 ML, WD MEDIC INSULIN SYR 0.5 ML, WD MEDIC INSULIN SYRNGE 1 ML, WD MEDIC SYR 0.3 ML 30GX5/16", WD MEDIC SYR 0.5 ML 29GX1/2", WD MEDIC SYR 0.5 ML 30GX5/16", WD MEDIC SYR 1 ML 29GX1/2", WDMEDIC INS SYR 1 ML 30GX5/16", WDMEDIC SYRING 0.3 ML 29GX1/2", INSULIN SYRINGE (DISP) U-100 0.3 ML, INSULIN SYRINGE (DISP) U-100 1 ML, INSULIN SYRINGE (DISP) U-100 1/2 ML, INSULIN SYRINGE U-500, INSUPEN 31G ULTRAFIN NEEDLE, INSUPEN 32G 6MM PEN NEEDLE, INSUPEN 32G 8MM PEN NEEDLE, INSUPEN PEN NEEDLE 31GX5/16", INSUPEN PEN NEEDLE 31GX8MM, ISOPROPYL ALCOHOL 0.7 ML/ML MEDICATED PAD, LITETOUCH INS 0.3 ML 29GX1/2", LITETOUCH INS 0.3 ML 30GX5/16", LITETOUCH INS 0.3 ML 31GX5/16", LITETOUCH INS 0.5 ML 31GX5/16", MINI PEN NEEDLE 32G 4MM, BL MONOJECT SYRINGE 0.5 ML, BL MONOJECT SYRINGE 1 ML, BL MONOJECT SYRINGE 3/10 ML, GNP MONOJECT SYRINGE 0.5 ML, GNP MONOJECT SYRINGE 1

ML, GNP MONOJECT SYRINGE 3/10 ML, KIN-RAY MONOJECT SYRINGE, KP MONOJECT SYRINGE 0.5 ML, KP MONOJECT SYRINGE 1 ML, KP MONOJECT SYRINGE 3/10 ML, LEADER MONOJECT SYR 0.5 ML, LEADER MONOJECT SYR 1 ML, LEADER MONOJECT SYR 3/10 ML, LEGEND MONOJECT SYRINGE 1 ML, LEGEND MONOJECT SYRNGE 0.3 ML, LEGEND MONOJECT SYRNGE 0.5 ML, MED SHOPPE MONOJCT SYR 3/10, MED SHOPPE MONOJECT SYR 0.5, MED SHOPPE MONOJECT SYR 1 ML, MED-FAST MONOJECT SYRINGE, MONOJECT 0.3 ML INSULIN SYR, MONOJECT 0.3 ML SYRN 29GX1/2", MONOJECT 1 ML SYRN 25X5/8", MONOJECT INSUL SYR U100, MONOJECT INSUL SYR U100 0.5 ML, MONOJECT INSUL SYR U100 1 ML, PHARM MONOJECT SYRINGE 0.5 ML, QC MONOJECT SYRINGE 0.5 ML, QC MONOJECT SYRINGE 1 ML, QC MONOJECT SYRINGE 3/10 ML, RUGBY MONOJECT SYRINGE 0.5 ML, RUGBY MONOJECT SYRINGE 1 ML, VALUE HEALTH MONOJECT SYRN, NANO 2ND GEN PEN NEEDLE, NEEDLES, INSULIN DISP., SAFETY, FIFTY50 PEN 31G X 3/16" NEEDLE, FIFTY50 PEN 31G X 5/16" NEEDLE, FIFTY50 PEN NEEDLE 32G X 5/32", GS PEN NEEDLE 31G X 1/4", GS PEN NEEDLE 31G X 5/16", GS PEN NEEDLE 31G X 5MM, GS PEN NEEDLE 31G X 6MM, GS PEN NEEDLE 31G X 8MM, GS PEN NEEDLE 32G X 4MM, KRO PEN NEEDLE 4MM X 32G, KRO PEN NEEDLE 5MM X 31G, KRO PEN NEEDLE 6MM X 31G, KRO PEN NEEDLE 8MM X 31G, PEN NEEDLE 30G 8MM, PEN NEEDLE 31G 5MM, PEN NEEDLE 31G 6MM, PEN NEEDLE 31G 8MM, PEN NEEDLE 31G X 1/4", PEN NEEDLE 31G X 3/16", PEN NEEDLE 31G X 5/16", PEN NEEDLE 32G 4MM, PEN NEEDLE 32G X 5/32", PEN NEEDLE 4MM 32G, PEN NEEDLE 5MM 31G, PV PEN NEEDLES 6MM 31G, QC UNIFINE PENTIP 6MM 31G, RELION PEN NEEDLE 31G 6MM, RELION PEN NEEDLE 31GX1/4", RELION PEN NEEDLE 31GX5/16", RELION PEN NEEDLE 32GX5/32", LEADER PEN NEEDLES 31G, PEN NEEDLES 6MM 31G, PV PEN NEEDLES 8MM 31G, QC UNIFINE PENTIP 8MM 31G, PRODIGY INS SYR 1ML 28GX1/2", PRODIGY SYRNG 0.5 ML 31GX5/16", RELION ULTRA COMFORT, FP STERILE PAD 2" X 2", BL STERILE PADS 2"X2", ECK STERILE PADS 2"X2", GNP STERILE PADS 2"X2", PV STERILE PADS 2" X 2", QC STERILE PADS 2"X2", RA STERILE PADS, SM STERILE PADS 2" X 2", STERILE PADS 2" X 2", STERILE PADS 2"X2", SURE COMFORT PEN NDL 32G 4MM, GNP ULTICARE PEN NDL 31G 8MM, GNP ULTICARE PEN NDL 32G 4MM, GNP ULTICARE PEN NDL 32G 6MM, HM ULTICARE PEN NEEDLE 4MM 32G, HM ULTICARE PEN NEEDLE 8MM 31G, ULTICARE PEN NEEDLE 4MM 32G, ULTICARE PEN NEEDLE 8 MM 31G, ULTICARE PEN NEEDLE 8MM 31G, ULTICARE PEN NEEDLES 4MM 32G, ULTICARE PEN NEEDLES 6MM 32G, ULTICARE PEN NEEDLES 8MM 31G, YOURX ULTICARE PEN NDL 4MM 32G, YOURX ULTICARE PEN NDL 8MM 31G, ULTRA COMFORT, CAREONE UNIFINE PENTIP 4MM 32G, CAREONE UNIFINE PENTIP 5MM 31G, CAREONE UNIFINE PENTIP 8MM 31G, CAREONE UNIFINE PNTP 12MM 29G, DR UNIFINE PENTIPS 12MM NDL, DR UNIFINE PENTIPS 8MM NDL, PC UNIFINE PENTIPS 12MM NEEDLE, PC UNIFINE PENTIPS 31GX3/16", PC UNIFINE PENTIPS 8MM NEEDLE, PV UNIFINE PENTIPS 31GX3/16", PV UNIFINE PENTIPS 32GX5/32", QC UNIFINE PENTIPS 32GX5/32", QC UNIFINE PENTIPS 4MM 32G, SHOPKO UNIFINE

PENTIPS 4MM 32G, SHOPKO UNIFINE PENTIPS 5MM 31G, SHOPKO UNIFINE PENTIPS 8MM 31G, SHOPKO UNIFINE PNTIPS 12MM 29G, UNIFINE PENTIP 0.5CC NEEDLE, UNIFINE PENTIPS 12MM 29G, UNIFINE PENTIPS 12MM NEEDLE, UNIFINE PENTIPS 31G 5MM, UNIFINE PENTIPS 31G 8MM, UNIFINE PENTIPS 31GX3/16", UNIFINE PENTIPS 32G 4MM, UNIFINE PENTIPS 32G 6MM, UNIFINE PENTIPS 32GX1/4", UNIFINE PENTIPS 32GX5/32", UNIFINE PENTIPS 8MM 31G, UNIFINE PENTIPS 8MM NEEDLE, UNIFINE PENTIPS 8MM NEEDLES, VANISHPOINT 29GX1/2" 1 ML SR, VEO INSULIN SYRINGE, VERIFINE PEN NEEDLE 31G X 8MM, VERIFINE PEN NEEDLE 32G X 4MM

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

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

PART B PREREQUISITE
N/A

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
PENDING CMS APPROVAL

PART B PREREQUISITE
N/A

DOXEPIN TOPICAL

MEDICATION(S)
DOXEPIN 5% CREAM

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 month

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

PART B PREREQUISITE
N/A

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

AGE RESTRICTION
18 years and older

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

COVERAGE DURATION
Initial: 2 months, Continuation: 1 year

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

PART B PREREQUISITE

N/A

DUPIXENT

MEDICATION(S)
DUPIXENT PEN, DUPIXENT 200 MG/1.14 ML SYRING, DUPIXENT 300 MG/2 ML 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. For AD: Diagnosis, pre-requisite treatments, BSA and/or SCORAD index value. If patient is new to plan, meets initial criteria at time they had started the medication. Documented dose and frequency are within the FDA approved Dosing and Frequency.

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

OTHER CRITERIA
PENDING CMS APPROVAL

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

ENBREL

MEDICATION(S)
ENBREL 25 MG/0.5 ML SYRINGE, ENBREL 25 MG/0.5 ML VIAL, ENBREL 50 MG/ML SYRINGE, ENBREL MINI, ENBREL SURECLICK

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

OFF LABEL USES
Graft versus host disease, Behcet's disease

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

REQUIRED MEDICAL INFORMATION
RA: diagnosis and disease severity, score from objective measure/tool at baseline and continuation. Provider has assessed disease severity utilizing an objective measure/tool. Examples include [Clinical Disease Activity Index (CDAI), Disease Activity Score with 28-joint counts (erythrocyte sedimentation rate or C-reactive protein), Patient Activity Scale (PAS or PAS-II), Routine Assessment of Patient Index Data 3 (RAPID3), Simplified Disease Activity Index (SDAI)]. Member has documented moderate to severe active disease and diagnosis of RA per American College of Rheumatology (ACR) criteria. pJIA: Diagnosis of pJIA as evidenced by 5 or more joints with active arthritis. Documented baseline 10-joint clinical juvenile arthritis disease activity score (cJADAS-10). PsA: Diagnosis, pre-requisite medication trials, reauth: positive clinical response. AS: Diagnosis, pre-requisite medication trials, objective measure at initiation and continuation (examples outlined in other criteria). 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. PP: Diagnosis, PASI score, reauth: positive response. GVHD: diagnosis, reauth: positive response. Behcet’s: Diagnosis, pre-requisite medication trial, reauth: positive response (Ex dependent upon organ involvement but may include best-corrected visual acuity, serum markers (e.g., CRP), ulcer depth, number and/or lesion size. For all diagnoses: If patient is new to plan, meets initial criteria at time they had started the medication. Documented dose and frequency are within the FDA approved Dosing and Frequency.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

RA/AS/pJIA prescribed by or in consultation with a rheumatologist. PsA, prescribed by or in consultation with a rheumatologist or a dermatologist. PP, prescribed by or in consultation with a dermatologist. GVHD, prescribed by or in consultation with an oncologist, hematologist, or a transplant center physician. Behcet's disease, prescribed by or in consultation with a rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist.

COVERAGE DURATION

GVHD: 1 month, continuation 3 months. All others: Initial 6 months, continuation 1 year

OTHER CRITERIA

PENDING CMS APPROVAL

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
Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD

REQUIRED MEDICAL INFORMATION
UC: The member must have a confirmed diagnosis of moderately to severely active ulcerative colitis confirmed by endoscopy and/or an objective score (e.g. modified Mayo score [MMS], Truelove and Witts criteria). Trial of preferred products. Reauth: Improvement on endoscopy or objective score. CD: Diagnosis, pre-requisite medication trials (if applicable), Reauth: positive clinical response.

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
1. Moderately to severely active Ulcerative Colitis-Initial therapy: Approve if the patient has tried TWO of the following preferred products: a preferred adalimumab product, Stelara SC, Rinvoq, Xeljanz/XR tablets and Zeposia. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074) and Simlandi. A previous trial with a non-preferred adalimumab would also count. Continuation therapy: Approve if the patient meets ALL of the following (i, ii, iii and iv): i.If patient is new to plan, meets initial criteria at time they had started the medication, ii. Patient has been established on the requested medication for at least 5 months
iii. Patient has experienced a positive clinical response compared to baseline as evidenced by

improvement on endoscopy or improvement using an objective scoring system (e.g. modified Mayo score [MMS], Truelove and Witts criteria) iv. Documented dose and frequency are within the FDA approved Dosing and Frequency. 2. Moderately to severely active Crohn's disease-Initial therapy: Approve if the patient meets ALL of the following (i, ii, iii and iv): i. Documented diagnosis of moderate to severe Crohn's disease, ii. Patient is currently experiencing one of the following (a, b, c, d or e): a. Frequent diarrhea and abdominal pain, b. At least 10% weight loss c.Complication such as obstruction, fever, abdominal mass, d. Abnormal lab values (e.g. C-reactive protein), e. CD Activity Index (CDAI) greater than 20, iii. 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, iv. Patient has tried TWO of the following preferred products: a preferred adalimumab product, Skyrizi SQ, Stelara SQ or Rinvoq. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074) and Simlandi. Continuation therapy: Approve if the patient meets ALL of the following (i, ii, iii and iv): i. If patient is new to plan, meets initial criteria at time they had started the medication, ii. Patient has been established on the requested medication for at least 5 months. iii. Patient has documentation of positive clinical response to therapy as evidenced by at least one of the following (a or b): a. Improvement in intestinal inflammation (e.g. mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level)] from baseline b. Reversal of high fecal output state iv. Documented dose and frequency are within the FDA approved Dosing and Frequency

PART B PREREQUISITE

N/A

EPCLUSA

MEDICATION(S)
EPCLUSA, SOFOSBUVIR-VELPATASVIR

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

OFF LABEL USES
Indications consistent with current AASLD/IDSA guidance

EXCLUSION CRITERIA
Combination use with other direct acting antivirals, excluding ribavirin

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
3 years or older

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

COVERAGE DURATION
Will be consistent with AASLD/IDSA guidance

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

PART B PREREQUISITE
N/A

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

ERIBULIN

MEDICATION(S)
ERIBULIN 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
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

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, TORPENZ

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
PENDING CMS APPROVAL

PART B PREREQUISITE
N/A

FILGRASTIM

MEDICATION(S)
ZARXIO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
1.Severe Chronic Neutropenia - Member must have a diagnosis of congenital, cyclic or idiopathic neutropenia
2.Neutropenia associated with acquired immunodeficiency syndrome - Member has diagnosis of AIDS with neutropenia
3.Aplastic anemia – approve
4.Agranulocytosis - Member must have diagnosis of congenital or drug-induced agranulocytosis

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
Evidence of autoantibodies against the C1-INH protein, underlying lymphoproliferative, malignant, or autoimmune disorder that causes angioedema attacks, use for prophylaxis of HAE attacks, Use in combination with other agents approved for acute treatment of HAE attack (e.g. Berinert, Kalbitor, Ruconest), severity and frequency of HAE attacks

REQUIRED MEDICAL INFORMATION
Diagnosis, lab results (C1-INH inhibitor, C1-INH functional level, C4 levels, C1q levels)

AGE RESTRICTION
18 years and older

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

COVERAGE DURATION
1 year

OTHER CRITERIA
Hereditary Angioedema due to C1 Inhibitor (C1-INH) deficiency (Type I or Type II): Treatment of acute attacks – initial therapy – patient meets all of the following (1 and 2): 1. The patient has HAE type I or II as confirmed by the following diagnostic criteria: a.Documentation of TWO separate measurements for each test (i, ii and iii): i. Low serum complement factor 4 (C4) level at baseline, as defined by the laboratory reference values AND ii. Low C1 inhibitor (C1-INH) level OR low C1-INH functional level (i.e. functional C1-INH less than 50% or below lower limit of normal laboratory reference range) at baseline, as defined by the laboratory reference values AND iii. C1q levels are within normal limits at baseline, as defined by the laboratory reference values 2. The patient is experiencing at least one symptom of

moderate to severe HAE attacks (e.g. airway swelling, severe abdominal pain, facial swelling, painful facial distortion, extremity swelling causing disability). Treatment of acute attacks – continuation therapy – patient meets all of the following (1 and 2): 1. If patient is new to plan, they met initial criteria at time of starting the medication, 2. Patients has had a favorable clinical response (e.g. decrease in the duration of HAE attacks, quick onset of symptom relief, complete resolution of symptoms, decrease in HAE acute attack frequency or severity) with icatibant treatment

PART B PREREQUISITE

N/A

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

GATTEX

MEDICATION(S)
GATTEX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
PENDING CMS APPROVAL

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, previous medication tried

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Lifetime

OTHER CRITERIA
For Type 2 diabetes mellitus (T2DM), member must meet all of the following: 1. Member has documented diagnosis of T2DM AND 2.Member has tried or has contraindication to metformin

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, previous medications tried

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Lifetime

OTHER CRITERIA
For Type 2 diabetes mellitus (T2DM), member must meet all of the following (1 and 2): 1. Member has documented diagnosis of T2DM AND 2. Member has tried or has contraindication to metformin

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

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
Growth Hormone in Children and Adolescents Initial Treatment. Must meet ONE of the following: 1. Patient had hypophysectomy, OR
2. Had congenital hypopituitarism AND had one growth hormone stimulation test less than 10 ng/ml OR deficiency in at least one other pituitary hormone and/or the patient has the imaging triad of ectopic posterior pituitary and pituitary hypoplasia with abnormal pituitary stalk OR 3. Patient with multiple pituitary deficiencies and patient has 3 or more pituitary hormone deficiencies or has had one growth hormone test less than 10 ng/ml, 4. Patient had a brain radiation or tumor resection and had one growth hormone stimulation test less than 10 ng/ml or has deficiency in at least 1 other pituitary hormone (e.g., ACTH, TSH, gonadotropin deficiency [LH and/or FSH are counted as one deficiency], or prolactin, 5. Patient had 2 growth hormone stimulation tests with the following: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon and both are less than 10 ng/ml OR had at least 1 GH test less than 10 ng/ml and has at least one risk factor for GHD (e.g., ht for age curve deviated down across 2 major height percentiles [e.g., from above the 25 percentile to below the 10 percentile], growth rate is less than the expected normal growth rate based on age and gender, low IGF-1 and/or IGFBP-3 levels). For continuing treatment: Prescriber confirms response to therapy.

AGE RESTRICTION
ISS 5 y/o or older, SGA 2 y/o or older, SBS 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 1 month, others 12 mos

OTHER CRITERIA

GH Def in Adults/Adol, Init: 1.Endo must certify tx is not being prescribed for anti-aging or to enhance athletic performance, 2.Pt has either childhood onset or adult onset GHD resulting from GH def alone, multiple hormone def form pituitary dz, hypothalamic dz, pituitary surgery, cranial radiation tx, tumor tx, TBI or subarachnoid hemorrhage AND 3. Meets 1 of the following: a.Known perinatal insults or congenital or genetic defects or structural hypothalamic pituitary defects, OR b.3 or more pituitary hormone def (ACTH, TSH, LH/FSH or prolactin, age/gender adjusted IGF-1 below lower limits of the normal reference range) AND other causes of low serum IGF-1 have been excluded, OR c.Neg response to 1 pref GH stim test (note: for transitional adol: must be off tx for at least 1 mo b/f retesting): i.Insulin peak response less than or equal to 5 mcg/L, ii.Glucagon peak less than or equal to 3 mcg/L (BMI is less than or equal to 25), iii. Glucagon peak less than or equal to 3 mcg/L and BMI is greater than or equal to 25 and less than or equal to 30 with a high pretest probability of GH def, iv.Less than or equal to 1 mcg/L and BMI is greater than or equal to 25 and less than or equal to 30 with a low pretest probability of GH def, v. Less than or equal to 1 mcg/L (BMI is greater than 30), vi. If insulin and glucagon are CI, then arginine test with peak of less than or equal to 0.4 mcg/L, vii. Macrilen peak less than 2.8 ng/ml and BMI is less than or equal to 40, e.For cont tx: endo must certify tx is not being prescribed for anti-aging or to enhance athletic performance. ISS, Init: 1.Baseline height is less than 1.2 percentile or SDS less than -2.25 for age/gender, open epiphyses, does not have CDGP and height velocity is either growth rate (GR): a. Less than 4 cm/year for pts greater than or equal to 5 or, b. Growth velocity is less than 10th percentile for age/gender. ISS: Cont Tx: Prescriber confirms response to tx. CKD: Init Tx: CKD must be defined by abnormal CrCl. Noonan Syndrome, Init: Baseline height must be less than the 5th percentile. Prader-Willi, Continuing treatment in adults or adolescents who don’t meet child requirements: MD must certify tx is not being prescribed for anti-aging or to enhance athletic performance. SHOX, Init: 1.SHOX must be defined by chromosomal analysis, 2.Open epiphyses, 3.Height less than the 3rd percentile for age and gender. SGA-Init: 1.Baseline height must be less than the 5th percentile for age/gender, 2.Born SGA age (birth weight/length that is more than 2 SD below the mean for gestational age/gender) AND did not have sufficient catch up growth by 2-4 y/o. SGA, Cont: Prescriber confirms response to tx. CKD, Noonan Syndrome, Prader-Willi in children/adolescents, SHOX, Turner Syndrome, Cont: Prescriber confirms response to therapy. SBS Init: Pt must be receiving specialized nutritional support. SBS Cont: A 2nd course of tx is allowed if responded to initial tx w/decr need 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), use for acute treatment of HAE attacks, evidence of autoantibodies against the C1-INH protein, underlying lymphoproliferative, malignant, or autoimmune disorder that causes angioedema attacks

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

AGE RESTRICTION
6 years or older

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

COVERAGE DURATION
Initial: 6 months, Continuation: 1 year

OTHER CRITERIA
Hereditary Angioedema (HAE) 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 and 2): 1. The patient has HAE type I or type II as confirmed by the following diagnostic criteria:
a. Documentation of TWO separate measurements for each test (i, ii and iii): i.Low serum complement factor 4 (C4) level at baseline, as defined by the laboratory reference values AND ii. Low C1 inhibitor (C1-INH) level OR low C1-INH functional level (i.e. functional C1-INH less than 50% or below lower limit of normal laboratory reference range) at baseline, as defined by the laboratory reference values

AND iii. C1q levels are within normal limits at baseline, as defined by the laboratory reference values, 2. Patient has a history of TWO or more severe HAE attacks (i.e. airway swelling, facial swelling, painful facial distortion, extremity swelling causing disability) per month. Continuation of therapy: Patient meets both of the following (1, 2 and 3): 1. If patient is new to plan, must meet initial criteria at time treatment had been started, 2.Medical chart documentation of the number and severity of HAE attacks occurring in the previous 6 months, 3. Patient has experienced a reduction in the number and/or severity of HAE attacks from baseline

PART B PREREQUISITE

N/A

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

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

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

COVERAGE DURATION
6 months initial, 12 months cont.

OTHER CRITERIA
Non-24 hour sleep-wake cycle disorder:
Initial: Approve if patient meets all of the following (1, 2 and 3):
1.Patient is totally blind with no perception of light,
2.Diagnosis is confirmed by either assessment of one physiologic circadian phase marker (e.g., measurement of urinary melatonin levels, dim light melatonin onset, assessment of core body temperature), or if assessment of physiologic circadian phase marker cannot be done, the diagnosis must be confirmed by actigraphy performed for at least 1 week plus evaluation of sleep logs recorded for at least 1 month,
3.Symptoms of insomnia are causing function impairment (i.e. excessive daytime drowsiness, reduced

daytime activity, etc.).
Continuation - Approve if patient meets all of the following (1,2 and 3):
1.If patient is new to plan, meets initial criteria at the time they had started the medication,
2.Documented dose and frequency are within the FDA approved dosing and frequency,
3.Patient received at least 4 months of therapy and there is documentation of a positive clinical response to therapy (i.e. improvement in nighttime total sleep time compared to baseline, improvement in nighttime sleep quality).
Smith Magenis Syndrome (SMS):
Initial – Approve if patient is experiencing nighttime sleep disturbances (i.e. difficulty falling asleep, frequent nighttime waking, early waking, etc.).
Continuation - Approve if patient meets all of the following (1, 2 and 3):
1.If patient is new to plan, meets initial criteria at the time they had started the medication,
2.Documented dose and frequency are within the FDA approved dosing and frequency,
3.Patient received at least 4 months of therapy and there is documentation of a positive clinical response to therapy (i.e. improvement in nighttime total sleep time compared to baseline, improvement in nighttime sleep quality).

PART B PREREQUISITE
N/A

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)
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(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) 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

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

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

REQUIRED MEDICAL INFORMATION
For all dx: If new to plan, meets init criteria at time they started the med. Documented dose/freq are w/in FDA approved Dosing/Freq. RA:Mod/severe active dz and dx of RA per ACR criteria. MD assessed dz severity utilizing an obj measure.Cont:pos response in obj measure compared to baseline (BL). Ex include CDAI, Disease Activity Score with 28-joint counts (ESR or CRP), PAS or PAS-II, RAPID3, SDAI, score from obj measure at BL and cont. pJIA:Dx of pJIA as evidenced by 5 or more joints with active arthritis, Documented BL cJADAS-10, score from obj measure/tool at BL and cont. PsA:Dx, pre-req med trials, cont: pos clinical response. AS:Dx, pre-req med trials, confirmed dx of AS as defined by presence of active dz for at least 4 wks defined by any dz specific functional scoring tool (i.e.BASDAI Index of at least 4, HAQ, MHAQ, etc.) and expert opinion based on clinical features, acute phase reactants and imaging. Cont:Pos clinical response to tx based on at least 1 obj measure compared to BL. Ex of obj measures include ASDAS, ASQoL, BASDAI, BASFI, BAS-G, BASMI, DFI, HAQ-S, and/or serum markers (e.g., CRP, ESR). PP: Dx, PASI score, cont: Approve if evidence of a pos response based on a or b: a.Achieved or maintained clear/minimal dz, b.Decr in PASI score compared to BL. CD:Dx, pre-req med trials, cont: Approve if meets a and b: a.Estab on med for at least

5 mo, b.Pos clinical response to tx based on i or ii: i.Improvement in intestinal inflammation (e.g. mucosal healing, labs [PLT counts, ESR, CRP]) from BL, ii.Reversal of high fecal output state. UC:Dx of mod/severely active UC confirmed by endoscopy and/or an obj score (e.g. MMS, Truelove and Witts criteria), Trial of pref products. Cont:Improvement on endoscopy or obj score. HS:Dx, pre-req med trials, obj measure at cont (ex Hurley Staging, PGA, HSSI). Uveitis: Dx (non-infectious intermediate, posterior or panuveitis that is chronic, recurrent, tx-refractory or vision-threatening). Pre-req trials, cont:pos response.

AGE RESTRICTION
PENDING CMS APPROVAL

PRESCRIBER RESTRICTION
RA/pJIA/AS-prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or dermatologist. PP, HS-prescribed by or in consultation with a dermatologist. UC/CD-prescribed by or in consultation with a gastroenterologist. UV-prescribed by or in consultation with an ophthalmologist or rheumatologist.

COVERAGE DURATION
Initial: 6 months, Continuation: 1 year

OTHER CRITERIA
PENDING CMS APPROVAL

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, PASI score, reauth: positive response

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a dermatologist

COVERAGE DURATION
Initial 6 months, continuation 1 year

OTHER CRITERIA
PENDING CMS APPROVAL

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 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
1.Graft versus host disease (GVHD) – approve if the patient has tried one conventional systemic treatment for GVHD (e.g. corticosteroids [methylprednisolone, prednisone], cyclosporine, tacrolimus, mycophenolate mofetil, imatinib),
2.B-cell Lymphoma – approve if the patient is using Imbruvica as second-line or subsequent therapy according to the prescribing physician,
3.Central Nervous System Lymphoma (primary) – approve if relapsed or refractory,
4.Hairy Cell Leukemia – approve if relapsed or refractory,
5.Mantle Cell Lymphoma, Marginal Zone Lymphomas, Chronic Lymphocytic Leukemia or Small

Lymphocytic Lymphoma – Approve if patient meets one of the following (a, b, c or d):
a.The patient has demonstrated a failure of or intolerance to one of the preferred products, Calquence or Brukinsa,
b.The patient has a documented contraindication to one of the preferred products, Calquence or Brukinsa,
c.The patient had an adverse reaction or would be reasonably expected to have an adverse reaction to one of the preferred products, Calquence or Brukinsa,
d.The patient has a clinical condition for which there is no listed preferred formulary alternatives to treat the condition based on published guidelines or clinical literature.

PART B PREREQUISITE
N/A

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
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 infectious disease specialist

COVERAGE DURATION
1 month

OTHER CRITERIA
N/A

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 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

INTRAROSA/OSPHENA

MEDICATION(S)
INTRAROSA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

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 1 MG TABLET, ISTURISA 5 MG TABLET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, prior treatments, Reauth: clinical response

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist

COVERAGE DURATION
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, FLEBOGAMMA DIF 5% VIAL, GAMMAGARD LIQUID, GAMMAGARD S-D, GAMUNEX-C, PRIVIGEN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION

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

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

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
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Mantle Cell Lymphoma, Chronic lymphocytic lymphoma, small lymphocytic lymphoma – Approve if patient meets one of the following (1, 2, 3 or 4):
1.The patient has demonstrated a failure of or intolerance to one of the preferred products, Calquence and Brukinsa
2.The patient has a documented contraindication to one of the preferred products, Calquence and Brukinsa
3.The patient had an adverse reaction or would be reasonably expected to have an adverse reaction to one of the preferred products, Calquence and Brukinsa
4.The patient has a clinical condition for which there is no listed preferred formulary alternatives to treat the condition based on published guidelines or clinical literature.

PART B PREREQUISITE

N/A

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

JYLAMVO

MEDICATION(S)
JYLAMVO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
PENDING CMS APPROVAL

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
PENDING CMS APPROVAL

PART B PREREQUISITE
N/A

KALYDECO

MEDICATION(S)
KALYDECO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

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

REQUIRED MEDICAL INFORMATION
Diagnosis, evidence of abnormal CFTR function, relevant mutation

AGE RESTRICTION
N/A

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

COVERAGE DURATION
3 years

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

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
RA: diagnosis and disease severity, score from objective measure/tool at baseline and continuation.
PMR: Diagnosis, pre-requisite medication trials, reauth: positive response

AGE RESTRICTION
PENDING CMS APPROVAL

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a rheumatologist

COVERAGE DURATION
Initial 6 months, continuation 1 year

OTHER CRITERIA
Rheumatoid arthritis:
1.Initial - approve if the patient meets all of the following:
i.Provider has assessed disease severity utilizing an objective measure/tool. Examples include [Clinical Disease Activity Index (CDAI), Disease Activity Score with 28-joint counts (erythrocyte sedimentation rate or C-reactive protein), Patient Activity Scale (PAS or PAS-II), Routine Assessment of Patient Index Data 3 (RAPID3), Simplified Disease Activity Index (SDAI)]
ii.Patient has documented moderate to severe active disease and diagnosis of RA per American College of Rheumatology (ACR) criteria
iii.Approve if the patient has tried two of the following: Enbrel, a preferred adalimumab product, Orencia, Rinvoq or Xeljanz/XR. Please Note: preferred adalimumabs include: Humira (NDCs starting

with -00074) and Simlandi.
2.Continuation - approve if the patient meets all of the following:
i.If patient is new to plan, meets initial criteria at time they had started the medication
ii.Member is responding positively to therapy based on improvement in objective measurement/tool as compared to baseline
iii.Documented dose and frequency is within the FDA approved Dosing and Frequency.
Polymyalgia Rheumatica:
1.Initial - Approve if the patient meets all of the following (a and b):
a.Patient has a diagnosis of polymyalgia rheumatica according to European League Against Rheumatism/American College of Rheumatology (ACR/EULAR) classification criteria.
b.Patient meets one of the following (i or ii):
i.Patient has tried and had an inadequate response to systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR for a minimum of 8 weeks
ii.Patient is currently being treated with systemic corticosteroids at a dose equivalent to at least 7.5 mg
2.Continuation - Approve if the patient meets all of the following (a, b and c):
a.If patient is new to plan, meets initial criteria at time they had started the medication
b.Patient has achieved or maintained a positive clinical response to therapy as evidenced by one of the following (i or ii):
i.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Kevzara) (e.g. C-reactive protein, erythrocyte sedimentation rate)
ii.Compared with baseline, patient experienced an improvement in at least one symptom, such as decreased shoulder, neck, upper arm, hip, or thigh pain or stiffness or improved range of motion
c.Documented Dose and Frequency are within the FDA approved Dosing and Frequency.

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 RA/sJIA: diagnosis and disease severity, score from objective measure/tool at baseline and continuation. For Cryopyrin Associated Periodic Syndrome: diagnosis reauth: positive response. DIRA: Diagnosis, genetic testing, reauth: positive response. For all diagnoses: Documented Dose and Frequency are within the FDA approved Dosing and Frequency. If patient is new to plan, meets initial criteria at time they had started the medication.

AGE RESTRICTION
RA: 18 years and older

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
Initial 6 months, continuation 1 year

OTHER CRITERIA
PENDING CMS APPROVAL

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)
MIFEPRISTONE 300 MG TABLET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Pregnancy.

REQUIRED MEDICAL INFORMATION
Diagnosis, reauth: positive response

AGE RESTRICTION
Aged 18 years or older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist or specialist in treating Cushing’s syndrome

COVERAGE DURATION
Initial – 6 months, Continuation: 1 year

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

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

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

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

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

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

LUPRON DEPOT

MEDICATION(S)
LUPRON DEPOT, LUPRON DEPOT (LUPANETA)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
Premenstrual disorders – 18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Endometriosis: 6 months, Uterine leiomyomata: 3 months All others: 1 year

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

Approve if patient meets both of the following (a and b):
a.Patient has severe refractory premenstrual symptoms,
b.Patient has tried a selective serotonin reuptake inhibitor (SSRI) AND a combined oral contraceptive for treatment of premenstrual disorder.

PART B PREREQUISITE
N/A

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

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

MOTEGRITY

MEDICATION(S)
MOTEGRITY

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
For chronic idiopathic constipation – the member must meet one of the following criteria (1, 2, 3 or 4):
1.The member has demonstrated a failure of or intolerance to the preferred product, Linzess
2.The member has a documented contraindication to the preferred products, Linzess
3.The member had an adverse reaction or would be reasonably expected to have an adverse reaction to the preferred products, Linzess OR
4.The patient has a clinical condition for which there is no listed preferred formulary alternatives to treat the condition based on published guidelines or clinical literature.

PART B PREREQUISITE
N/A

MYALEPT

MEDICATION(S)
MYALEPT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

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

REQUIRED MEDICAL INFORMATION
Diagnosis, Reauth: positive clinical response

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist or a geneticist

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
Initial criteria – Approve if patient meets both of the following (1 and 2):
1.Patient has diagnosis of congenital or acquired generalized lipodystrophy,
2.Patient has experienced one or more signs of leptin deficiency (e.g. hyperinsulinemia, type 2 diabetes mellitus, and hypertriglyceridemia).
Continuation Criteria – Approve if patient meets all of the following (1, 2 and 3):
1.If patient is new to plan, meets initial criteria at time they had started the medication,
2.Documented dose and frequency are within the FDA approved Dosing and Frequency,
3.Patient has experienced a positive clinical response to treatment (e.g. sustained improvement in triglyceride levels, hemoglobin A1c from baseline)

PART B PREREQUISITE

N/A

MYLOTARG

MEDICATION(S)
MYLOTARG

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

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

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

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by a neurologist or a psychiatrist.

COVERAGE DURATION
Initial: 3 months, Continuation: 1 year.

OTHER CRITERIA
Pseudobulbar Affect - Diagnosis is confirmed by all of the following:
a.Physician attestation that the patient has experienced involuntary, sudden, or frequent episodes of laughing and/or crying consistent with PBA at baseline
b.Documentation of a Center for Neurologic Study-Lability Scale (CNS-LS) baseline score of at least 13.
c.Patient has a brain injury or neurologic disease 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

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

OJEMDA

MEDICATION(S)
OJEMDA

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
RA: diagnosis and disease severity, score from objective measure/tool at baseline and continuation. Alopecia areata: diagnosis, scalp involvement, length of current episode, pre-requisite medication trials, reauth: positive response.

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 6 months, continuation 1 year

OTHER CRITERIA
Rheumatoid arthritis:
1.Initial - approve if the patient meets all of the following:
i.Provider has assessed disease severity utilizing an objective measure/tool. Examples include [Clinical Disease Activity Index (CDAI), Disease Activity Score with 28-joint counts (erythrocyte sedimentation rate or C-reactive protein), Patient Activity Scale (PAS or PAS-II), Routine Assessment of Patient Index Data 3 (RAPID3), Simplified Disease Activity Index (SDAI)]
ii.Patient has documented moderate to severe active disease and diagnosis of RA per American

College of Rheumatology (ACR) criteria
iii.Approve if the patient has tried two of the following: Enbrel, a preferred adalimumab product, Orencia, Rinvoq or Xeljanz/XR. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074) and Simlandi.
2.Continuation - approve if the patient meets all of the following (i, ii, and iii):
i.If patient is new to plan, meets initial criteria at time they had started the medication
ii.Member is responding positively to therapy based on improvement in objective measurement/tool as compared to baseline
iii.Documented dose and frequency are within the FDA approved Dosing and Frequency.
Alopecia Areata:
1.Initial – approve if the patient meets all of the following (a, b, c and d):
a.Patient has a current episode of alopecia areata lasting for 6 months or more
b.Patient has 50 percent or more scalp hair loss
c.Patient has tried at least one of the following for alopecia areata (a or b):
i.Conventional systemic therapy (e.g. corticosteroids, methotrexate and cyclosporine.)
ii.Topical corticosteroids
d.Patient does not have hair loss due to androgenetic alopecia, chemotherapy-induced hair loss, or other causes of hair loss other than alopecia areata
2.Continuation - approve if the patient meets all of the following (a, b and c):
a.If patient is new to plan, meets initial criteria at time they had started the medication
b.Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Olumiant) in extent and density of scalp hair loss
c.Documented dose and frequency are within the FDA approved Dosing and Frequency

PART B PREREQUISITE
N/A

OMNIPOD

MEDICATION(S)
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
UC: The member must have a confirmed diagnosis of moderately to severely active ulcerative colitis confirmed by endoscopy and/or an objective score (e.g. modified Mayo score [MMS], Truelove and Witts criteria). Trial of preferred products. Reauth: Improvement on endoscopy or objective score

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
1.Initial therapy: Approve if the patient has tried TWO of the following preferred products: a preferred adalimumab product, Stelara SC, Rinvoq, Xeljanz/XR tablets and Zeposia. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074) and Simlandi. A previous trial with a non-preferred adalimumab would also count.
2.Continuation therapy: Approve if the patient meets ALL of the following (i, ii, iii and iv):
i.If patient is new to plan, meets initial criteria at time they had started the medication
ii.Patient has been established on the requested medication for at least 5 months
iii.Patient has experienced a positive clinical response compared to baseline as evidenced by

improvement on endoscopy or improvement using an objective scoring system (e.g. modified Mayo score [MMS], Truelove and Witts criteria).
iv.Documented dose and frequency are within the FDA approved Dosing and Frequency

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

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 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

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
RA: diagnosis and disease severity, score from objective measure/tool at baseline and continuation. Disease severity utilizing an objective measure/tool. Examples include [Clinical Disease Activity Index (CDAI), Disease Activity Score with 28-joint counts (erythrocyte sedimentation rate or C-reactive protein), Patient Activity Scale (PAS or PAS-II), Routine Assessment of Patient Index Data 3 (RAPID3), Simplified Disease Activity Index (SDAI)]. Patient has documented moderate to severe active disease and diagnosis of RA per American College of Rheumatology (ACR) criteria. JIA: diagnosis and disease severity, score from objective measure/tool at baseline and continuation. For all diagnoses: If patient is new to plan, meets initial criteria at time they had started the medication. Documented dose and frequency are within the FDA approved Dosing and Frequency.

AGE RESTRICTION
RA: 18 and older. pJIA/PsA: 2 years and older.

PRESCRIBER RESTRICTION
RA/JIA: Prescribed by or in consultation with a rheumatologist. Prescribed by or in consultation with a Rheumatologist, Dermatologist

COVERAGE DURATION
Initial 6 months, continuation 1 year

OTHER CRITERIA
PENDING CMS APPROVAL

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
Diagnosis, evidence of abnormal CFTR function, relevant mutation

AGE RESTRICTION
N/A

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

COVERAGE DURATION
3 years

OTHER CRITERIA
1. Diagnosis is cystic fibrosis, AND 2. Patient must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF AND 3. Evidence of abnormal CFTR function as demonstrated by a, b or c:
a. Elevated sweat chloride test, b. Two CFTR mutations, c. Abnormal nasal potential difference, 4. For Orkambi: The patient who has two mutated copies of F508del mutation in the CFTR gene.

PART B PREREQUISITE
N/A

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

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 all diagnoses: If patient is new to plan, meets initial criteria at time they had started the medication. Documented Dose and Frequency are within the FDA approved Dosing and Frequency. PsA: Diagnosis, pre-requisite medication trials, reauth: positive clinical response. PP: Diagnosis, PASI score, reauth: positive response. Behcet's: Diagnosis, pre-requisite medication trial, reauth: positive response.

AGE RESTRICTION
PP: 6 years of age and older. All others: 18 years and older.

PRESCRIBER RESTRICTION
PsA: Prescribed by or in consultation with a Rheumatologist, Dermatologist. PP: Prescribed by or in consultation with a dermatologist. Behcet's: prescribed by or in consultation with a rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist.

COVERAGE DURATION
Initial - 6 months, continuation 1 year

OTHER CRITERIA
PENDING CMS APPROVAL

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

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, APREPITANT, ARFORMOTEROL TARTRATE, ARSENIC TRIOXIDE, ARZERRA, ASPARLAS, ASTAGRAF XL, AZACITIDINE, AZATHIOPRINE 50 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, 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, 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, EMPLICITI, ENGERIX-B ADULT, ENGERIX-B PEDIATRIC-ADOLESCENT, ENHERTU, ENVARSUS XR, EPIRUBICIN 200 MG/100 ML VIAL, EPIRUBICIN 50 MG/25 ML VIAL, ERBITUX, 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, HEPLISAV-B, HERCEPTIN 150 MG VIAL, HERCEPTIN HYLECTA, HERZUMA,

IDARUBICIN HCL, IFOSFAMIDE, IMFINZI, INTRALIPID, IPRATROPIUM BR 0.02% SOLN, IPRATROPIUM-ALBUTEROL, IRINOTECAN HCL, IXEMPRA, JEVTANA, JYNNEOS, JYNNEOS (NATIONAL STOCKPILE), KADCYLA, KANJINTI, KEYTRUDA, 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, 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, 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, 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, VECTIBIX, VEGZELMA, VINBLASTINE SULFATE, VINCASAR PFS, VINCRISTINE SULFATE, VINORELBINE TARTRATE, VYXEOS, YERVOY, YONDELIS, 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.

PAZOPANIB

MEDICATION(S)
PAZOPANIB HCL

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

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)
NYVEPRIA, STIMUFEND

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

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)

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
PENDING CMS APPROVAL

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.

COVERAGE DURATION
ITP 90 day initial, w/pos clinical resp then 1 yr. Hep C & MDS thrmbocytpna and Apalstc Anema 12mo.

OTHER CRITERIA
PENDING CMS APPROVAL

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

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

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)
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
For all dx: If pt is new to plan, meets init criteria at time they had started the med. Documented dose/frequency are w/in the FDA approved Dosing/Freq. RA:dx and dz severity, score from objective measure/tool at baseline and cont. Pt has documented mod/severe active dz and dx of RA per ACR criteria. Provider has assessed dz severity utilizing an objective measure/tool. Examples include CDAI, Disease Activity Score with 28-joint counts (ESR or CRP), PAS or PAS-II, RAPID3, SDAI. PsA:Dx, pre-requisite med trials, reauth: pos clinical response. AD: Dx (mod/severe AD involvement and has either involvement of at least 10 percent BSA or SCORAD index value of at least 25), pre-req tx, BSA and/or SCORAD index value. UC:The pt must have a confirmed dx of mod/severely active UC confirmed by endoscopy and/or an objective score (e.g. MMS, Truelove and Witts criteria). Trial of pref products. Reauth: Improvement on endoscopy or objective score. CD: Dx, pre-req med trials (if applicable), Reauth: positive clinical response. AS: Dx, pre-req med trials, reauth: positive clinical response to tx as evidenced by at least 1 objective measure compared to baseline. Ex of objective measures include ASDAS, ASQoL, BASDAI, BASFI, BAS-G, BASMI), DFI, HAQ-S, and/or serum markers (e.g., CRP, ESR). Nr-asXpA: Dx, objective signs of inflammation (CRP elevated beyond the ULN for the reporting lab OR Sacroiliitis on MRI, pre-req med trials, objective signs of inflammation, reauth: positive clinical response (Dz activity (e.g. pain, fatigue, inflammation, stiffness), Labs (CRP), Axial status (e.g. lumbar spine motion, chest expansion) or Total active (swollen and tender) joint count). pJIA: Dx of pJIA as evidenced by 5 or more joints with active arthritis and documented baseline cJADAS-10.

AGE RESTRICTION
Rheumatoid arthritis (RA), Ulcerative colitis (UC), Ankylosing Spondylitis (AS), Non-radiographic Axial Spondyloarthritis (nr-axSpA), Crohn’s Disease (CD)-18 years and older. Atopic dermatitis (AD)-12

years and older. Psoriatic arthritis, pJIA,: 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

Initial - 6 months, continuation 1 year

OTHER CRITERIA

PENDING CMS APPROVAL

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

RYTELO

MEDICATION(S)
RYTELO 47 MG VIAL

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

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
PENDING CMS APPROVAL

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)
CUVITRU, HIZENTRA, HYQVIA, XEMBIFY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, Reauth: positive clinical response

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
CIDP: prescribed by or in consultation with a neurologist.

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

OTHER CRITERIA
All requests will be subject to a Part B vs Part D review. If patient is new to plan, must meet initial criteria at time they had started the medication. Documented dose and frequency must be within the FDA approved dosing and frequency or consistent with compendial sources (e.g. Micromedex, current clinical guidelines, etc.). PI – 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
PENDING CMS APPROVAL

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

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, PASI score, reauth: positive response

AGE RESTRICTION
18 years of age or older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a dermatologist.

COVERAGE DURATION
Initial 6 months, continuation 1 year

OTHER CRITERIA
PENDING CMS APPROVAL

PART B PREREQUISITE
N/A

SIMBRINZA

MEDICATION(S)
SIMBRINZA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

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

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

PART B PREREQUISITE

N/A

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 all diagnoses: If patient is new to plan, meets initial criteria at time they had started the medication. Documented Dose and Frequency are within the FDA approved Dosing and Frequency. AS: 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. Reauth: positive clinical response to therapy as evidenced by at least one objective measure compared to baseline. Examples of objective measures include ASDAS, ASQoL, BASDAI, BASFI, BAS-G, BASMI, DFI, HAQ-S, and/or serum markers (e.g., CRP, ESR). PsA: Diagnosis, pre-requisite medication trials, reauth: positive clinical response. RA: diagnosis and disease severity per ACR criteria, score from objective measure/tool at baseline and continuation (e.g. CDAI, Disease Activity Score with 28-joint counts (ESR or CRP), PAS or PAS-II, RAPID3, SDAI.) UC: The member must have a confirmed diagnosis of moderately to severely active ulcerative colitis confirmed by endoscopy and/or an objective score (e.g. modified Mayo score [MMS], Truelove and Witts criteria). Trial of preferred products. Reauth: Improvement on endoscopy or objective score.

AGE RESTRICTION
18 years and older

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.

COVERAGE DURATION

Initial - 6 months, Continuation - 1 year

OTHER CRITERIA

PENDING CMS APPROVAL

PART B PREREQUISITE

N/A

SKYCLARYS

MEDICATION(S)
SKYCLARYS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Severe hepatic impairment (Child-Pugh C)

REQUIRED MEDICAL INFORMATION
Diagnosis based on genetic test, BNP, LVEF, A1c, mFARS score

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 (mutation of the FXN gene),
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, AND
b.Patient has a left ventricular ejection fraction greater than or equal to 40%, AND
c.Patient has a hemoglobin A1c (HbA1c) less than or equal to 11 percent, 3.Patient has been assessed using the modified Friedreich's Ataxia Rating Scale (mFARS) and has a score greater than or equal to 20, but less than or equal to 80, 4.Patient is ambulatory. Continuation Therapy – approve if patient meets all of the following (1, 2, 3 and 4): 1. If patient is new to plan, meets initial criteria at time

they had started the medication, 2. Documented dose and frequency are within the FDA approved Dosing and Frequency, 3.Patient has had a trinucleotide repeat expansion assay genetic test confirming the diagnosis of Friedreich’s ataxia, 4.Patient continues to benefit from therapy, as demonstrated by improvement or stabilization on the modified Friedreich’s Ataxia Rating Scale

PART B PREREQUISITE

N/A

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
For all diagnoses: If patient is new to plan, meets initial criteria at time they had started the medication. Documented dose and frequency are within the FDA approved Dosing and Frequency. PP: Diagnosis, PASI score, reauth: positive response. PsA: Diagnosis, pre-requisite medication trials, reauth: positive clinical response. CD: Diagnosis, pre-requisite medication trials (if applicable), Reauth: positive clinical response.

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-prescribed by or in consultation with a gastroenterologist.

COVERAGE DURATION
Initial 6 months, continuation 1 year

OTHER CRITERIA
PENDING CMS APPROVAL

PART B PREREQUISITE
N/A

SODIUM OXYBATE PRODUCTS

MEDICATION(S)
SODIUM OXYBATE

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
Diagnosis, ESS or MWT score

AGE RESTRICTION
PENDING CMS APPROVAL

PRESCRIBER RESTRICTION
Prescribed by a sleep specialist physician or a Neurologist

COVERAGE DURATION
Initial – 3 months, Continuation – 1 year

OTHER CRITERIA
PENDING CMS APPROVAL

PART B PREREQUISITE
N/A

SOMATULINE

MEDICATION(S)
LANREOTIDE 120 MG/0.5 ML SYRNG

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

OFF LABEL USES
Pheochromocytoma/paraganglioma

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, previous treatments/therapies

AGE RESTRICTION
N/A

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

COVERAGE DURATION
1 year

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

PART B PREREQUISITE

N/A

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

REQUIRED MEDICAL INFORMATION
Diagnosis, PASI score, reauth: positive response

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a dermatologist

COVERAGE DURATION
Initial 6 months, continuation 1 year

OTHER CRITERIA
PENDING CMS APPROVAL

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
PP: Diagnosis, PASI score, reauth: positive response. PsA: Diagnosis, pre-requisite medication trials, reauth: positive clinical response. UC: The member must have a confirmed diagnosis of moderately to severely active ulcerative colitis confirmed by endoscopy and/or an objective score (e.g. modified Mayo score [MMS], Truelove and Witts criteria). Trial of preferred products. Reauth: Improvement on endoscopy or objective score. CD: Diagnosis, pre-requisite medication trials (if applicable), Reauth: positive clinical response. For all diagnoses: If patient is new to plan, meets initial criteria at time they had started the medication. Documented dose and frequency are within the FDA approved Dosing and Frequency.

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

PRESCRIBER RESTRICTION
PP (Plaque Psoriasis)-prescribed by or in consultation with a dermatologist. PsA(Psoriatic Arthritis)-prescribed by on in consultation with a rheumatologist or dermatologist. CD /UC (Ulcerative Colitis)-prescribed by or in consultation with a gastroenterologist.

COVERAGE DURATION
Initial 6 months, continuation 1 year

OTHER CRITERIA
PENDING CMS APPROVAL

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

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
Concurrent use with Orkambi, Kalydeco or Trikafta. Patients with unknown CFTR gene mutations.

REQUIRED MEDICAL INFORMATION
Diagnosis, specific CFTR gene mutations

AGE RESTRICTION
6 years of age or older.

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

COVERAGE DURATION
3 years

OTHER CRITERIA
Cystic Fibrosis: Approve if the patient meets the following criteria (1, 2, 3, 4 and 5): 1. Diagnosis of cystic fibrosis, 2. Patient meets one of the following (a or b): a.Patient has at least one mutation in the CFTR gene that is considered to be pathogenic or likely pathogenic and responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence, b. Patient is homozygous for the F508del mutation, 3. Patient has at least one mutation in the CFTR gene that is considered to be pathogenic or likely pathogenic, 4. Patient must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF, 5. Evidence of abnormal CFTR function as demonstrated by a, b or c: a. Elevated sweat chloride test, b. Two CFTR mutations, c. Abnormal nasal potential difference

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. Presence of primary (light chain) amyloidosis. Prior liver or heart transplantation or implanted cardiac mechanical assist device.

REQUIRED MEDICAL INFORMATION
Diagnosis, genetic and/or diagnostic tests as outlined in other criteria, NYHA functional class, NT-proBNP. Reauth: positive response.

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
PENDING CMS APPROVAL

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

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
For all diagnoses: If patient is new to plan, meets initial criteria at time they had started the medication. Documented dose and frequency are within the FDA approved Dosing and Frequency. PP: Confirmed diagnosis 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. PASI score, reauth: positive response. AS: Diagnosis, pre-requisite medication trials, 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. Continuation: Patient has experienced a positive clinical response to therapy as evidenced by at least one objective measure compared to baseline. Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondyloarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate). Nr-asXpA: Diagnosis, pre-requisite medication trials, objective signs of inflammation, reauth: positive clinical response.

AGE RESTRICTION

Plaque psoriasis 6 years and older. All other diagnoses - 18 years of age and older.

PRESCRIBER RESTRICTION

Plaque Psoriasis (PP)-prescribed by or in consultation with a dermatologist. Psoriatic Arthritis (PsA)-Prescribed by or in consultation with a rheumatologist or a dermatologist. AS/nr-asXpA -prescribed by or in consultation with a rheumatologist.

COVERAGE DURATION

Initial - 6 months, Continuation - 1 year

OTHER CRITERIA

PENDING CMS APPROVAL

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

TAVNEOS

MEDICATION(S)
TAVNEOS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
18 years and older (initial and continuation therapy)

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

COVERAGE DURATION
Initial 6 months, Continuation 1 year

OTHER CRITERIA
Anti-Neutrophil Cytoplasmic Autoantibody (ANCA)-Associated Vasculitis, initial-approve if the patient meets (i, ii, iii and iv):
i.Patient has granulomatosis with polyangiitis or microscopic polyangiitis, AND
Note: Granulomatosis with polyangiitis is also known as Wegener's granulomatosis.
ii.Patient has active disease, AND
Note: This includes patients that have newly diagnosed or relapsed disease. This does not include patients already in remission.
iii.Patient is positive for proteinase 3 antibodies, anti-neutrophil cytoplasmic autoantibody (ANCA) or myeloperoxidase antibodies, AND
iv.Patient is using this medication in combination with at least one immunosuppressant
Note: Examples of immunosuppressants include cyclophosphamide, rituximab, azathioprine, or

mycophenolate mofetil.

Anti-Neutrophil Cytoplasmic Autoantibody (ANCA)-Associated Vasculitis, continuation-approve if the patient meets at least one of the following (a and b):
a)If patient is new to plan, meets initial criteria at time they had started the medication,
b)Patient meets one of the following (1 or 2):
(1)When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Tavneos), OR
Note: Examples of objective measure include improvement in estimated glomerular filtration rate, decrease in urinary albumin creatinine ratio, or improvement in the Birmingham Vasculitis Activity Score [BVAS].
(2)Compared with baseline (prior to receiving Tavneos), patient experienced an improvement in at least one symptom, such as joint pain, ulcers, myalgia, persistent cough, abdominal pain, or improvement in function or activities of daily living.

PART B PREREQUISITE
N/A

TAZAROTENE

MEDICATION(S)
TAZAROTENE 0.1% CREAM, TAZAROTENE 0.1% GEL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Pregnancy. Fine wrinkle disorder/fine wrinkles on face.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Lifetime.

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

PART B PREREQUISITE
N/A

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
PENDING CMS APPROVAL

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

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

OFF LABEL USES
Gender dysphoria in transgender male patients.

EXCLUSION CRITERIA
Erectile dysfunction. Decreased Libido.

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

AGE RESTRICTION
Aged 18 years or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Lifetime.

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

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

PART B PREREQUISITE

N/A

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

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)

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)
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

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, TRETINOIN 0.01% GEL, TRETINOIN 0.025% CREAM, TRETINOIN 0.025% GEL, TRETINOIN 0.05% CREAM, 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
PP: Diagnosis, PASI score, reauth: positive response. PsA: Diagnosis, pre-requisite medication trials, reauth: positive clinical response.

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 6 months, continuation 1 year

OTHER CRITERIA
PENDING CMS APPROVAL

PART B PREREQUISITE
N/A

TRETINOIN

MEDICATION(S)
TRETINOIN 10 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

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

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 125 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

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

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

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 confirmed by endoscopy and/or an objective score (e.g. modified Mayo score [MMS], Truelove and Witts criteria). Trial of preferred products. Reauth: Improvement on endoscopy or objective score

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
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, Xeljanz/XR tablets and Zeposia. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074), and Simlandi. b. Continuation therapy: Approve if the patient meets all of the following (1, 2, 3 and 4): 1. If patient is new to plan, meets initial criteria at time they had started the medication, 2. Patient has been established on the requested medication for at least 5 months, 3. Patient has experienced a positive clinical response compared to baseline as evidenced by improvement on endoscopy or improvement using an objective scoring system (e.g. modified Mayo score [MMS], Truelove and Witts criteria, 4.Documented dose and frequency are within the FDA approved Dosing

and Frequency

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

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
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
For advanced or metastatic breast cancer – the member must meet one of the following criteria (1, 2, 3 or 4):
1.The member has demonstrated a failure of or intolerance to one of the preferred products, Ibrance and Kisqali, for the given diagnosis
2.The member has a documented contraindication to one of the preferred products, Ibrance and Kisqali
3.The member had an adverse reaction or would be reasonably expected to have an adverse reaction to one of the preferred products, Ibrance and Kisqali, OR
4.The patient has a clinical condition for which there is no listed preferred formulary alternatives to treat the condition based on published guidelines or clinical literature.

PART B PREREQUISITE

N/A

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

VOWST

MEDICATION(S)
VOWST

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

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

COVERAGE DURATION
One month

OTHER CRITERIA
Prevention of C. difficile infection (CDI): Patient must meet all of the following (1, 2, 3 and 4):
1.Patient has a diagnosis of recurrent CDI as defined by all of the following (a, b and c):
a.Greater than or equal to 3 episodes of CDI in a 12 month period, b.A positive C. difficile stool sample during each episode, c. A CDI episode of diarrhea greater than or equal to 3 unformed stools per day for at least 2 consecutive days during each episode, 2. The patient has completed at least 10 days of standard of oral vancomycin or fidaxomicin for recurrent CDI at least 2 to 4 days before initiating treatment with the requested medication,
3.The patient has had an adequate clinical response to standard of care oral antibiotic regimen as defined by less than 3 unformed stools in 24 hours for 2 or more consecutive days,
4.The patient will not be using the requested agent in combination with any antibiotic regimen for any indication

PART B PREREQUISITE

N/A

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

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 percent 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. Prescribed by or in consultation with a bariatric provider.

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

AGE RESTRICTION
PENDING CMS APPROVAL

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

COVERAGE DURATION
1 year

OTHER CRITERIA
PENDING CMS APPROVAL

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

XDEMVY

MEDICATION(S)
XDEMVY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

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

COVERAGE DURATION
2 months

OTHER CRITERIA
PENDING CMS APPROVAL

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
RA, JIA: diagnosis and disease severity, score from objective measure/tool at baseline and continuation. PsA: Diagnosis, pre-requisite medication trials, reauth: positive clinical response. UC: The member must have a confirmed diagnosis of moderately to severely active ulcerative colitis confirmed by endoscopy and/or an objective score (e.g. modified Mayo score [MMS], Truelove and Witts criteria). Trial of preferred products. Reauth: Improvement on endoscopy or objective score. AS: Diagnosis, pre-requisite medication trials, objective measure at initiation and continuation (examples outlined in other criteria). For continuation: If patient is new to plan, must meet initial criteria at time they had started the medication.

AGE RESTRICTION
JIA: 2 and older. All others – 18 and older.

PRESCRIBER RESTRICTION
RA, JIA, 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.

COVERAGE DURATION
Initial 6 months, Continuation 1 year

OTHER CRITERIA

RA–approve tabs if following are met:1. Init–approve if pt meets a, b and c: a. Provider has assessed dz severity utilizing an objective measure/tool. Ex include CDAI, Disease Activity Score with 28-joint counts (ESR or CRP), PAS or PAS-II, RAPID3, SDAI b. Mod to severe active dz and dx of RA per ACR criteria, b. Had a 3 mo trial of at least 1 TNFi or unable to tolerate 3 mo trial. 1. Cont–approve if pt is responding positively to tx based on improvement in objective measurement/tool as compared to baseline. PsA–approve tabs if the following are met: 1. Init–approve if pt meets a and b: a. Currently experiencing 1 of the following (i, ii, iii, iv or v): i.Actively inflamed joints, ii.Dactylitis, iii.Enthesitis, iv.Axial disease, v.Active skin and/or nail involvement, b.Active mod to severe dz and meets i or ii: i.Pt has had a 3 mo trial of at least 1 TNFi or was unable to tolerate a 3 mo trial, ii.Member has predominantly axial dz, 2. Cont therapy–approve if there is documentation of pos clinical response to tx as evidenced by improvement in i, ii or iii: i.Number of swollen joints, ii.Number of tender joints, iii.Dactylitis, iv.Enthesitis, v.Axial dz. Mod to severely active UC–approve tabs if following are met: 2. Init: Approve if pt meets a or b: a. Had a 3 mo trial of at least 1 TNFi or was unable to tolerate a 3 mo trial, b. Pt meets i and ii: i.Pt has pouchitis AND ii.Pt has tried an abx, probiotic, corticosteroid enema, or mesalamine enema. 1.Cont therapy: Approve if pt meets BOTH i and ii: i.Pt has been established on the med for at least 5 mo, ii.Pt has experienced a positive clinical response compared to baseline as evidenced by improvement on endoscopy or using an objective scoring system (e.g. MMS, Truelove and Witts criteria). pJIA: approve IR tabs or sol if the following are met: 1. Init-approve if pt meets a, b and c: a. JIA/JRA dx as evidenced by 5 or more joints with active arthritis b. Documented baseline cJADAS-10, c. pt had a 3 mo trial of at least 1 TNFi or was unable to tolerate a 3 mo trial 1. Cont-approve if pt has experienced improvement in dz response based on 1 of the following (i, ii, iii or iv): i. Number of tender and swollen joint counts, ii. Reduction of CRP, iii. Improvement of pt global assessment, iv. Improvement in cJADAS-10 score. AS–approve tabs if following are met: Init-approve if pt meets a and b: a. Confirmed dx of AS as defined by presence of active dz for at least 4 weeks defined by any dz specific functional scoring tool (i.e. a BASDAI Index of at least 4, HAQ, MHAQ, etc.) and an expert opinion based on clinical features, acute phase reactants and imaging modalities, b.Pt had a 3 month trial of at least 1 TNFi or was unable to tolerate a 3 mo trial. Cont-approve if the patient has experienced a positive clinical response to therapy as evidenced by at least one objective measure compared to baseline (e.g. ASDAS, ASQoL, BASDAI, BASFI, BAS-G, BASMI, DFI, HAQ-S, and/or serum markers (e.g. CRP, ESR)

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. Hyperkinetic dystonia. Hemiballism.

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

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

AGE RESTRICTION
18 years of age or older

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

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

OTHER CRITERIA
PENDING CMS APPROVAL

PART B PREREQUISITE
N/A

XERMELO

MEDICATION(S)
XERMELO

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

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 0.92 MG CAPSULE, ZEPOSIA STARTER KIT (28-DAY), ZEPOSIA STARTER PACK (7-DAY)

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
MS: Diagnosis, UC: The member must have a confirmed diagnosis of moderately to severely active ulcerative colitis confirmed by endoscopy and/or an objective score (e.g. modified Mayo score [MMS], Truelove and Witts criteria). Trial of preferred products. Reauth: Improvement on endoscopy or objective score.

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: 1.Initial therapy: Approve if the patient meets one of the following (a or b):
a.Patient has had a trial of one systemic agent for ulcerative colitis (e.g. 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, corticosteroid. A trial of another biologic other than the requested drug also counts as a trial of one systemic agent for ulcerative colitis.)
b.Patient meets both of the following (i and ii):
i.Patient has pouchitis AND

ii.Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema
2.Continuation therapy: Approve if the patient meets ALL of the following (a, b, c and d):
a.If patient is new to plan, meets initial criteria at time they had started the medication
b.Patient has been established on the requested medication for at least 5 months
c.Patient has experienced a positive clinical response compared to baseline as evidenced by improvement on endoscopy or improvement using an objective scoring system (e.g. modified Mayo score [MMS], Truelove and Witts criteria)
d.Documented dose and frequency are within the FDA approved Dosing and Frequency

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, previous antiepileptic therapy, Reauth: positive response

AGE RESTRICTION
2 years of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist

COVERAGE DURATION
1 year

OTHER CRITERIA
Seizures associated with CDKL5 deficiency disorder: 1.Initial criteria - approve if the patient meets the following criteria:
a.Has a molecularly confirmed pathogenic or likely pathogenic mutation in the CDKL5 gene,
b.Documented inadequate response to two other antiepileptic drugs. 2. Continuation criteria – approve if the patient meets the following criteria:
a.If patient is new to plan, meets initial criteria at time they had started the medication,
b.Documented Dose and Frequency are within the FDA approved Dosing and Frequency,
c.Patient has experienced beneficial clinical response (e.g. reduced seizure activity, frequency and/or duration)

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