Prior Authorization Criteria

2023

For information on obtaining an updated coverage determination or an exception to a coverage determination please contact Optimum HealthCare Member Services at 1-866-245-5360 or, for TTY/TDD users 711. Our hours are October 1 to March 31 from 8:00 am to 8:00 pm 7 days a week and April 1 to September 30 from 8:00 am to 8:00 pm Monday through Friday or visit www.youroptimumhealthcare.com.

Last Updated 03/01/2023

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

ADCIRCA

MEDICATION(S)
ALYQ, TADALAFIL (PAH)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Using tadalafil-PAH formulations for the treatment of benign prostatic hyperplasia or erectile dysfunction.

REQUIRED MEDICAL INFORMATION
For initial use, Individual has diagnosis of Pulmonary Arterial Hypertension World Health Organization (WHO) Group 1. Individual has the diagnosis of PAH confirmed by a right heart catheterization showing all of the following: (a) Mean pulmonary artery 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 Individual has WHO functional class II- IV symptoms.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For continuation, there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in walk distance, dyspnea and/or functional class).

PART B PREREQUISITE

N/A

ADEMPAS

MEDICATION(S)
ADEMPAS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Pulmonary Arterial Hypertension, individual has the diagnosis of PAH confirmed by a right heart catheterization showing all of the following: (a) Mean pulmonary artery 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 Individual has WHO functional class II- IV symptoms. For CTEPH confirmed by a right-heart catheterization showing a mPAP greater than 25 mm Hg caused by thromboemboli in the pulmonary arterial system (ACCF/AHA 2009).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For Initial use, for diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 AND has WHO functional class II-IV symptoms. For diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH), WHO Group 4 AND has WHO functional class II-IV symptoms AND using for one of the following: Persistent or recurrent pulmonary hypertension after at least 180 days following surgical

treatment with pulmonary endarterectomey OR Inoperable (via pulmonary endarterectomey) CTEPH. For continued use, there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in walk distance, dyspnea and/or functional class).

PART B PREREQUISITE

N/A

AFINITOR

MEDICATION(S)
EVEROLIMUS 10 MG TAB, EVEROLIMUS 2 MG TAB SOL, EVEROLIMUS 2.5 MG TAB, EVEROLIMUS 3 MG TAB SOL, EVEROLIMUS 5 MG TAB, EVEROLIMUS 5 MG TAB SOL, EVEROLIMUS 7.5 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

AIMOVIG

MEDICATION(S)
AIMOVIG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Episodic migraine defined as at least 4 and fewer than 15 migraine days per month and fewer than 15 headache days per month on average during the previous 3-month period. Chronic migraine defined as a headache occurring on 15 or more days per month for more than 3 months, which, on at least 8 days per month, has features of a migraine headache (ICHD-3 beta).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial: 3 months. Continuation: 1 year

OTHER CRITERIA
For initial requests: (I) Individual has a diagnosis of one of the following: (a) Episodic migraine OR (b) Chronic migraine AND (II) Individual is using for migraine prophylaxis. And (III) Individual has had a trial of and inadequate response or intolerance to a 2-month trial at target or usual effective dose or intolerance to two agents for migraine prophylaxis (at least one agent in any two of the following classes) or has a contraindication to all of the following medications (AAN/AHA 2012/2015, Level A and B evidence, ICSI 2013, high quality evidence, AHS 2019): (a)The following antidepressants: amitriptyline, venlafaxine, nortriptyline, duloxetine or (b) One of the following beta blockers: Metoprolol, propranolol, timolol (oral), nadolol, atenolol, nebivolol or (c) The following calcium channel blocker:

verapamil or (d) One of the following antiepileptic agents: valproate sodium, divalproex sodium, topiramate, gabapentin or (e) Botox (for chronic migraine). AND If individual is also currently using botulinum toxin for prophylaxis and is going to be using Aimovig and botulinum toxin together (i.e., not switching from one agent to another), the following will apply: (a) Individual has had a reduction in the overall number of migraine days or reduction in number of severe migraine days per month with the initial agent AND (b) Individual continues to experience a significant number of migraine headache days or severe migraine days per month requiring additional therapy for migraine prevention. For Renewal requests: (I) Individual has a reduction in the overall number of migraine days or reduction of severe migraine days per month AND (II) Individual has obtained clinical benefit deemed significant by individual or prescriber including any of the following (AHS 2019): (a) 50% reduction in frequency of days with headache or migraine OR (b) Significant decrease in attack duration OR (c) Significant decrease in attack severity OR (d) Improved response to acute treatment OR (e) Reduction in migraine-related disability and improvements in functioning in important areas of life OR (f) Improvements in health related quality of life and reduction in psychological stress due to migraine. AND If individual is using concurrently with botulinum toxin for migraine prophylaxis, the following will apply: Individual has had further reduction in the overall number of migraine days or reduction in number of severe migraine days per month compared to monotherapy with the initial agent (either botulinum toxin or CGRP).

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

ALIMTA

MEDICATION(S)
ALIMTA, PEMETREXED DISODIUM 100 MG RECON SOLN, PEMETREXED DISODIUM 500 MG RECON SOLN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Written or verbal attestation is provided for confirmation of mutations (actionable molecular markers) where applicable based on use/diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For dx malignant mesothelioma, individual has ECOG performance status of 0-2.

PART B PREREQUISITE
N/A

ALPHA1-PROTEINASE INHIBITOR

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Initial use, Confirmed alpha-1 antitrypsin level is less than or equal to 11micro-mol/L (approximately equivalent to 80mg/dL measured by radial immunodiffusion or 57 mg/dL measured by nephelometry) (ATS/ERS 2003, Stoller 2017). Individual has clinically evident emphysema.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For Continued use, there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to decreased frequency of exacerbations, slowed rate of FEV1 decline, preservation of CT scan lung density or improvement in symptom burden).

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

AMPHETAMINE SALTS

MEDICATION(S)
AMPHETAMINE-DEXTROAMPHET ER, AMPHETAMINE-DEXTROAMPHETAMINE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
For dx ADHD, 3 years of age or older for immediate release. For Narcolepsy, 6 years of age or older for immediate release

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

AMPYRA

MEDICATION(S)
DALFAMPRIDINE ER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For renewal, individual achieved and sustained clinically significant improvement in ambulation related functional status.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial approval 12 weeks, renewal 1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

APOKYN

MEDICATION(S)
APOMORPHINE HCL 30 MG/3ML SOLN CART

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Erectile Dysfunction (ED) use

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ARCALYST

MEDICATION(S)
ARCALYST

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis. For initial use, for DIRA, disease is in remission from previous anakinra treatment. For Recurrent Pericarditis (RP), individual is using for treatment of RP or reduction in risk of recurrence AND has a history of at least two pericarditis episodes (i.e. presents with at least the third episode) (Klein 2021).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For continued use, mbr has confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

PART B PREREQUISITE
N/A

AUSTEDO

MEDICATION(S)
AUSTEDO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial: 3 months. Continuation: 1 year

OTHER CRITERIA
For initial requests, Individual has a diagnosis of chorea associated with Huntington’s disease. Has a diagnosis of Tardive dyskinesia confirmed (written or verbal attestation) by the following DSM-5 AND (a.) At least 30 days of stable (drug, dose) medication exposure (either typical or first generation antipsychotic agents [such as, chlorpromazine, haloperidol, fluphenazine], atypical or second-generation antipsychotic agents [such as, clozapine, risperidone, olanzapine, quetiapine, aripiprazole], or certain dopamine receptor-blocking drugs used in treatment of nausea and gastroparesis [such as, prochlorperazine, promethazine, metoclopramide]) and (b.) Presence of involuntary athetoid or choreiform movements. For continuation requests, Individual has experienced an improvement in symptoms deemed to be clinically significant by the provider (written or verbal attestation) based on stabilization or improvement in Abnormal Involuntary Movement Scale (AIMS) score (for TD) or total maximal chorea score (for Huntington’s disease).

PART B PREREQUISITE

N/A

AUVELITY

MEDICATION(S)
AUVELITY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For MDD.

AGE RESTRICTION
Individual is 18 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

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
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis. For Advanced Systemic Mastocytosis (AdvSM), individual has a platelet count of greater than or equal to 50 x 109/L.

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
Individual has confirmed (written or verbal attestation) disease susceptible to genetic alterations.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

BANZEL

MEDICATION(S)
RUFINAMIDE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
1 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

BARACLUDE

MEDICATION(S)
BARACLUDE 0.05 MG/ML SOLUTION, ENTECAVIR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual has a diagnosis of Chronic Hepatitis B virus (HBV) infection and has not been previously treated with lamivudine (AASLD 2016) OR is using as prophylaxis for hepatitis B reactivation in the setting of immune suppression (AGA 2015) or in combination with hepatitis C direct-acting antiviral therapy (AASLD 2017) OR Individual is a solid organ transplant recipient and using as prophylaxis for hepatitis B reactivation post (AASLD 2018).

AGE RESTRICTION
2 years of age and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

BAVENCIO

MEDICATION(S)
BAVENCIO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Receiving treatment with another anti PD-1 agent or anti PD-L1 agent. Receiving therapy for an autoimmune disease or chronic condition requiring treatment with systemic immunosuppressant.

REQUIRED MEDICAL INFORMATION
Current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2 for metastatic merkel cell carcinoma, advanced RCC, endometrial carcinoma, and locally advanced or metastatic urothelial carcinoma

AGE RESTRICTION
Individual is 12 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

BENLYSTA

MEDICATION(S)
BENLYSTA 200 MG/ML SOLN A-INJ, BENLYSTA 200 MG/ML SOLN PRSYR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
For initial treatment of SLE, individual has a Clinical diagnosis of SLE per the American College of Rheumatology [ACR] criteria AND Unequivocally positive ANA (anti-nuclear antibody) titer greater than or equal to 1:80 or anti-dsDNA (double stranded DNA antibody) greater than or equal to 30 IU/mL AND SLE is active as documented by a SELENA-SLEDAI score greater than or equal to 6 while on current treatment regimen AND SLE remains active while on corticosteroid, antimalarials, and/or immunosuppressants for at least the last 30 days AND is using in combination with standard therapy (for example, corticosteroids, antimalarials, and/or immunosuppressants [but not other biologics or IV cyclophosphamide]). For Initial treatment of active lupus nephritis, individual has autoantibody-positive SLE (anti-nuclear antibody (ANA) titer greater than or equal to 1:80 or anti-dsDNA greater than or equal to 30 IU/mL) AND has Class III, IV, or V lupus nephritis showing active or chronic lesions, and confirmed by renal biopsy AND has a urinary protein to creatinine ratio of greater than or equal to 1

AND did not have disease progression to lupus nephritis while on Benlysta therapy for SLE without LN AND individual's disease remains active while on corticosteroids, antimalarials, or immunosuppressants (alone or as combination therapy) for at least the last 30 days AND is using in combination with standard therapy (for example, corticosteroids, antimalarials, and/or immunosuppressants [but not other biologics or IV cyclophosphamide]). For continuation of therapy, confirmation (written or verbal attestation) of previous improvement in disease activity following treatment with belimumab indicating a therapeutic response including lack of disease progression to lupus nephritis while on Benlysta if initially only using for SLE without LN AND there is no evidence of active central nervous system lupus. AND individual is using in combination with standard therapy (for example, corticosteroids, antimalarials, and/or immunosuppressants [but not other biologics or IV cyclophosphamide]).

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
18 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

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
Written or verbal attestation is provided for confirmation of mutations or disease progression where applicable based on use/diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

BRAFTOVI

MEDICATION(S)
BRAFTOVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Written or verbal attestation has been provided for either BRAF V600E or V600K genetic mutation.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

BRIVIACT

MEDICATION(S)
BRIVIACT 10 MG TAB, BRIVIACT 10 MG/ML SOLUTION, BRIVIACT 100 MG TAB, BRIVIACT 25 MG TAB, BRIVIACT 50 MG TAB, BRIVIACT 75 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL 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
Individual has no prior BTK inhibitor usage.

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

BUPHENYL

MEDICATION(S)
SODIUM PHENYLBUTYRATE 3 GM/TSP POWDER, SODIUM PHENYLBUTYRATE 500 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Using as adjunctive therapy for chronic management of hyperammonemia

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For continuation, there is confirmation of clinically significant improvement or stabilization in plasma ammonia level.

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

CAPLYTA

MEDICATION(S)
CAPLYTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Individual is 18 years of age or older.

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

CARBAGLU

MEDICATION(S)
CARGLUMIC ACID

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/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 initial use, (A) member has a diagnosis of acute hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS) AND Using as adjunctive therapy with other ammonia lowering therapies OR (B) has a diagnosis of chronic hyperammonemia due to the deficiency of the hepatic enzyme NAGS AND Using as maintenance therapy OR (C) Individual is using as adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MA). For Continuation use, there is confirmation of clinically significant improvement or stabilization in plasma ammonia level.

PART B PREREQUISITE
N/A

CAYSTON

MEDICATION(S)
CAYSTON

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
7 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

CHANTIX

MEDICATION(S)
CHANTIX, CHANTIX CONTINUING MONTH PAK, CHANTIX STARTING MONTH PAK, VARENICLINE TARTRATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

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 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

CHOLBAM

MEDICATION(S)
CHOLBAM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Initial use of the following: For diagnosis of bile acid synthesis disorders (BASDs) due to single enzyme defects (SEDs), Diagnosis is confirmed by any of the following (NORD 2020): (1) Fast atom bombardment-mass spectrometry (FABS-MS) OR (2) Electrospray ionization-mass spectrometry (ESI-MS) OR (3) Gas chromatography-mass spectrometry (GC-MS) OR (4) Molecular genetic testing. For diagnosis of peroxisomal disorders (PDs) [including but not limited to Zellweger spectrum disorders (ZSD)], Individual has one of the following present: (A) Manifestations of liver disease for example, jaundice, hepatomegaly) OR (B) Steatorrhea OR (C.) Complications from decreased fat soluble vitamin (such as but not limited to, vitamin D and K) absorption (for example, rickets, hypocalcemia, bleeding). For Continuation use, Individual has had a clinical improvement (symptoms, lab values) in liver function and/or cholestasis and has not developed a complete biliary obstruction.

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 (100 MG DAILY DOSE), COMETRIQ (140 MG DAILY DOSE), COMETRIQ (60 MG DAILY DOSE)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL 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
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

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
For continuation, confirmation (verbal or written) of continuing clinical benefit (e.g., complete response, partial response or stable disease).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

CORLANOR

MEDICATION(S)
CORLANOR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For INITIAL use: (A) Individual is using for the treatment of New York Heart Association (NYHA) class II, III or IV heart failure symptoms AND has a left ventricular ejection fraction less than or equal to 35% AND will be utilizing in combination with a beta-blocker (bisoprolol, carvedilol, metoprolol succinate) OR has a contraindication or intolerance to beta-blocker therapy AND is in normal sinus rhythm AND individual has a resting heart rate greater than or equal to 70 beats per minute. OR (B) Individual is using for the treatment of New York Heart Association (NYHA) class II, III, or IV heart failure symptoms due to dilated cardiomyopathy AND has a left ventricular ejection fraction less than or equal to 45% AND is in normal sinus rhythm AND individual has an elevated resting heart rate. For Continuation use in the treatment of New York Heart Association (NYHA) class II, III or IV heart failure symptoms AND (a) There is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in heart failure symptoms, reduction in

heart failure related physical limitations, reduction in hospitalization) AND (b) Individual continues to receive concomitant beta-blocker (bisoprolol, carvedilol, metoprolol succinate) therapy unless contraindicated or not tolerated. For Continuation use in the treatment of inappropriate sinus tachycardia (IST) (DrugDex IIb), there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

PART B PREREQUISITE

N/A

COSENTYX

MEDICATION(S)
COSENTYX, COSENTYX (300 MG DOSE), COSENTYX SENSOREADY (300 MG), COSENTYX SENSOREADY PEN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual has chronic moderate to severe plaque psoriasis with either of the following: Individual has greater than 3% of body surface area with plaque psoriasis OR Less than or equal to 3% of body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia). Individual is using for the treatment of Non-radiographic Axial Spondyloarthritis (nr-axSpA) with objective signs of inflammation.

AGE RESTRICTION
For plaque psoriasis, 6 years of age or older. For Enthesitis-Related Arthritis (ERA), 4 years of age or older. For Psoriatic Arthritis, 2 years of age or older. 18 years of age or older for all other indications.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For initial use: moderate to severe Ankylosing Spondylitis (AS), individual had an inadequate response to/intolerant of or has a contraindication to ONE conventional therapy [such as, NSAIDs or nonbiologic DMARDS such as sulfasalazine. For moderate to severe plaque psoriasis (Ps), individual had an inadequate response to/intolerant of or has contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine or methotrexate). For moderate to severe Psoriatic Arthritis (PsA),

individual has had an inadequate response to/intolerant of or has a contraindication to ONE conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine or leflunomide)] (ACR 2019). For Non-radiographic Axial Spondyloarthritis (nr-axSpA), individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)] (ACR 2019). For Enthesitis-Related Arthritis (ERA), individual has moderate to severe ERA AND has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy [such as NSAIDs or nonbiologic DMARDs]. For Continuation use, there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

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
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For unresectable or metastatic melanoma, Individual is using in combination with Zelboraf (vemurafenib) with or without Tecentriq (atezolizumab).

PART B PREREQUISITE
N/A

CYRAMZA

MEDICATION(S)
CYRAMZA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For urothelial cancer, an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

AGE RESTRICTION
For urothelial cancer, 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For locally advanced, unresectable or metastatic urothelial cancer originating from bladder, urethra, ureter or renal pelvis and using in combination with docetaxel AND disease has progressed after platinum-containing chemotherapy (cisplatin or carboplatin) AND individual has received treatment with no more than one immune checkpoint inhibitor (such as, atezolizumab, avelumab, durvalumab, nivolumab or pembrolizumab) AND has received treatment with no more than one prior systemic chemotherapy regimen in the relapsed or metastatic setting AND individual has not received prior systemic taxane therapy in any setting (neoadjuvant, adjuvant or metastatic).

PART B PREREQUISITE

N/A

DALIRESP

MEDICATION(S)
DALIRESP, ROFLUMILAST 500 MCG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual is currently or will be concomitantly using in combination with a long-acting bronchodilator.

PART B PREREQUISITE
N/A

DARZALEX

MEDICATION(S)
DARZALEX 400 MG/20ML SOLUTION, DARZALEX FASPRO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Has received treatment with daratumumab or another anti-CD38 agent

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

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
Individual is 75 years old or older OR has comorbidities that preclude use of intensive induction chemotherapy.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

DIACOMIT

MEDICATION(S)
DIACOMIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/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 dx of seizures associated with Dravet Syndrome AND is taking in combination with clobazam AND has responded inadequately to previous antiepileptic drugs (e.g. valproic acid, topiramate, clobazam) (Wirrell 2017, Ziobro 2018).

PART B PREREQUISITE
N/A

DIFICID

MEDICATION(S)
DIFICID

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
30 Days

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

DUAVEE

MEDICATION(S)
DUAVEE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Age 18 through age 75

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual is using for ONE of the following: Treatment of moderate to severe vasomotor symptoms associated with menopause OR Individual is using for prevention of postmenopausal osteoporosis AND is using solely for prevention of osteoporosis and has had a trial of and inadequate response or intolerance or has a contraindication to non-estrogen agents for osteoporosis.

PART B PREREQUISITE
N/A

DUOPA

MEDICATION(S)
DUOPA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/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 advanced Parkinsons disease with complicated motor fluctuations AND individual has a percutaneous endoscopic gastrostomy with jejunal tube (PEG-J) or naso-jejunal tube AND symptoms have not been adequately controlled with optimal medical therapy with any TWO of the following: Oral levodopa-carbidopa, a Dopamine agonist [such as, but limited to Apokyn (apomorphine), Mirapex (pramipexole), Requip (ropinirole) and Neupro (rotigotine)], a catechol-0-methyl transferase (COMT) inhibitor [such as, but not limited to Comtan (entacapone) and Tasmar (tolcapone)], or a monoamine oxidase B (MAO)-B inhibitor [such as, but not limited to Eldepryl (selegiline), and Azilect (rasagiline)].

PART B PREREQUISITE
N/A

DURAGESIC PATCH

MEDICATION(S)
FENTANYL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Individual is 2 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial 3 months. Maintenance 6 months. Cancer Pain/Terminal Dx or Palliative Care 1 Year.

OTHER CRITERIA
For initial use, Individual has one of the following: (a) Diagnosis of cancer related pain and/or is actively undergoing cancer therapy (provide cancer diagnosis) OR (b) Diagnosis of terminal illness and is receiving palliative/end-of-life care (provide terminal diagnosis) OR Individual has pain severe enough to require daily, around-the-clock, long term opioid treatment (provide diagnosis) AND Individual has one of the following: (a) An inadequate response to ONE alternative treatment options, such as but not limited to non-opioid analgesics and immediate-release opioids OR (b) Alternative treatment options would otherwise be inadequate to provide sufficient management of pain OR (c) Individual has contraindications to non-opioid analgesics (such as NSAID use in individuals with active ulcer condition/gastrointestinal bleeding, renal failure) AND Individual is not opioid naïve as noted by the following: (a) Individual is currently using a short-acting opioid analgesic, including use of opioid analgesia as an inpatient for post-surgical pain OR (b) Individual is transitioning from one long-acting

opioid analgesic to another long-acting opioid analgesic OR (c) already receiving at least 60 mg/day of oral morphine, 30 mg/day of oral oxycodone, 8 mg/day of oral hydromorphone, or an equianalgesic dose of another opioid. For continued use, (I) individual has a diagnosis of cancer related pain and/or is actively undergoing cancer therapy (provide cancer diagnosis) OR (II) diagnosis of terminal illness and is receiving palliative/end-of-life care (provide terminal diagnosis) OR (III) Individual has pain severe enough to require daily, around-the-clock, long term opioid treatment (provide diagnosis) AND Attestation (verbal or written) that long-acting opioid therapy has provided meaningful improvement in pain and/or function compared to baseline AND prescriber has consulted with individual regarding risks of opioid therapy AND clear treatment goals have been defined and outlined as part of overall pain.

PART B PREREQUISITE

N/A

EGRIFTA

MEDICATION(S)
EGRIFTA SV

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial requests, individual has a body mass index (BMI) is greater than 20 kg/m2 AND waist circumference and a waist-to-hip ratio of one of the following (Falutz 2010): (a) For males, waist circumference greater than or equal to 95cm and waist-to-hip ratio greater than or equal to 0.94 OR (b) For females, waist circumference greater than or equal to 94cm and waist-to-hip ratio greater than or equal to 0.88 AND fasting blood glucose (FBG) is less than 150 mg/dL (8.33 mmol/L) AND no history of type 1 diabetes or insulin-treated type 2 diabetes AND no active malignancy (e.g., a potential cancer which is being evaluated or a diagnosed cancer which is being treated) AND is not currently pregnant or breast feeding. For continuation, individual must demonstrate there is a clear response in reduction of visceral adipose tissue measured by waist circumference or computed tomography (CT) scan.

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial 6 months, Continuation 1 Year.

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

ELIDEL

MEDICATION(S)
PIMECROLIMUS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Individual is 2 years of age and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Individual had a trial of and inadequate response or intolerance to one topical prescription strength corticosteroid.

PART B PREREQUISITE
N/A

ELIGARD_GNRH

MEDICATION(S)
ELIGARD 22.5 MG KIT, ELIGARD 7.5 MG KIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Prostate cancer: Clinically localized disease with intermediate (T2b to T2c cancer, Gleason score of 7/Gleason grade group 2-3, or prostate specific antigen (PSA) value of 10-20 ng/mL) OR higher risk of recurrence as neoadjuvant therapy with radiation therapy or cryosurgery OR Other advanced, recurrent, or metastatic disease. OR for castration-recurrent disease OR Progressive castration-naïve disease OR Used as androgen deprivation therapy as a single agent or in combination with antiandrogen.

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, EMGALITY (300 MG DOSE)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Episodic migraine defined as at least 4 and fewer than 15 migraine days per month and fewer than 15 headache (HA) days per month on average during the previous 3 month period. Chronic migraine defined as HA occurring on 15 or more days per month for more than 3 months, which on at least 8 days per month, has features of a migraine HA (ICHD-3). Cluster HA meeting the following IHS diagnostic criteria (ICHD3): (a) Individual has 5 or more HA attacks AND (b) has severe or very severe unilateral orbital supraorbital and/or temporal pain lasting 15 to 180 minutes if untreated AND (c) HA accompanied by 1 or both of the following: (i) 1 or more of following sx or signs, ipsilateral to the HA: (1) Conjunctival injection and/or lacrimation (2) nasal congestion and/or rhinorrhea (3) eyelid edema (4) forehead and facial sweating or (5) miosis and/or ptosis OR (ii) sense of restlessness or agitation AND (d) Attacks have frequency from 1 every other day to 8/day AND (e) HA is not attributed to another HA disorder AND (IV) Cluster HA are episodic per following diagnostic criteria (ICHD-3 Beta): (a) Individual has cluster HA attacks that occur in bouts (cluster periods) AND (b) Individual has at least 2 cluster periods lasting from 7 days to 1 year (when untreated) and separated by pain-free remission periods of greater than or equal to 3 months.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial: 3 months. Continuation: 1 year

OTHER CRITERIA

For Initial requests: (I) Individual has a diagnosis of one of the following: (a) Episodic migraine OR (b) Chronic migraine AND (c) is using for migraine prophylaxis AND (d) has had a trial of and inadequate response or intolerance to a 2-month trial at target or usual effective dose or intolerance to two agents for migraine prophylaxis (at least one agent in any two of the following classes) or has a contraindication to all of the following medications (AAN/AHA 2012/2015, Level A and B evidence, ICSI 2013, high quality evidence, AHS 2019): (1) The following antidepressants: amitriptyline, venlafaxine, nortriptyline, duloxetine or (2) One of the following beta blockers: Metoprolol, propranolol, timolol (oral), nadolol, atenolol, nebivolol or (3) One of following calcium channel blocker: verapamil or (4) One of the following antiepileptic agents: valproate sodium, divalproex sodium, topiramate, gabapentin or (5) Botox (for chronic migraine). OR (II) For individuals currently using botulinum toxin for prophylaxis and is going to be using Emgality and botulinum toxin together (i.e., not switching from one agent to another), the following must apply: (a) mbr has had a reduction in the overall number of migraine days or reduction in number of severe migraine days per month with the initial agent (botulinum toxin) AND (b) mbr continues to experience a SGFNT number of migraine HA days or severe migraine days per month requiring additional therapy for migraine prevention. OR (III) Mbr is using for tx of episodic cluster HA AND has had a trial of and inadequate response or intolerance to one of the following agents for the tx of cluster HA (AHS 2016): (a) Sumatriptan (subcutaneous or nasal spray) OR (b) Zolmitriptan (nasal spray or oral). For Renewal requests of migraine prophylaxis: mbr has a reduction in the overall number of migraine days or reduction in number of severe migraine days per month AND Individual has obtained clinical benefit deemed SGFNT by individual or prescriber including any of the following (AHS 2019): (i) 50% reduction in frequency of days with HA or migraine OR (ii) SGFNT dec in attack dur OR (iii) SGFNT decr in attack severity OR (iv) Improved response to acute tx OR (v)Red in migraine-related disability and improvements in fx in important areas of life OR (vi)Improvements in health related QOL and reduction in psychological stress due to migraine. AND If is using concurrently with botulinum toxin for migraine prophy, the following must apply: mbr has had further reduction in the overall number of migraine days or reduction in number of severe migraine days per month compared to monotherapy with the initial agent (either botulinum toxin or Emgality). For Renewal requests of Episodic Cluster HA: mbr has a reduction in the overall number of cluster HA periods AND has obtained clinical benefit deemed SGFNT by ind or prescriber.

PART B PREREQUISITE

N/A

EMSAM

MEDICATION(S)
EMSAM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual has no known contraindications to the use of a monoamine oxidase inhibitor (MAOI).

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ENBREL

MEDICATION(S)
ENBREL, ENBREL MINI, ENBREL SURECLICK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For chronic moderate to severe plaque psoriasis with either of the following: Individual has greater than 3% of body surface area with plaque psoriasis OR Less than or equal to 3% of body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia).

AGE RESTRICTION
Individual is 18 years of age or older, except for the diagnosis of JIA and plaque psoriasis. For JIA individual is 2 years of age or older. For plaque psoriasis, 4 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For Initial use: moderate to severe Ankylosing Spondylitis, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapies: (such as sulfasalazine) (ACR 2019). For Moderate to severe Chronic Plaque Psoriasis, individual has had inadequate response to, is intolerant of, or has a contraindication to phototherapy OR ONE other systemic therapies (such as, methotrexate, acitretin, or cyclosporine). For moderate to severe Rheumatoid Arthritis, individual has had an inadequate response to, methotrexate titrated to maximally tolerated dose (ACR 2021) OR If methotrexate is not tolerated or contraindicated, individual has had an

inadequate response to, is intolerant of, or has a contraindication to ONE other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine). For moderate to severe Polyarticular JIA, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy [nonbiologic DMARDs such as methotrexate] (ACR 2019). For moderate to severe Psoriatic Arthritis, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine or leflunomide)] (AAD 2019). For Continuation use: there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

PART B PREREQUISITE

N/A

ENHERTU

MEDICATION(S)
ENHERTU

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual has unresectable or metastatic Her2-positive (HER2+) breast cancer OR Her2+ gastric/gastroesophageal junction adenocarcinoma confirmed (written or verbal) by either Immunohistochemistry (IHC) is 3+ OR In situ hybridization (ISH) positive.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For breast cancer use, Individual is using Enhertu as monotherapy.

PART B PREREQUISITE
N/A

EPCLUSA

MEDICATION(S)
SOFOSBUVIR-VELPATASVIR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes genotype and positive HCV RNA result (AASLD/IDSA 2017, CDC 2013) AND Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy AND Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2016).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
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

EPIDIOLEX

MEDICATION(S)
EPIDIOLEX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/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 tx of seizures associated with Lennox-Gastaut syndrome or Dravet Syndrome, Individual has responded inadequately to two previous antiepileptic drugs (e.g., valproic acid, topiramate, clobazam) (Hancock 2013. Wirrell 2017. Ziobro 2018). Individual is using for tuberous sclerosis complex.

PART B PREREQUISITE
N/A

EPOGEN AND PROCRIT

MEDICATION(S)
PROCRIT, RETACRIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial use of EPO: Baseline Hemoglobin (Hgb) levels are less than 10.0 g/dL AND baseline evaluation of the individual iron status is adequate as defined by one of the following: transferrin saturation at least 20% or ferritin at least 80 ng/mL or bone marrow demonstrates adequate iron stores. For MDS, endogenous EPO level is less than or equal to 500 mU/ml. For anemia related to zidovudine (ZDV) in HIV-infected mbr when the dose of ZDV is less than or equal to 4200 mg per week, endogenous EPO level is less than or equal 500 mU/ml. For tx of anemia due to myelosuppressive chemotherapy known to produce anemia when the following are met: chemo is planned for a minimum of 2 months and the dx is non-myeloid cancer and the anticipated outcome is not cure. For anemia associated with CKD ON dialysis use is to achieve and maintain hgb levels within the range of 10.0 to 11.0 g/dL. For anemia associated with CKD NOT ON dialysis, use is to achieve and maintain hgb levels of 10.0g/dL. For continued use, mbr demonstrates continued need for ESA tx and has confirmation of response to tx as evidenced by an inc in HGB levels from baseline AND is using the lowest ESA dose necessary to avoid transfusions AND meets one of the following criteria: (a) HGB level is not greater than 11.0 g/dL for CKD individuals on dialysis, or greater than 10.0 g/dL for CKD non-dialysis, unless otherwise specified (for example, pediatric individuals with CKD where target Hgb levels is within the range of 10 to 12 g/dL) OR (b) HGB is not greater than 12.0. [11.0 g/dL for indv using for myelosuppressive chemotherapy related anemia or myelodysplastic syndrome (NCCN)] OR (c) HGB level is not greater than 12.0 g/dL for ZDV-related anemia in patients with HIV AND if using for myelosuppressive chemotherapy-related anemia, individual is not using beyond 6 weeks after chemotherapy has completed.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Dialysis Dependent use: 1 year. All other use: 6 months.

OTHER CRITERIA

For ESA use for elective, non-cardiac, non-vascular surgery to reduce the need for allogenic blood transfusions AND Baseline Hgb level is greater than 10 g/dL and less than or equal to 13 g/dL AND is at high risk for perioperative transfusions with significant, anticipated blood loss AND Baseline iron status is adequate as defined by one of the following: (i) Transferrin saturation 20% or greater OR (ii) Ferritin 80 ng/mL or greater OR (iii) Bone marrow demonstrates adequate iron stores.

PART B PREREQUISITE

N/A

ERAXIS

MEDICATION(S)
ERAXIS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL 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
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For continuation, individual does not show evidence of progressive disease while on vismodegib therapy.

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
Individual is concomitantly receiving a gonadotropin-releasing hormone (GnRH) analog [e.g. Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)] OR Has had a bilateral orchiectomy. For non-metastatic castration-resistant prostate cancer (nmCRPC), Individual has a PSA doubling time (PSADT) less than or equal to 10 months.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ERWINASE

MEDICATION(S)
RYLAZE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual has developed a confirmed (written or verbal) systemic allergic reaction or anaphylaxis to prior treatment with E. Coli-derived asparaginase.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ESBRIET

MEDICATION(S)
ESBRIET, PIRFENIDONE 267 MG TAB, PIRFENIDONE 534 MG TAB, PIRFENIDONE 801 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial use for Diagnosis of idiopathic pulmonary fibrosis (IPF) is confirmed (written or verbal) by: Exclusion of other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity AND High resolution computed tomography (HRCT) with or without lung tissue sampling. Individual has pulmonary function tests within prior 60 days confirming a Forced Vital Capacity (% FVC) greater than or equal to 50%.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For continued use, there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to decreased frequency of exacerbations, slowed rate of FVC decline or improvement in respiratory symptom burden).

PART B PREREQUISITE
N/A

EXJADE

MEDICATION(S)
DEFERASIROX 125 MG TAB SOL, DEFERASIROX 250 MG TAB SOL, DEFERASIROX 500 MG TAB SOL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Individual is 2 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

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
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual has a current ECOG performance status of 0-2 AND has not progressed on prior therapy with Exkivity (mobocertinib) AND is using as monotherapy.

PART B PREREQUISITE
N/A

FENTORA

MEDICATION(S)
FENTANYL CITRATE 100 MCG TAB, FENTANYL CITRATE 200 MCG TAB, FENTANYL CITRATE 400 MCG TAB, FENTANYL CITRATE 600 MCG TAB, FENTANYL CITRATE 800 MCG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual has a diagnosis of active cancer (such as, metastatic or locally invasive cancer for which the individual is currently seeking treatment) with breakthrough cancer pain (provide diagnosis) AND has had a trial and inadequate response or intolerance to fentanyl citrate lozenge (generic Actiq) AND Individual is already receiving opioid therapy and is TOLERANT to opioid therapy as defined as receiving around the clock medicine consisting of one of the following: At least 60mg morphine per day, OR At least 25mcg/hr transdermal fentanyl/hour, OR At least 30mg of oxycodone daily, OR At least 8mg of oral hydromorphone daily, OR At least 25mg of oral oxymorphone daily, OR An equianalgesic dose of another opioid for a week or longer. Individual will also continue around the clock opioids when taking fentanyl citrate for cancer related breakthrough pain.

PART B PREREQUISITE

N/A

FERRIPROX

MEDICATION(S)
DEFERIPRONE, FERRIPROX 1000 MG TAB, FERRIPROX TWICE-A-DAY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

FETZIMA

MEDICATION(S)
FETZIMA, FETZIMA TITRATION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/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 MDD, individual has had a trial of TWO of the following: Desvenlafaxine, fluoxetine, fluvoxamine, escitalopram, citalopram, paroxetine, sertraline, mirtazapine, venlafaxine, or bupropion.

PART B PREREQUISITE
N/A

FINTEPLA

MEDICATION(S)
FINTEPLA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual is using for weight loss/reduction.

REQUIRED MEDICAL INFORMATION
Diagnosis: Lennox-Gastaut syndrome (LGS), Dravet Syndrome (DS).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual has a diagnosis of seizures associated with Dravet Syndrome AND has responded inadequately to two previous antiepileptic drugs (Lagae 2019, Wirrell 2017, Ziobro 2018).

PART B PREREQUISITE
N/A

FIRAZYR

MEDICATION(S)
ICATIBANT ACETATE, SAJAZIR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Prophylaxis for HAE attacks.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual has a history of moderate or severe attacks (for example, airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, painful facial distortion) and using Icatibant for acute HAE attacks.

PART B PREREQUISITE
N/A

FIRMAGON

MEDICATION(S)
FIRMAGON, FIRMAGON (240 MG DOSE)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Prostate cancer: Clinically localized disease with intermediate (T2b to T2c cancer, Gleason score of 7/Gleason grade group 2-3, or prostate specific antigen (PSA) value of 10-20 ng/mL) OR higher risk of recurrence as neoadjuvant therapy with radiation therapy or cryosurgery OR Used for progressive castration-naïve disease or for castration-recurrent disease OR Other advanced, recurrent, or metastatic disease.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

FORTEO

MEDICATION(S)
FORTEO, TERIPARATIDE (RECOMBINANT)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial use, Osteoporosis is defined as a BMD T-Score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to young adult reference population OR a Clinical diagnosis based on a history of a low trauma fracture (fragility fracture) at high risk for fracture OR associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5mg or greater of prednisone for at least 3 months) at high risk for fracture.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For initial use, Individual meets one of the following: (A) Individual has been refractory to a trial of an a oral bisphosphonate therapy OR (B) Intolerance or contraindications to oral bisphosphonate as defined by having at least one of the following: 1. Hypersensitivity to TWO oral bisphosphonates (one of which must be alendronate) 2. Inability to sit or stand upright for at least 30 minutes, 3. Pre-existing gastrointestinal disorders (Barrett's esophagus, hypersecretory disorders, delayed esophageal emptying, etc.). 4. Uncorrected hypocalcemia. 5. Severe renal insufficiency as defined by creatinine clearance less than 35 mL/min for alendronate agents and zoledronic acid or creatinine clearance less

than 30 mL/min for risedronate and ibandronate. (C) Individual is a postmenopausal female at very high risk for fracture as defined by one or more of the following (AACE/ACE 2020): Recent fracture (within the past 12 months), Fractures while on approved osteoporosis therapy, Multiple fractures, Fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoids), Very low T-score (less than -3.0), High risk for falls or history of injurious falls, or Very high fracture probability by FRAX (fracture risk assessment tool) (e.g. major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or other validated fracture risk algorithm. For continued use, there is confirmation (written or verbal) of clinically significant response to therapy (including but not limited to confirmation of no new fractures reduction of fractures, or no worsening vertebral fractures, or no clinically significant adverse reaction) AND has been on therapy less than or equal to 24 months of treatment, a repeat BMD demonstrates a stable or increase in BMD.

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
For RCC, individual has received at least two prior systemic therapies AND at least one prior systemic therapy included a vascular endothelial growth factor receptor tyrosine kinase inhibitor (VEGFR TKI), such as axitinib, cabozantinib, lenvatinib, sunitinib, or pazopanib (Rini 2020).

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
3 - All Medically-Accepted Indications

OFF LABEL USES
N/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 initial use, in the diagnosis of Short Bowel Syndrome (SBS) individual has been stable on parenteral nutrition/intravenous (PN/IV) support, defined as the inability to significantly reduce PN/IV support, for at least 3 months AND requires PN at least 3 times per week. For continued use, Individual has experienced improvement as compared to baseline.

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
Individual has written or verbal confirmation of RET fusion (or rearrangement) positive tumors.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual is using as monotherapy.

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
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Gazyva may be approved for treatment of chronic lymphocytic leukemia/small lymphocytic lymphoma for any of the following: In combination with bendamustine for first-line treatment in individuals without del(17p)/TP53 mutation OR In combination with chlorambucil for first-line treatment in individuals without del(17p)/TP53 mutation who have significant comorbidity or age greater than 65 OR In combination with ibrutinib for first-line treatment in individuals without del(17p)/TP53 mutation who have significant comorbidity or age greater than 65 OR In combination with acalabrutinib for first line treatment in individuals with or without del (17p)/TP53 mutation or In combination with Venclexta (venetoclax) for the first line treatment in individuals with or without del (17p)/TP53 mutation OR as first-line single agent in individuals who are frail or with del (17p)/TP53 mutation OR as a single agent for the treatment of relapsed/refractory disease without del (17p)/TP53 mutation. For the treatment of

follicular lymphoma, using in combination with ONE of the following combination therapies regimens and as monotherapy for up to 24 months or until disease progression, following the listed combination therapy regimens: cyclophosphamide, doxorubicin, vincristine and prednisone (CHOP regimen) or cyclophosphamide, vincristine, and prednisone (CVP regimen) or bendamustine.

PART B PREREQUISITE

N/A

GILENYA

MEDICATION(S)
FINGOLIMOD HCL, GILENYA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
I. Individual has had a trial and inadequate response or intolerance to one of the following: Avonex (interferon beta-1a), Betaseron (interferon beta-1b), MSB Tecfidera, MSB Copaxone OR II. Individual has high disease activity despite treatment with a disease modifying drug (including Aubagio, Avonex, Bafiertam, Extavia, Kesimpta, Plegridy, Rebif, Betaseron, Lemtrada, Mavenclad, Mayzent, Ocrevus, Copaxone/Glatiramer/Glatopa, Tecfidera, Tysabri, Vumerity and Zeposia) defined as the following: At least 1 relapse in the previous year while on therapy AND At least 9 T2-hyperintense lesions in cranial MRI OR At least 1 Gadolinium-enhancing lesion. OR III. Individual is treatment naive (no previous history of use of disease modifying drugs such as Aubagio, Avonex, Bafiertam, Betaseron, Copaxone/Glatiramer/Glatopa, Extavia, Kesimpta, Lemtrada, Mavenclad, Mayzent, Ocrevus, Plegridy, Rebif, Tecfidera, Tysabri, Vumerity and Zeposia) AND IV. Individual has rapidly evolving severe relapsing multiple sclerosis defined as the following: Two or more disabling relapses in 1 year AND One or more Gadolinium-enhancing lesions on brain MRI. OR V. Individual is between 10-17 years of age and has a diagnosis relapsing MS (RMS).

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
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

GLEEVEC

MEDICATION(S)
IMATINIB MESYLATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

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

GRANIX

MEDICATION(S)
GRANIX 300 MCG/ML SOLUTION, GRANIX 480 MCG/1.6ML SOLUTION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Febrile neutropenic Individuals who are at high risk for infection-associated complications by any of the following: Expected prolonged (greater than 10 day) and profound (less than 0.1 x 10 to the power of 9/L) neutropenia, Age greater than 65 years, Pneumonia or other clinically documented infections, Hypotension and multi organ dysfunction (sepsis syndrome), Invasive fungal infection, Prior episode of febrile neutropenia, Hospitalized at the time of the development of fever. Primary prophylaxis of FN in patients who have a risk of FN of 20% or greater based on chemotherapy regimens. OR when the risk of developing FN is greater than or equal to 10% and less than 20% based on chemotherapy in patients who have risk factors for FN including any of the following: age greater than 65 years, Poor performance status (ECOG status 3-4) or HIV infection (in particular, those with low CD4 counts (less than or eq 450/µL) but chemotherapy still indicated (Lyman 2014), Prior radiation therapy (within previous 1 year) (Terbuch 2018) (Fujiwara 2017) (Shigeta 2015), Bone marrow involvement by tumor producing cytopenias, persistent neutropenia (ANC less than 1500mm3), poor renal function (GFR less than 60mL/min) , liver dysfunction (liver function tests at least 2x upper limit of normal or bilirubin gr than 2.0 mg/dL) (Lyman 2014) (Aagaard 2018), recent surgery performed as part of cancer management within previous 30 days (not to include a procedure such as port placement, drain placement, IVC filter, etc) (Lyman 2014, Aagaard 2018). History of active infection within previous 60 days(Lyman 2014, Aagaard 2018). Current open wound and chemotherapy cannot be delayed (Lyman 2014, Aagaard 2018).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Individual has trial and inadequate response to Zarxio (filgrastim-sndz). Individual is using to mobilize progenitor cells into peripheral blood for collection by leukapheresis as adjunct to peripheral blood/hematopoietic stem cell transplantation (PBSCT/PHSCT).

PART B PREREQUISITE

N/A

HAEGARDA

MEDICATION(S)
HAEGARDA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Hereditary angioedema (HAE) is confirmed (written or verbal) by a C4 level below the lower limit of normal as defined by laboratory testing AND ANY of the following (a, b, or c): (a) C1 inhibitor (C1-INH) antigenic level below the lower limit of normal (b) C1-INH functional level below the lower limit of normal or (c) Presence of a known HAE-causing C1-INH mutation.

AGE RESTRICTION
Individual is 6 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual has a history of moderate or severe attacks and is using as prophylaxis for short-term use prior to surgery, dental procedures or intubation OR for long-term prophylaxis to minimize the frequency and severity of recurrent attacks.

PART B PREREQUISITE
N/A

HARVONI

MEDICATION(S)
LEDIPASVIR-SOFOSBUVIR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation is provided for a diagnosis of chronic Hepatitis C virus (CHC) infection, which includes Genotype and a positive HCV RNA result (AASLD/IDSA 2017, CDC 2013) AND Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy AND Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2016).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
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

HEPSERA

MEDICATION(S)
ADEFOVIR DIPIVOXIL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
12 years of age and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Individual has had a previous trial and inadequate response or intolerance to or has a contraindication to an alternative antiviral agent with a higher genetic barrier to resistance for Hepatitis B [such as entecavir or tenofovir] (AASLD 2016).

PART B PREREQUISITE
N/A

HETLIOZ

MEDICATION(S)
HETLIOZ

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual has confirmed dx (written or verbal) of Smith-Magenis Syndrome (SMS) based on one of the following: (a) Demonstration of a 17p11.2 deletion OR (b) Detection of mutation in RAI1 gene.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

HRM AGE

MEDICATION(S)

AMOXAPINE, CHLORDIAZEPOXIDE-AMITRIPTYLINE, CLOMIPRAMINE HCL 25 MG CAP, CLOMIPRAMINE HCL 50 MG CAP, CLOMIPRAMINE HCL 75 MG CAP, DESIPRAMINE HCL 10 MG TAB, DESIPRAMINE HCL 100 MG TAB, DESIPRAMINE HCL 150 MG TAB, DESIPRAMINE HCL 25 MG TAB, DESIPRAMINE HCL 50 MG TAB, DESIPRAMINE HCL 75 MG TAB, DOXEPIN HCL 10 MG CAP, DOXEPIN HCL 10 MG/ML CONC, DOXEPIN HCL 100 MG CAP, DOXEPIN HCL 150 MG CAP, DOXEPIN HCL 25 MG CAP, DOXEPIN HCL 50 MG CAP, DOXEPIN HCL 75 MG CAP, IMIPRAMINE HCL 10 MG TAB, IMIPRAMINE HCL 25 MG TAB, IMIPRAMINE HCL 50 MG TAB, IMIPRAMINE PAMOATE, PERPHENAZINE-AMITRIPTYLINE, PHENOBARBITAL 100 MG TAB, PHENOBARBITAL 15 MG TAB, PHENOBARBITAL 16.2 MG TAB, PHENOBARBITAL 20 MG/5ML ELIXIR, PHENOBARBITAL 30 MG TAB, PHENOBARBITAL 32.4 MG TAB, PHENOBARBITAL 60 MG TAB, PHENOBARBITAL 64.8 MG TAB, PHENOBARBITAL 97.2 MG TAB, PROTRIPTYLINE HCL

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Prescriber must acknowledge this is a high risk medication (HRM) (as identified by American Geriatric Society) for individuals greater than 65 and medication benefits outweigh potential risk for this individual.

AGE RESTRICTION

Individuals that are 64 years of age or younger are NOT subject to the prior authorization requirements. Prior Authorization applies to individuals that are 65 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

HRM AGE AU

MEDICATION(S)

AMABELZ, BENZTROPINE MESYLATE 0.5 MG TAB, BENZTROPINE MESYLATE 1 MG TAB, BENZTROPINE MESYLATE 2 MG TAB, CARBINOXAMINE MALEATE 4 MG TAB, CARBINOXAMINE MALEATE 4 MG/5ML SOLUTION, CHLORZOXAZONE 500 MG TAB, CLEMASTINE FUMARATE 2.68 MG TAB, CYCLOBENZAPRINE HCL 10 MG TAB, CYCLOBENZAPRINE HCL 5 MG TAB, CYPROHEPTADINE HCL 2 MG/5ML SYRUP, DIGITEK 250 MCG TAB, DIGOX 250 MCG TAB, DIGOXIN 250 MCG TAB, DISOPYRAMIDE PHOSPHATE, ERGOLOID MESYLATES 1 MG TAB, ESTRADIOL 0.025 MG/24HR PATCH TW, ESTRADIOL 0.0375 MG/24HR PATCH TW, ESTRADIOL 0.05 MG/24HR PATCH TW, ESTRADIOL 0.075 MG/24HR PATCH TW, ESTRADIOL 0.1 MG/24HR PATCH TW, KETOROLAC TROMETHAMINE 10 MG TAB, MEGESTROL ACETATE 625 MG/5ML SUSPENSION, MENEST, MEPROBAMATE, METAXALONE, PREMARIN 0.3 MG TAB, PREMARIN 0.45 MG TAB, PREMARIN 0.625 MG TAB, PREMARIN 0.9 MG TAB, PREMARIN 1.25 MG TAB, PREMPRO, PROMETHAZINE HCL 12.5 MG SUPPOS, PROMETHAZINE HCL 25 MG SUPPOS, PROMETHEGAN, TRIHEXYPHENIDYL HCL 0.4 MG/ML SOLUTION

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Prescriber must acknowledge this is a high risk medication (HRM) (as identified by American Geriatric Society) for individuals greater than 65 and medication benefits outweigh potential risk for this individual.

AGE RESTRICTION

Individuals that are 64 years of age or younger are NOT subject to the prior authorization requirements. Prior Authorization applies to individuals that are 65 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

HUMAN GROWTH HORMONE

MEDICATION(S)
NORDITROPIN FLEXPRO, OMNITROPE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
GH tx used for reconstruction should not continue when BA =16 yr (M), or = 14 yr (F) is reached OR Epiphyseal fusion has occurred OR Mid-parenteral height is achieved. Child over 12: an X-ray report with evidence that epiphyses have closed or SMR of 3 or more.

REQUIRED MEDICAL INFORMATION
Initial Requests, For idiopathic GHD, has signs/sym of GHD, GV 2 SD below age-appropriate mean or ht 2.25 SD below age-appropriate mean and A subnormal (SubNL) response (less than10ng/ml)to 2GH stim tests OR Neonates with hypoglycemia and clinical/hormone evidence of hypopit and low GH (less than 10ng/ml)OR 2other pit hormone deficiencies and low IGF-1 OR mbr has cranial irradiation with low IGF1 and normal thyroid tests. Child born SGA(birth wt or length 2 or more SD below the mean for gest age),Child fails to manifest catch up growth by age 2 yr(ht 2 or more SD below the mean for age,gender)AND Other causes for SS have been ruled out. Transitioning adolescent: completed linear growth(growth rate of less than 2cm/yr) AND either of the following: A)GH tx has been stopped at least a month and GHD reconfirmed by: 1)idiopathic isolated GHD(SubNL response to 2 GH stim tests OR SubNL response (GH conc of less than10 ng/mL)to 1 provocative test and low IGF-I/IGFBP-3) OR 2)multiple pit hormone deficiency,(SubNL response to 1 provocative GH test and/or low IGF-I/IGFBP-3)or 3) with cranial irradiation, low IGF with normal thyroid OR B) any of the following:known genetic mutation assoc with def GH production/secretion or Hypothalamic-pit tumor/structural defect or 3 other pit hormone deficiencies. Adult GHD confirmed/reconfirmed:SubNL response in adults to 2 GH stim tests (GH conc of less than or equal to 5ng/ml when using insulin induced hypoglycemia OR GH conc of less than or equal to 4.1ng/ml when using arginine)OR SubNL response to 1 stim test for adults with hypothalamic or pit dz and 1 pit hormone deficits OR 3 other pit hormone deficiencies. Initial requests for therapy in child: For Reconstructive GH tx, if either mean ht is at least 2.25 but less than 2.5SD below the mean for age, gender and GV is less than the 10th percentile over 1yr OR mean ht is at least 2.5SD below the mean for age, gender for conditions known responsive to GH.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Continuation therapy in child (including reconstructive tx) when following are met: individual evaluated AND growth rate remains above 2.5cm/year (does not apply to children with prior documented hypopituitarism) (Grimberg2016). GH for Adolescents with childhood onset GHD who have completed linear growth.

PART B PREREQUISITE

N/A

HUMIRA

MEDICATION(S)
HUMIRA, HUMIRA PEDIATRIC CROHNS START, HUMIRA PEN, HUMIRA PEN-CD/UC/HS STARTER, HUMIRA PEN-PEDIATRIC UC START, HUMIRA PEN-PS/UV/ADOL HS START, HUMIRA PEN-PSOR/UVEIT STARTER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Chronic moderate to severe plaque psoriasis with either of the following: Patient has greater than 3% of body surface area with plaque psoriasis OR Less than or equal to 3% of body surface area with plaque psoriasis involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia) AND agent is used to reduce signs/symptoms OR to induce/maintain clinical response.

AGE RESTRICTION
Individual is 18 years of age or older for all indications except JIA, uveitis, UC, Hidradenitis Suppurativa (HS) and Crohn’s disease. Patient must be at least 2 years old for JIA and uveitis. Individual must be at least 6 years of age for Crohn’s disease. Individual must be at least 12 years old for HS. Individual must be 5 years of age or older for UC.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For initial use: For moderate to severe RA, individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021) OR If methotrexate is not tolerated or contraindicated,

individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine). For moderate to severe Psoriatic Arthritis, individual has had an inadequate response to, is intolerant of, has contraindication to ONE conventional therapy [non-biologic DMARDs (such as methotrexate, sulfasalazine or leflunomide)]. For moderate to severe Ankylosing Spondylitis (AS), individual has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE conventional therapy (such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine). For moderate to severe Crohn's disease, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy (e.g. systemic corticosteroids, or immunosuppressants). For chronic moderate to severe plaque psoriasis, individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or ONE other systemic therapy (e.g. methotrexate, acitretin, or cyclosporine). For moderate to severe Polyarticular Juvenile Idiopathic Arthritis (PJIA), individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy [nonbologic DMARDs (such as methotrexate)] (ACR 2011). For moderate to severe Ulcerative Colitis (UC), individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy (such as 5-ASA products, Sulfasalazine, systemic corticosteroids, or immunosuppressive drugs). For uveitis, individual has chronic, recurrent, treatment-refractory or vision-threatening disease and has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as corticosteroids or immunosuppressive drugs [azathioprine, cyclosporine, or methotrexate]). For chronic, progressive, treatment-refractory Sarcoidosis (Sweiss 2014), individual has had an inadequate response to, is intolerant of or has a contraindication to systemic corticosteroids AND nonbiologic DMARDs (such as methotrexate or azathioprine). For moderate to severe Hidradenitis Suppurativa (Hurley stage II or Hurley stage III disease) AND has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as oral antibiotics). For continued use, there is confirmation (verbal or written) of clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

PART B PREREQUISITE

N/A

HUMULIN U500

MEDICATION(S)
HUMULIN R U-500 (CONCENTRATED), HUMULIN R U-500 KWIKPEN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual has a diagnosis of diabetes mellitus AND requires more than 200 units of U-100 insulin per day.

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
Individual has confirmed (written or verbal attestation) isocitratedehydrogenase-2 (IDH2) mutation.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

IMBRUVICA

MEDICATION(S)
IMBRUVICA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

INCRELEX

MEDICATION(S)
INCRELEX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial treatment of growth failure associated with severe primary IGF-1 deficiency as defined by: Height standard deviation score of less than or equal to -3.0 AND Basal IGF-1 standard deviation score of less than or equal to -3.0 AND normal or elevated growth hormone levels (greater than 10ng/mL on standard GH stimulation tests) are present OR GH gene deletion who have development of neutralizing antibodies to GH.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For Continuation of treatment with Increlex (mecasermin), Final adult height has not been reached.

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
Written or verbal attestation is provided for histological confirmation where applicable based on use/diagnosis.

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
Individual has intermediate to high-risk myelodysplastic syndrome (MDS) or chronic myelomonocytic leukemia (CMML) disease.

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
Individual is 18 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

INTERFERONS FOR MS

MEDICATION(S)
AVONEX PEN, AVONEX PREFILLED, BETASERON

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual has diagnosis of relapsing multiple sclerosis (RMS) (including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

INTUNIV

MEDICATION(S)
GUANFACINE HCL ER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual is using for Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD).

AGE RESTRICTION
Individual is 6 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

IRESSA

MEDICATION(S)
IRESSA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual has a diagnosis of recurrent, advanced, or metastatic Non-small cell lung cancer (NSCLC).

PART B PREREQUISITE
N/A

ITRACONAZOLE

MEDICATION(S)
ITRACONAZOLE 100 MG CAP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
For fingernail/toenail onychomycosis 12 weeks. For all other indications 1 year.

OTHER CRITERIA
For second-line non-onychomycosis indications include tinea infections (including, but limited to tinea versicolor, tinea cruris, tinea corporis, tinea pedis, tinea manuum, and tinea capitis) where the individual has received at least one prior topical therapy: ciclopirox, clotrimazole, ketoconazole, econazole, or nystatin.

PART B PREREQUISITE
N/A

IVIG

MEDICATION(S)
GAMUNEX-C 1 GM/10ML SOLUTION, OCTAGAM 1 GM/20ML SOLUTION, OCTAGAM 2 GM/20ML SOLUTION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
HIE synd when dx confirmed (written or verbal) by high level of serum IgE and recur sinopulmonary/skin infection and chronic eczematous derm. Autoimmune (AI) MC blistering dx when mbr had inadeq response/intolerance/contraindication to other tx such as steroids/ISx. For AI neutropenia, active INFECT is excluded as cause. For tx of 1 neurologic DZ: A) Lambert-Eaton myasthenic syndrome when having muscle weakness AND dx confirmed w/characteristic electrodiagnostic (ED) finding using nerve conduction tests, repetitive nerve stimulation (RNS), exercise testing or single fiber EMG (SFE) or presence of AB directed against voltage-gated Ca channels B) For MG and dx confirmed by presence of AB against the ach receptor or muscle specific tk or characteristic ED findings using RNS or SFE AND using for exacerbation or acute MG crisis or short-term therapy as ISx tx is taking effect or MAINT therapy of MG when mbr had inadeq response/intolerance/CI to Pyridostigmine, Corticosteroids and Non-steroidal ISx. C) For CIDP, as INIT when muscle weakness or sensory dysfx is caused by neuropathy in more than 1 limb and evidence of demyelinating neuropathy confirmed by EFNS/PNS or AAN guidelines or CSF analysis and other polyneuropathies. For cont use of CIDP, clinically/objective sig improvement in neurological sx on exam and cont need is shown by clinical effect. For INIT MMN, dx is confirmed by EFNS/PNS 2010/AANEM 2003 guidelines. For cont MMN use, clinically sgfnt and obj improvmnt in neuro sym on phys exam and cont need is shown by clinical effect. For AE, dx is confirmed by specific autoab assoc with AE and Clinical present inc neuro symptoms (i.e, memory deficits, seizures, movement disorders, speech disturbances, behav changes, or psych symptoms) and Alternative etiologies of encephalitis syndrome have been ruled out, such as infectious etiologies, other neurological disorders, or other AI conditions.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Tx of primary (PI) when hx of recurrent (SI) req ABX tx AND lack of/inadeq response to immunization AND no evidence of renal (nephrotic synd) and GI as causes of HGG AND INIT pre-tx total serum IgG below the lower limit of age adj lab ref range or more than 2SD below adj mean. hyperimmunoadj mean AND hx of recurrent SI requiring ABX therapy AND lack of/inadeq response to immunization OR Use for ONE: A) B-cell CLL w/ hx of recur bacterial or active INFECT not responding to antimicrobial therapy and HGG w/ total IgG less than 500mg/dL B)MM with hx of recur bacterial or clinically severe INFECT and HGG with total IgG less than 400mg/dL C) HIV infected children to prevent opportunistic bacterial infection w/HGG (IgG less than 400mg/dL) or recurrent INFECT D) PARVO B19 chronic INFECT and severe anemia assoc w/BM suppression E) 2ndry HGG or AGG OR using in context of transplant (TX) for ONE: 1) HSCT 2) Solid organ transplantation (TP) including prior desensitization for TP for suppression of panel reactive anti-HLA antibody (AB) in ppl with high panel reactive AB (PRA/cPRA) levels to human leukocyte antigens or in mbr w/hx of high levels of donor-specific ab OR TX recipients at risk of CMV 3) TX recipients exp AB-mediated rejection w/ donor-specific AB OR for tx of AI DZ: A) ITP w/either active bleed or platelet count less than 30,000 mcL B) Fetal alloimmune TCP w/AB to paternal platelet antigen in maternal serum and ONE: Previously affected PREG, family hx of maternofetal alloimmune TCP or fetal blood sample shows TCP C) Isoimmune hemolytic dx of newborn, tx of severe hyperbilirubinemia D) Dermatomyositis (DMM) or polymyositis when mbr had inadeq response/intolerance/contraindication to other tx,e.g., corticosteroids, non-steroidal immunosuppressive agents AND Dx confirmed having at least 4 sx: weak trunk/proximal extremities, high serum CK or aldolase levels, unexplainable muscle pain, electromyography findings, anti-Jo-1 AB, arthralgia/arthritis w/out joint destruction, sign of systemic inflamm, e.g.,fever/elevated C-reactive protein/high SED rate or inflamm myositis seen on muscle biopsy AND using for DMM and skin lesions present or E) AI Encephalitis (AE), eval for neoplasm associated w/AE. For CONT use of AE, is clinically sig improv in symptoms on phys exam and need is demon by clinical effect (i.e, pos response, stable on current dose, or worsening of symptoms occurs from a dose dec or inc in dose intervals, or prev dc resulted in relapse and Cancer screening continues. For 1 MISC DX: post-exposure prophy to stop measles, give in 6dys of exposure (not w/VACC having measles virus), eligible/exposed/non-immune mbr will get a VACC w/measles virus greater than/equal to 8 mth after Ig admin and used in

mbrs at risk of severe dx/complications and no evidence of measles immun in PREG or severely ICP OR for Kawasaki Dz tx initiated w/in 10dys of onset and tx for more than 5dys.

PART B PREREQUISITE

N/A

JADENU

MEDICATION(S)
DEFERASIROX 180 MG TAB, DEFERASIROX 360 MG TAB, DEFERASIROX 90 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
For dx non-transfusion-dependent thalassemia (NTDT) syndrome, 10 years of age or older. For dx of chronic iron overload, 2 years of age or older.

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

JUXTAPID

MEDICATION(S)
JUXTAPID

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual has a clinical diagnosis of homozygous familial hypercholesterolemia (HoFH), confirmed (written or verbal) by (Cuchel 2014, Singh 2015): (A) Genetic confirmation of two (2) mutant alleles at the LDL receptor, apoB, PCSK9 or ARH adaptor protein (LDLRAP1) gene locus OR (B) Presence of the following: 1. an untreated LDL-C concentration greater than 500 mg/dL (13 mmol/L) OR 2. Treated LDL-C greater than or equal to 300 mg/dL (7.76 mmol/L) AND one of the following: (i) cutaneous or tendonous xanthoma before age of 10 years OR (ii) untreated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents (greater than 190 mg/dL).

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual meets one of the following: (a) on high intensity statin therapy or statin therapy at the maximum tolerated dose (high intensity statin is defined as atorvastatin 40 mg or higher or rosuvastatin 20 mg or higher) (AHA/ACC 2018) OR (b) is statin intolerant AND Individual has had a trial and inadequate response or intolerance to Repatha (evolocumab) and achieved suboptimal lipid lowering response despite at least 90 days of Repatha therapy (AHA/ACC 2018). For Continuation use,

Individual continues to receive concomitant lipid lowering therapy including maximally tolerated statin therapy (unless contraindication or individual is statin intolerant) and/or PCSK9 inhibitor therapy AND there is confirmation (written or verbal) of LDL-C reduction has been provided.

PART B PREREQUISITE

N/A

KADCYLA

MEDICATION(S)
KADCYLA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Tumor(s) have been evaluated with an assay validated to predict HER2 positive (HER2+) protein overexpression. Individuals are considered HER2 positive (HER2+) as documented (written or verbal) by one of the following, immunohistochemistry (IHC) 3+ or In Situ hybridization (ISH) positive.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For metastatic breast cancer, individual has previously received trastuzumab (or trastuzumab biosimilars) and a taxane, separately or in combination. AND has either received prior therapy for metastatic disease OR developed disease recurrence during or within six (6) months of completing adjuvant therapy. Kadcyla is only used as a single agent. FOR early non-metastatic breast cancer for residual invasive disease in the breast or axilla after surgery after receiving at least 6 cycles (16 weeks) of neoadjuvant therapy containing a taxane (with or without anthracycline) and trastuzumab (or trastuzumab biosimilars).

PART B PREREQUISITE

N/A

KALYDECO

MEDICATION(S)
KALYDECO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual has a diagnosis of cystic fibrosis (CF). Individual has confirmed (verbal or written attestation) mutation positive result in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

KEVEYIS

MEDICATION(S)
KEVEYIS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial 3 months, renewal 1 year

OTHER CRITERIA
For initial therapy, individual experiences greater than or equal to one episode of muscle weakness per week. For continuation therapy individual has achieved and sustained clinically significant improvement in the number of episodes of muscle weakness experienced per week AND results have been confirmed (written or verbal).

PART B PREREQUISITE
N/A

KEYTRUDA

MEDICATION(S)
KEYTRUDA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Previous treatment with another anti-PD-1 or anti-PD-L1 agent. Receiving therapy for an autoimmune disease or chronic condition requiring treatment with an systemic immunosuppressant.

REQUIRED MEDICAL INFORMATION
Current ECOG (Eastern Cooperative Oncology Group) performance status of 0-2. Written or verbal attestation is provided for confirmation of (known or unknown) mutations where applicable based on use/diagnosis. For high risk non-muscle invasive (T1, high grade Ta, and/or carcinoma in situ [CIS]) Urothelial Carcinoma of the Bladder with or without papillary tumors (Label, NCT02625961) AND has Bacillus Calmette-Guerin (BCG)- unresponsive disease defined as one of the following: (a) Persistent disease despite adequate BCG therapy (adequate defined as administration of at least 5 doses of an initial induction course plus either at least 2 doses of maintenance therapy or at least 2 doses of a second induction course) or (b) dz recurrence after an initial tumor-free state following adequate BCG therapy (adequate defined as administration of at least 5 doses of an initial induction course plus either at least 2 doses of maintenance therapy or at least 2 doses of a second induction course) or (c) T1 disease (i.e., tumor has spread to the connective tissue, but not the muscle) following a single induction course of BCG AND is ineligible for cystectomy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA

For melanoma, 1st line in untreated dz or 2nd line in dz progression while receiving or since completing most recent therapy. For colorectal cancer, monotherapy, primary tx as single agent for dMMR/MSIH and previous adjuvant FOLFOX or Cape OX w/in past 12mon or subsequent therapy as single agent if nivolumab or pembrolizumab not previously given following oxaliplatin-irinotecan and fluropyrimidine based therapy or oxaliplatin-irinotecan OR first line tx as single agent for dMMR/MSIH. For adv/metastatic NSCLC, used as 1st line, monotherapy, cytologically confirmed stage III or IV, tumor expresses PD_L1 gene on at least 1% or grtr of tumor cells. For 1st line adv/ recrnt /metastatic nonsquamous NSCLC, used in combo w/pemetrexed and carboplatin, cytologically confirmed stage IIIb or IV. For 1st line adv/recrnt/metastatic squamous NSCLC, used in combo with carboplatin and nab/paclitaxel and cytologically confirmed stage IV and has not undergone prev systemic tx for dz. For CONT/MAINT of adv, recrnt /metastatic nonsquamous NSCLC, used in combo w/pemetrexed if part of 1st line pembrolizumab/pemetrexed and platinum based regimen and achieved tumor response or stable dz after initial cytotoxic therapy. For CONT/MAINT therapy of adv, recrnt /metastatic squamous NSCLC, used as single agent, given 1st line as part of pembrolizumab/carboplatin/paclitaxel regimen, achieved tumor response or stable dz after initial cytotoxic therapy. For adv,recrnt, metastatic NSCLC, Used 2nd line, monotherapy, tumors w/ PD-L1 gene expression level greater than/equal to 1% w/demonstrated dz progression or after platinum-containing chemo, ALK or EGFR genomic tumor aberrations present and dz progression on FDA approved therapy for aberrations prior to receiving pembrolizumab. For Merkel-cell carcinoma (MCC), used as monotherapy, Presence of metastatic or recurrent locoregional MCC determined to be not amendable to definitive surgery or radiation therapy. For unresectable or metastatic solid tumors (dMMR/MSIH only), used as monotherapy. For hepatocellular carcinoma, used as single agent, demonstrated dz progression or intolerance on or after tx w/an approved 1st line agent.

PART B PREREQUISITE

N/A

KISQALI

MEDICATION(S)
KISQALI (200 MG DOSE), KISQALI (400 MG DOSE), KISQALI (600 MG DOSE), KISQALI FEMARA (400 MG DOSE), KISQALI FEMARA (600 MG DOSE), KISQALI FEMARA(200 MG DOSE)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

KORLYM

MEDICATION(S)
KORLYM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Initial therapy: Individual is not a candidate for surgery that is expected to correct the cause of endogenous Cushings Syndrome OR disease persists or recurs following surgery intended to correct the cause of endogenous Cushings Syndrome. For continuation of therapy: Individual continues to meet the initial request approval criteria AND has experienced an improvement in or stabilization of glucose control as assessed by fasting serum glucose test, oral glucose tolerance test or hemoglobin A1c test.

PART B PREREQUISITE
N/A

KUVAN

MEDICATION(S)
JAVYGTOR, SAPROPTERIN DIHYDROCHLORIDE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial requests, Individual has Dx of Hyperphenylalaninemia (HPA) due to tetrahydrobiopterin-(BH4) responsive PKU. For continued use, has Dx of Hyperphenylalaninemia (HPA) due to tetrahydrobiopterin-(BH4) responsive PKU AND individual is showing signs of continuing improvement as evidenced by maintaining acceptable blood phenylalanine levels.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial 8 weeks, 1 year for continuation

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

LENVIMA

MEDICATION(S)
LENVIMA (10 MG DAILY DOSE), LENVIMA (12 MG DAILY DOSE), LENVIMA (14 MG DAILY DOSE), LENVIMA (18 MG DAILY DOSE), LENVIMA (20 MG DAILY DOSE), LENVIMA (24 MG DAILY DOSE), LENVIMA (4 MG DAILY DOSE), LENVIMA (8 MG DAILY DOSE)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

LETAIRIS

MEDICATION(S)
AMBRISENTAN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial use, Individual has diagnosis of Pulmonary Arterial Hypertension World Health Organization (WHO) Group 1. Individual has the diagnosis of PAH confirmed by a right heart catheterization showing all of the following: (a) Mean pulmonary artery 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 Individual has WHO functional class II- IV symptoms.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For continuation use, there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in walk distance, dyspnea and/or functional class).

PART B PREREQUISITE

N/A

LIDOCAINE 4

MEDICATION(S)
LIDOCAINE HCL 4 % SOLUTION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual is using for anesthesia of accessible mucous membranes of the oral and nasal cavities and proximal portions of the digestive tract.

PART B PREREQUISITE
N/A

LIDODERM PATCH

MEDICATION(S)
LIDOCAINE 5 % PATCH

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

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

LORBRENA

MEDICATION(S)
LORBRENA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

LOTRONEX

MEDICATION(S)
ALOSETRON HCL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual is a Female with Severe diarrhea-predominant Irritable Bowel Syndrome (IBS) defined as including diarrhea and 1 or more of the following: Frequent and severe abdominal pain/discomfort, Frequent bowel urgency or fecal incontinence, Disability or restriction of daily activities due to IBS. Member is female AND Member has chronic symptoms of IBS that have persisted for 6 months or longer AND does not have an anatomic or biochemical abnormality of the gastrointestinal tract.

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual has a trial and inadequate response or intolerance TWO (2) of the following medications: (a) Loperamide (b) antispasmodics (for example, dicyclomine), or (c) tricyclic antidepressants (AGA 2021).

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
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For NSCLC, individual has confirmed (written or verbal) disease progression after one or more prior lines of systemic therapy and using as monotherapy.

PART B PREREQUISITE
N/A

LUPRON DEPOT

MEDICATION(S)
LUPRON DEPOT (1-MONTH) 3.75 MG KIT, LUPRON DEPOT (3-MONTH) 22.5 MG KIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Prostate cancer: Clinically localized dz with intermediate (T2b to T2c cancer, Gleason score of 7/Gleason grade group 2-3, or prostate specific antigen (PSA) value of 10-20 ng/mL) or higher risk of recurrence as neoadjuvant therapy with radiation therapy or cryosurgery OR Other advanced, recurrent, or metastatic disease. For Gynecology Uses: Initial treatment/retreatment of endometriosis OR Preoperative tx as adjunct to surgical tx of uterine fibroids (leiomyoma uteri). May be used to reduce size of fibroids to allow for a vaginal procedure, prior to surgical tx (myomectomy or hysterectomy) in patients with confirmed anemia (Letheby et al. 2001, 2017). To induce amenorrhea in women (such as but not limited to menstruating women diagnosed with severe thrombocytopenia or aplastic anemia). For Endocrine Uses: Precocious puberty, defined as beginning of secondary sexual characteristics before age 8 in girls and before age 9 in boys. For Ovarian Cancer (including fallopian tube cancer and primary peritoneal cancer): Hormonal therapy for clinical relapse in individuals with stage II-IV granulosa cell tumors or Hormonal therapy for treatment of epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer as a single agent for persistent dz or recurrence.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA

For Gender Dysphoria in Adolescents (Hembree 2009)m 2017): Fulfills the DSM V criteria for gender dysphoria (American Psychiatric Assoc 2013) AND has experienced puberty to at least Tanner stage 2 (Hembree 2009, 2017) AND has (early) pubertal changes that have resulted in an increase of their gender dysphoria (Hembree 2009, 2017) AND does not suffer from a psychiatric comorbidity that interferes with the diagnostic work-up or treatment (Hembree 2009, 2017) AND has psychological and social support during treatment (Hembree 2009, 2017) AND demonstrates knowledge and understanding of the expected outcomes of GnRH analog treatment(Hembree 2009, 2017).

PART B PREREQUISITE

N/A

LUPRON KIT IR

MEDICATION(S)
LEUPROLIDE ACETATE 1 MG/0.2ML KIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Prostate cancer: Clinically localized disease with intermediate (T2b to T2c cancer, Gleason score of 7/Gleason grade group 2-3, or prostate specific antigen (PSA) value of 10-20 ng/mL) or higher risk of recurrence as neoadjuvant therapy with radiation therapy or cryosurgery OR Other advanced, recurrent, or metastatic disease.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

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
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

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
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes a genotype and a positive HCV RNA result (AASLD/IDSA 2017, CDC 2013) AND Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy AND Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2017).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
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

MEGACE SUSPENSION HRM

MEDICATION(S)
MEGESTROL ACETATE 40 MG/ML SUSPENSION, MEGESTROL ACETATE 400 MG/10ML SUSPENSION, MEGESTROL ACETATE 800 MG/20ML SUSPENSION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual is using for the treatment of cachexia, or unexplained weight loss in individuals with HIV/AIDS. Prescriber must acknowledge this is a high risk medication (HRM) [as identified by American Geriatric Society] for individuals greater than 65 and medication benefits outweigh potential risk for this individual.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

MEGACE TABS HRM

MEDICATION(S)
MEGESTROL ACETATE 20 MG TAB, MEGESTROL ACETATE 40 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Prescriber must acknowledge this is a high risk medication (HRM) [as identified by American Geriatric Society] for individuals greater than 65 and medication benefits outweigh potential risk for this individual.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
Individual has advanced, inoperable, recurrent breast cancer and using for palliative management.
Individual has endometrial/uterine cancer and is using for palliative management.

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
BRAF V600E or V600K mutation results must be confirmed (written or verbal attestation).

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
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

MEPRON

MEDICATION(S)
ATOVAQUONE 750 MG/5ML SUSPENSION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Intolerance to trimethoprim-sulfamethoxazole (TMP-SMX)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

METHYLPHENIDATE

MEDICATION(S)
METHYLPHENIDATE HCL 10 MG TAB, METHYLPHENIDATE HCL 20 MG TAB, METHYLPHENIDATE HCL 5 MG TAB, METHYLPHENIDATE HCL ER (CD) 10 MG CAP ER, METHYLPHENIDATE HCL ER (CD) 20 MG CAP ER, METHYLPHENIDATE HCL ER (CD) 30 MG CAP ER, METHYLPHENIDATE HCL ER (CD) 40 MG CAP ER, METHYLPHENIDATE HCL ER (CD) 60 MG CAP ER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual is using for Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) or Narcolepsy.

AGE RESTRICTION
6 years of age and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

MODAFINIL

MEDICATION(S)
MODAFINIL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Narcolepsy type 1: confirmed by the presence of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months and at least one of the following: 1. Clear cataplexy (defined as more than one episode of generally brief) usually bilaterally symmetrical, sudden loss of muscle tone with retained consciousness) AND 2.Multiple Sleep Latency Test (MSLT) showing one of the following: a. Mean sleep latency of less than 8 minutes with evidence of two sleep-onset rapid eye movement periods (SOREMPs) (ICSD-3, 2014)OR b. At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG) OR 3.Cerebrospinal fluid hypocretin-1 deficiency (less than 100pg/mL or less than one-third of the normative values with the same standardized assay). For Narcolepsy type 2: confirmed by 1.Multiple sleep latency test (MSLT) with one of the following: a.Mean sleep latency of less than 8 minutes with and evidence of two sleep-onset rapid eye movement periods (SOREMPs) ICSD-3, 2014) OR b. At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG) AND 2.The absence of cataplexy AND 3.Exclusion of alternative causes of excessive daytime sleepiness by history, physical exam and Polysomnography.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA

For obstructive sleep apnea/hypopnea syndrome objectively confirmed by polysomnography (PSG) or home testing with portable monitor showing one of the following (AASM 2017, ICSD-3): (1).Greater than 15 obstructive events (defined as apneas, hypopneas plus respiratory event related arousal) per hour of sleep OR (2)Greater than 5 obstructive events per hour of sleep and individual reports any of the following: a.Unintentional sleep episodes during wakefulness or b. Daytime sleepiness or c. Unrefreshing sleep or d. Fatigue or e. Insomnia or f.Waking up breath holding, gasping or choking or g.Bed partner describing loud snoring, breathing interruptions or both or h. Presence of comorbid conditions including hypertension, mood disorder, cognitive dysfunction, coronary artery disease, stroke, congestive heart failure, atrial fibrillation or type 2 diabetes mellitus. And has an Epworth Sleepiness Scale score greater than or equal to 10. For Shift-Work Sleep Disorder (SWSD) confirmed by all of the following: (1)No other medical disorder or mental disorder accounts for the symptoms AND (2)Symptoms do not meet criteria for any other sleep disorder (i.e. jet lag) AND (3)Symptoms have occurred for at least 3 months, AND (4)Individual has one of the following: a.Individual has excessive sleepiness or insomnia associated with a work period that occurs during the usual sleep phase OR b.Polysomnography demonstrates loss of a normal sleep-wake pattern (such as, disturbed chronobiological rhythmicity).

PART B PREREQUISITE

N/A

MYALEPT

MEDICATION(S)
MYALEPT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

NAMENDA LINE

MEDICATION(S)
MEMANTINE HCL 10 MG TAB, MEMANTINE HCL 2 MG/ML SOLUTION, MEMANTINE HCL 28 X 5 MG & 21 X 10 MG TAB, MEMANTINE HCL 5 MG TAB, MEMANTINE HCL ER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Individuals that are 50 years of age or older are NOT subject to the prior authorization requirements. Prior Authorization applies to individuals that are 49 years of age or younger.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Individual has a diagnosis of moderate to severe dementia of the Alzheimers type.

PART B PREREQUISITE
N/A

NATPARA

MEDICATION(S)
NATPARA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Diagnosis of chronic (duration of greater than or equal to 18 months, mannstadt et, al 2013) hypoparathyroidism.

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
Individual has HER2- overexpressed/amplified confirmed (written or verbal) by one of the following: (A) Immunohistochemistry (IHC) is 3+ or (B) In situ hybridization (ISH) positive.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

NEXAVAR

MEDICATION(S)
NEXAVAR, SORAFENIB TOSYLATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Confirmed (verbal or written attestation) results of FLT3-ITD mutation with acute myeloid leukemia, relapsed/refractory disease.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

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
For multiple myeloma, individual received at least two prior therapies, including immunomodulatory agent and a proteasome inhibitor AND demonstrated disease progression on or within 60 days of completion therapy AND Ninlaro is given as part of a treatment regimen containing dexamethasone and pomalidomide.

PART B PREREQUISITE
N/A

NITYR

MEDICATION(S)
NITYR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial requests, Individuals plasma tyrosine level is maintained below 500 micromol/L to reduce risk of ocular symptoms, developmental delay, or hyperkeratotic plaques.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

NORTHERA

MEDICATION(S)
DROXIDOPA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual has had a trial and inadequate response or intolerance to one prior symptomatic nOH pharmacologic therapy (which may include midodrine or fludrocortisone [AHFS]).

PART B PREREQUISITE
N/A

NOXAFIL

MEDICATION(S)
NOXAFIL 40 MG/ML SUSPENSION, POSACONAZOLE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

NP CSF SA AGENTS

MEDICATION(S)
NIVESTYM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Febrile neutropenic Individuals who are at high risk for infection-associated complications by any of the following: Expected prolonged (greater than 10 day) and profound (less than 0.1 x 10 to the power of 9/L) neutropenia, Age greater than 65 years, Pneumonia or other clinically documented infections, Hypotension and multi organ dysfunction (sepsis syndrome), Invasive fungal infection, Prior episode of febrile neutropenia, Hospitalized at the time of the development of fever. Primary prophylaxis of FN in patients who have a risk of FN of 20% or greater based on chemotherapy regimens. OR when the risk of developing FN is greater than or equal to 10% and less than 20% based on chemotherapy in patients who have risk factors for FN including any of the following: age greater than 65 years, Poor performance status (ECOG status 3-4) or HIV infection (in particular, those with low CD4 counts (less than or eq 450/µL) but chemotherapy still indicated (Lyman 2014), Prior radiation therapy (within previous 1 year) (Terbuch 2018) (Fujiwara 2017) (Shigeta 2015), Bone marrow involvement by tumor producing cytopenias, persistent neutropenia (ANC less than 1500mm3), poor renal function (GFR less than 60mL/min) , liver dysfunction (liver function tests at least 2x upper limit of normal or bilirubin gr than 2.0 mg/dL) (Lyman 2014) (Aagaard 2018), recent surgery performed as part of cancer management within previous 30 days (not to include a procedure such as port placement, drain placement, IVC filter, etc) (Lyman 2014, Aagaard 2018). History of active infection within previous 60 days(Lyman 2014, Aagaard 2018). Current open wound and chemotherapy cannot be delayed (Lyman 2014, Aagaard 2018).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Individual has had a trial and inadequate response to intolerance to Zarxio (Filgrastim-sndz). Secondary Prophylaxis for patients who experienced a neutropenic complication from a prior cycle of chemotherapy (for which primary prophylaxis was not received), in which a reduced dose may compromise disease-free or overall survival or treatment outcome. Using for adjunctive tx for FN and has been prophylactic therapy with GCSF agent or has not received prophylactic therapy with a GCSF and who are at high risk for infection-associated complications. Use in individuals with acute myeloid leukemia (AML) shortly after the completion of induction or repeat induction chemotherapy, or after the completion of consolidation chemotherapy for AML. For tx of moderate to severe aplastic anemia. Tx of severe neutropenia in individuals with hairy cell leukemia. For myelodysplastic syndromes (MDS) with severe neutropenia (absolute neutrophil count (ANC) less than or equal to 500 mm3 or experiencing recurrent infection. For dose dense therapy (treatment given more frequently, such as every two weeks instead of every three weeks) for adjuvant treatment of breast cancer. For chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic individuals with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia. For tx of (non-chemotherapy) drug-induced neutropenia. For tx of low neutrophil counts in individuals with glycogen storage disease type 1b. For tx of neutropenia associated with human immunodeficiency virus (HIV) infection and antiretroviral therapy. In individuals receiving radiation therapy in the absence of chemotherapy if prolonged delays secondary to neutropenia are expected. After accidental or intentional total body radiation of myleosuppressive doses (greater than 2 Grays [Gy] (such as Hematopoietic Syndrome of Acute Radiation Syndrome). After hematopoietic progenitor stem cell transplant (HPCT/HSCT) to promote myeloid reconstitution or when engraftment is delayed or has failed. To mobilize progenitor cells into peripheral blood for collection by leukapheresis, as an adjunct to peripheral blood/hematopoietic stem cell transplantation (PBSCT/PHSCT). Use as an alternate or adjunct to donor leukocyte infusions (DLI) in individuals with leukemic relapse after an allogeneic hematopoietic stem cell transplant.

PART B PREREQUISITE

N/A

NP HUMAN GROWTH HORMONE

MEDICATION(S)
ZORBTIVE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial idiopathic GHD requests, has signs/sym sx of GHD, GV 2 SD below age-appropriate mean or ht 2.25 SD below age-appropriate mean and A subnormal (SubNL) response (less than10ng/ml)to 2GH stim tests OR Neonates with hypoglycemia and clinical/hormone evidence of hypopit and low GH (less than 10ng/ml)OR 2other pit hormone deficiencies and low IGF-1 OR mbr has cranial irradiation with low IGF1 and normal thyroid tests.Child born SGA(birth wt or length 2 or more SD below the mean for gest age),Child fails to manifest catch up growth by age 2yr(ht 2 or more SD below the mean for age,gender)AND Other causes for SS have been ruled out.Transitioning adolescent: individual completed linear growth (less than 2cm/yr) AND either GH tx has been stopped for at least a month, and GHD has been reconfirmed:idiopathic isolated GHD(SubNL response to 2 GH stim tests, OR SubNL response (GH conc of less than10 ng/mL)to 1 provocative test and low IGF-I/IGFBP-3)OR multiple pit hormone deficiency,(SubNL response to 1 provocative GH test and/or low IGF-I/IGFBP-3)or for mbr with cranial irradiation, low IGF with normal thyroid or any of the following, known genetic mutation associated with def GH production or secretion or Hypothalamic-pit tumor or structural defect or 3 other pit hormone deficiencies.Adult GHD must be confirmed/reconfirmed:SubNL response in adults to 2 GH stim tests (GH conc of less than or equal to 5ng/ml when using insulin induced hypoglycemia OR GH conc of less than or equal to 4.1ng/ml when using arginine)OR SubNL response to 1 stim test for adults with hypothalamic or pit dz and 1 pit hormone deficits OR 3 other pit hormone deficiencies.Initial request for Reconstructive GH tx in child w/ mean ht is at least 2.25 but less than 2.5SD below the mean for age, gender and GV is less than 10th percentile over 1yr or mean ht at least 2.5SD below the mean for age, gender for conditions known responsive to GH.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

For Non-Preferred Growth hormone agents, individual has had trial of TWO preferred GH agents (Norditropin AND Omnitrope) or preferred GH agent is not FDA-approved and does not have an accepted off-label use per CMS recognized compendia for the prescribed indication and the requested non-preferred agent is. GH for Adolescents with childhood onset GHD who have completed linear growth. GH tx in other populations approved when: individual is requesting Serostim, AND individual has AIDS wasting (defined as greater than 10% of baseline wt loss that is not explained by concurrent illness other than HIV) AND is being treated with antiviral therapy AND will continue tx until definition not met OR individual is requesting Zorbtive AND individual dx with short bowel syndrome AND is receiving specialized nutritional support.

PART B PREREQUISITE

N/A

NP LA OPIOID

MEDICATION(S)

BUPRENORPHINE 10 MCG/HR PATCH WK, BUPRENORPHINE 15 MCG/HR PATCH WK, BUPRENORPHINE 20 MCG/HR PATCH WK, BUPRENORPHINE 5 MCG/HR PATCH WK, BUPRENORPHINE 7.5 MCG/HR PATCH WK, METHADONE HCL 10 MG TAB, METHADONE HCL 5 MG TAB, MORPHINE SULFATE ER 100 MG TAB ER, MORPHINE SULFATE ER 15 MG TAB ER, MORPHINE SULFATE ER 200 MG TAB ER, MORPHINE SULFATE ER 30 MG TAB ER, MORPHINE SULFATE ER 60 MG TAB ER, MORPHINE SULFATE ER BEADS, TRAMADOL HCL ER 100 MG TAB ER 24H, TRAMADOL HCL ER 200 MG TAB ER 24H, TRAMADOL HCL ER 300 MG TAB ER 24H, TRAMADOL HCL ER (BIPHASIC)

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial 3 months. Maintenance 6 months. Cancer Pain/Terminal Dx or Palliative Care 1 Year.

OTHER CRITERIA

For initial use, Individual has one of the following: (a) Diagnosis of cancer related pain and/or is actively undergoing cancer therapy (provide cancer diagnosis) OR (b) Diagnosis of terminal illness and is receiving palliative/end-of-life care (provide terminal diagnosis) OR Individual has pain severe enough to require daily, around-the-clock, long term opioid treatment (provide diagnosis) AND Individual has

one of the following: (a) An inadequate response to ONE alternative treatment options, such as but not limited to non-opioid analgesics and immediate-release opioids OR (b) Alternative treatment options would otherwise be inadequate to provide sufficient management of pain OR (c) Individual has contraindications to non-opioid analgesics (such as NSAID use in individuals with active ulcer condition/gastrointestinal bleeding, renal failure) AND for initial therapy, individual is not opioid naïve as noted by the following: (a) Individual is currently using a short-acting opioid analgesic, including use of opioid analgesia as an inpatient for post-surgical pain OR (b) Individual is transitioning from one long-acting opioid analgesic to another long-acting opioid analgesic. For continued use, (I) individual has a diagnosis of cancer related pain and/or is actively undergoing cancer therapy (provide cancer diagnosis) OR (II) diagnosis of terminal illness and is receiving palliative/end-of-life care (provide terminal diagnosis) OR (III) Individual has pain severe enough to require daily, around-the-clock, long term opioid treatment (provide diagnosis) AND Attestation (verbal or written) that long-acting opioid therapy has provided meaningful improvement in pain and/or function compared to baseline AND Prescriber has consulted individual regarding risks of opioid therapy AND clear treatment goals have been defined and outline as part of overall plan.

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
Individual has Metastatic hormone-sensitive prostate cancer (mHSPC) OR Individual has a diagnosis of non-metastatic castration resistant prostate cancer (nmCRPC) AND has a PSA doubling time (PSADT) less than or equal to 10 months AND One of the following: (a) individual is concomitantly receiving a gonadotropin-releasing hormone (GnRH) analog [e.g. Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (Degarelix] OR (b) Has had a bilateral orchiectomy.

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
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For severe eosinophilic asthma: In the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease and known or suspected parasitic infections, the individual has a blood eosinophil count that is either greater than or equal to 150 cells/microliter at ignition of therapy OR greater than or equal 300 cells/microliter in the prior 12 months. Evidence of asthma is demonstrated by the following (NAEPP 2008): The individual has a pretreatment forced expiratory volume in one second (FEV1) less than 80% predicted AND FEV1 reversibility of at least 12% and 200mL after albuterol (salbutamol) administration. For initial severe eosinophilic asthma, mbr had a 3-mon trial/inadeq response to combo controller therapy (hi dose inhaled corticosteroids plus LA beta2-agonist, leukotriene modifiers, theophylline or oral corticosteroids) (ERS/ATS 2013) AND exp 2 or more asthma exacerbations in past 12 mon requiring use of a systemic corticosteroid or temp increase in the mbr usual maint. of oral corticosteroids (ERS/ATS 2013). For Continuation of individuals w/severe eosinophilic asthma, tx resulted in clinical improv as confirmed by either i) Decreased utilization of rescue meds OR ii) decreased freq of exacerbation (defined as worsening of asthma that requires inc in inhaled corticosteroid dose or tx w/systemic corticosteroid) OR iii) increase in percent predicted FEV1 from pretreatment baseline OR iv) A reduction in reported asthma-related sx, such as, to wheezing, SOB, coughing, fatigue, sleep disturbance or asthmatic upon awakening.

AGE RESTRICTION
For eosinophilic asthma: 6 years old or older. For eosinophilic granulomatosis with polyangitis (EGPA) and chronic rhinosinusitis with nasal polyp: 18 years old or older. For hypereosinophilic syndrome (HES): 12 years old or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 6 months. Continuation: 1 Year.

OTHER CRITERIA

For initial EGPA, has been dx for at least 6 months or greater and 1) a history or presence of asthma and 2) blood eosinophil level greater than or equal to 10% of leucocytes or ANC of greater than 1000 cells/mm3 (in absence of other potential causes of eosinophilia, including HES, neoplastic dz and known or suspected parasitic INF) and 3) presence of 2 or more features of eosinophilic granulomatosis w/polyangiitis (such as, biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration or eosinophil-rich granulomatosis inflamm, neuropathy, mono or poly(motor deficit or nerve conduction abnormality), pulmonary infiltrates, non-fixed sino-nasal abnormality, cardiomyopathy, glomerulonephritis, alveolar hemorrhage, palpable purpura or antineutrophil cytoplasmic antibody positive status AND 4) mbr is on concurrent oral corticosteroid therapy (Wechsler, 2017). For EGPA Continuation, tx has resulted in clinical improv as confirmed by the achievement of remission at some point during tx, defines as the following: Birmingham Vasculitis Activity Score, version 3, of 0 on scale from 0 to 63 and receipt of prednisolone or prednisone at dose of 4mg or less per day. For hypereosinophilic syndrome (HES), mbr has been dx for at least 6 mon AND had trial/inadeq response to oral corticosteroids AND mbr experienced 2 or more HES flares w/in the past 12 mon requiring escalation in therapy (increase in oral corticosteroid dose or increase/addition of immunosuppressive or cytotoxic therapy) AND has blood eosinophil count greater than or equal to 1000cells/microliter. For HES continuation, tx resulted in confirmed clinically significant improvement or stabilization in clinical signs/sx of disease (including but not limited to decrease or absence of HES flares, improvement in fatigue). For chronic rhinosinusitis with nasal polyps (CRSwNP), there is presence of nasal polyps confirmed by a) anterior rhinoscopy b) nasal endoscopy OR c) computed tomography AND mbr had trial/inadeq response to MAINT intranasal corticosteroids AND is refractory to ineligible or intolerant systemic corticosteroids OR sinonasal surgery AND mbr is requesting Nucala as add-on therapy to MAINT intranasal corticostetroids. For CRSwNP continuation therapy, tx resulted in confirmed clinically significant improvement in clinical signs and sx of disease (including but not limited to improvement in nasal congestion or reduced nasal polyp size) AND continues to use Nucala in combo w/ MAINT intranasal corticosteroids.

PART B PREREQUISITE

N/A

NUEDEXTA

MEDICATION(S)
NUEDEXTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual has a diagnosis of pseudobulbar affect (PBA) AND has a concomitant diagnosis with an unrelated neurologic disease or injury [amyotrophic lateral sclerosis (AAN 2020, Pioro et al. 2010), multiple sclerosis (AAN 2019, Pioro et al, 2010), stroke (2016 AHA/ASA)].

PART B PREREQUISITE
N/A

NUPLAZID

MEDICATION(S)
NUPLAZID

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial:3 months, Maintenance: 1 Year

OTHER CRITERIA
Initial therapy: Individual has a diagnosis of Parkinsons disease AND Symptoms of psychosis developed after the PD diagnosis AND Symptoms of psychosis include at least one of the following: (1) Visual hallucinations, (2) Auditory hallucination OR (3) Delusions AND Symptoms have been present for at least one month AND Individual has experienced symptoms at least once weekly. 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. For continued therapy, the individual has had a reduction in symptoms of psychosis compared to baseline.

PART B PREREQUISITE
N/A

NURTEC

MEDICATION(S)
NURTEC

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/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 the acute treatment of migraine headaches, Individual has had a trial of and inadequate response or intolerance to two oral triptans (AHS 2019) OR has one of the following cardiovascular or non-coronary vascular contraindications to use of triptans: (a) Ischemic coronary artery disease (CAD) including angina pectoris, history of myocardial infarction, documented silent ischemia, coronary artery vasospasm (including Prinzmetal's angina) or (b) History of stroke or transient ischemic attack (TIA) or (c) Peripheral vascular disease or (d) Ischemic bowel disease or (e) Uncontrolled hypertension. For prevention of episodic migraine headaches, individual has had a trial and inadequate response to a 30 day trial at target or usual effective dose or intolerance to two agents for migraine prophylaxis (at least one agent in any two of the following classes) or has a contraindication to all of the following medications (AAN/AHA 2012/2015, Level A and B evidence, ICSI 2013, high quality evidence, AHS 2019): a) The following antidepressants: amitriptyline, venlafaxine, nortriptyline, duloxetine OR b) One

of the following beta blockers: Metoprolol, propranolol, timolol (oral), nadolol, atenolol, nebivolol OR c) the following calcium channel blocker, verapamil OR d) One of the following antiepileptic agents: valproate sodium, divalproex sodium, topiramate, gabapentin OR e) Botox (for chronic migraine).

PART B PREREQUISITE

N/A

NUVIGIL

MEDICATION(S)
ARMODAFINIL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Narcolepsy type 1: confirmed by the presence of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months and at least one of the following: 1. Clear cataplexy (defined as more than one episode of generally brief) usually bilaterally symmetrical, sudden loss of muscle tone with retained consciousness) AND 2.Multiple Sleep Latency Test (MSLT) showing one of the following: a. Mean sleep latency of less than 8 minutes with evidence of two sleep-onset rapid eye movement periods (SOREMPs) OR b. At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG) OR 3.Cerebrospinal fluid hypocretin-1 deficiency (less than 100pg/mL or less than one-third of the normative values with the same standardized assay). For Narcolepsy type 2: confirmed by 1.Multiple sleep latency test (MSLT) with one of the following: a.Mean sleep latency of less than 8 minutes with and evidence of two sleep-onset rapid eye movement periods (SOREMPs) ICSD-3, 2014) OR b. At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG) AND 2.The absence of cataplexy AND 3.Exclusion of alternative causes of excessive daytime sleepiness by history, physical exam and Polysomnography.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA

For obstructive sleep apnea/hypopnea syndrome objectively confirmed by polysomnography (PSG) or home testing with portable monitor showing one of the following (AASM 2017, ICDSD-3): (1).Greater than 15 obstructive events (defined as apneas, hypopneas plus respiratory event related arousal) per hour of sleep OR (2)Greater than 5 obstructive events per hour of sleep and individual reports any of the following: a.Unintentional sleep episodes during wakefulness or b. Daytime sleepiness or c. Unrefreshing sleep or d. Fatigue or e. Insomnia or f.Waking up breath holding, gasping or choking or g.Bed partner describing loud snoring, breathing interruptions or both or h. Presence of comorbid conditions including hypertension, mood disorder, cognitive dysfunction, coronary artery disease, stroke, congestive heart failure, atrial fibrillation or type 2 diabetes mellitus. And has an Epworth Sleepiness Scale score greater than or equal to 10. For Shift-Work Sleep Disorder (SWSD) confirmed by all of the following: (1) No other medical disorder or mental disorder accounts for the symptoms AND (2)Symptoms do not meet criteria for any other sleep disorder (i.e. jet lag) AND (3) Symptoms have occurred for at least 3 months, AND (4) Individual has one of the following: a.Individual has excessive sleepiness or insomnia associated with a work period that occurs during the usual sleep phase OR b.Polysomnography demonstrates loss of a normal sleep-wake pattern (such as, disturbed chronobiological rhythmicity).

PART B PREREQUISITE

N/A

OCALIVA

MEDICATION(S)
OCALIVA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual has a diagnosis of primary biliary cholangitis (PBC) as confirmed by TWO of the following (AASLD 2018): (a) Elevated alkaline phosphatase. (b) Positive antimitochondrial antibodies (AMA) or other PBC-specific auto antibody titer. (c) Liver biopsy with findings consistent with PBC.

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
For Initial request, Individual has had a one year trial of ursodiol (Urso 250, Urso Forte) with an inadequate response as demonstrated by one of the following (FDA Ad Com, Lindor, 2009): (a) Alkaline phosphatase greater than or equal to 1.67 times the upper limit of normal OR (b) Total bilirubin greater than the upper limit of normal but less than two times the upper limit of normal) AND Individual will be utilizing Ocaliva (obeticholic acid) in combination with ursodiol (Urso 250, Urso Forte) OR has an intolerance to ursodiol (Urso 250, Urso Forte). For continuing treatment with Ocaliva (obeticholic acid), individual has previously met the initiation criteria above and: (a) Individual has achieved an adequate response of alkaline phosphatase or total bilirubin AND (b) Individual has not experienced clinically significant hepatic adverse reactions while on therapy, including hepatic decompensation or

compensated cirrhosis with portal hypertension.

PART B PREREQUISITE

N/A

OCTREOTIDE LINE

MEDICATION(S)
OCTREOTIDE 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

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
For initial requests, basal cell carcinoma (BCC), individual has locally advanced recurrent disease following surgery or radiation OR has locally advanced disease and is not a candidate for surgery or radiation therapy. For continued treatment, individual does not show evidence of progressive disease while on sonidegib therapy.

PART B PREREQUISITE
N/A

OFEV

MEDICATION(S)
OFEV

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Initial: dx of idiopathic pulmonary fibrosis (IPF) is confirmed (verbal or written) by (Raghu 2018): Exclusion of other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity AND High resolution computed tomography (HRCT) with or without lung tissue sampling AND Individual has pulmonary function tests within prior 60 days confirming Forced Vital Capacity (% FVC) greater than or equal to 50%. For dx systemic sclerosis-associated interstitial lung disease (SSc-ILD), mbr has been confirmed (verbal or written) by chest high resolution computed tomography (HRCT) scan showing fibrosis affecting greater than or equal to 10% of the lungs and individual has pulmonary function tests within prior 60 days confirming Forced Vital Capacity (%FVC) greater than or equal to 40%. For dx of chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype, mbr has been confirmed (written or verbal) by chest (HRCT) scan showing fibrosis affecting greater than or equal to 10% of the lungs AND progressive disease has been confirmed by one of the following within the last 24 months while on treatment: (a) FVC decline of greater than or equal to 10% OR (b) 2 of the following: (1) FVC decline greater than or equal to 5% and less than 10% or (2) Worsening respiratory symptoms or (3) Increased fibrosis on HRCT AND individual has pulmonary function tests within prior 60 days confirming FVC greater than or equal to 45%.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

For Continuation, there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to decreased frequency of exacerbations, slowed rate of FVC decline or improvement in respiratory symptom burden).

PART B PREREQUISITE

N/A

ONFI

MEDICATION(S)
CLOBAZAM, SYMPAZAN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis (all ages) and if over 65 years of age or older, Prescriber must acknowledge this is a high risk medication (HRM) [as identified by American Geriatric Society] and medication benefits outweigh potential risk for this individual.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

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
Individual has a diagnosis of acute myeloid leukemia (AML), including de novo AML and AML secondary to prior myelodysplastic disease or chronic myelomonocytic leukemia (NCT01757535) AND has achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy AND is unable to complete intensive curative therapy (e.g. allogeneic hematopoietic stem cell transplant) AND is used as a single agent.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

OPSUMIT

MEDICATION(S)
OPSUMIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial requests, Individual has diagnosis of Pulmonary Arterial Hypertension World Health Organization (WHO) Group 1. Individual has the diagnosis of PAH confirmed by a right heart catheterization showing all of the following: (a) Mean pulmonary artery 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 Individual has WHO functional class II- IV symptoms.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual is using for the treatment of chronic thromboembolic pulmonary hypertension (CTEPH) OR Individual is using for the treatment of Fontan-Palliated patients . For continuation therapy, there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in walk distance, dyspnea and/or functional class).

PART B PREREQUISITE

N/A

ORENITRAM

MEDICATION(S)
ORENITRAM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial requests, Individual has diagnosis of Pulmonary Arterial Hypertension World Health Organization (WHO) Group 1. Individual has the diagnosis of PAH confirmed by a right heart catheterization showing all of the following: (a) Mean pulmonary artery 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 Individual has WHO functional class II- IV symptoms.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For continuation requests, there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in walk distance, dyspnea and/or functional class).

PART B PREREQUISITE

N/A

ORFADIN

MEDICATION(S)
NITISINONE, ORFADIN 20 MG CAP, ORFADIN 4 MG/ML SUSPENSION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial requests, Individuals plasma tyrosine level is maintained below 500 micromol/L to reduce risk of ocular symptoms, developmental delay, or hyperkeratotic plaques.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

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
For initial therapy, Individual presents with ONE of the following disease state presentations: (a) Evidence of biochemical (PSA) or clinical relapse following local primary intervention with curative intent, such as surgery, radiation therapy, cryotherapy, or high-frequency ultrasound and not a candidate for salvage treatment by surgery OR (b) Newly diagnosed androgen-sensitive metastatic disease OR (c) Advanced localized disease unlikely to be cured by local primary intervention with either surgery or radiation with curative intent. AND is using as androgen deprivation therapy.

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial and Continuation 6 months.

OTHER CRITERIA
For continuation therapy, individual meets the initial criteria AND does not show evidence of progressive disease while on therapy AND has serum testosterone level less than 50 ng/dL.

PART B PREREQUISITE
N/A

ORKAMBI

MEDICATION(S)
ORKAMBI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Mutation testing confirms (verbal or written) the individual has two copies of the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.

AGE RESTRICTION
Individual is 1 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

OXANDRIN

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

OXYCONTIN

MEDICATION(S)
OXYCODONE HCL ER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Individual is 11 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial 3 months. Maintenance 6 months. Cancer Pain/Terminal Dx or Palliative Care 1 Year.

OTHER CRITERIA
For initial use, Individual has one of the following: (a) Diagnosis of cancer related pain and/or is actively undergoing cancer therapy (provide cancer diagnosis) OR (b) Diagnosis of terminal illness and is receiving palliative/end-of-life care (provide terminal diagnosis) OR Individual has pain severe enough to require daily, around-the-clock, long term opioid treatment (provide diagnosis) AND Individual has one of the following: (a) An inadequate response to ONE alternative treatment options, such as but not limited to non-opioid analgesics and immediate-release opioids OR (b) Alternative treatment options would otherwise be inadequate to provide sufficient management of pain OR (c) Individual has contraindications to non-opioid analgesics (such as NSAID use in individuals with active ulcer condition/gastrointestinal bleeding, renal failure). Individual is not opioid naïve as noted by the following: (a) Individual is currently using a short-acting opioid analgesic, including use of opioid analgesia as an inpatient for post-surgical pain OR (b) Individual is transitioning from one long-acting

opioid analgesic to another long-acting opioid analgesic OR (c) already receiving and tolerating a minimum daily opioid dose of at least 20mg oxycodone orally or its equivalent. For continued use, (I) individual has a diagnosis of cancer related pain and/or is actively undergoing cancer therapy (provide cancer diagnosis) OR (II) diagnosis of terminal illness and is receiving palliative/end-of-life care (provide terminal diagnosis) OR (III) Individual has pain severe enough to require daily, around-the-clock, long term opioid treatment (provide diagnosis) AND Attestation (verbal or written) that long-acting opioid therapy has provided meaningful improvement in pain and/or function compared to baseline AND Prescriber has consulted with individual regarding risks of opioid therapy AND Clear treatment goals have been defined and outlined as part of overall plan.

PART B PREREQUISITE

N/A

PART D VS PART B

MEDICATION(S)

ABELCET, ACETYLCYSTEINE 10 % SOLUTION, ACETYLCYSTEINE 20 % SOLUTION, ACYCLOVIR SODIUM, ALBUTEROL SULFATE (2.5 MG/3ML) 0.083% NEBU SOLN, ALBUTEROL SULFATE (5 MG/ML) 0.5% NEBU SOLN, ALBUTEROL SULFATE 0.63 MG/3ML NEBU SOLN, ALBUTEROL SULFATE 1.25 MG/3ML NEBU SOLN, ALBUTEROL SULFATE 2.5 MG/0.5ML NEBU SOLN, AMBISOME, AMINOSYN-PF 7 % SOLUTION, AMPHOTERICIN B 50 MG RECON SOLN, AMPHOTERICIN B LIPOSOME, APREPITANT, AZASAN, AZATHIOPRINE 100 MG TAB, AZATHIOPRINE 50 MG TAB, AZATHIOPRINE 75 MG TAB, BUDESONIDE 0.25 MG/2ML SUSPENSION, BUDESONIDE 0.5 MG/2ML SUSPENSION, BUDESONIDE 1 MG/2ML SUSPENSION, CALCITRIOL 0.25 MCG CAP, CALCITRIOL 0.5 MCG CAP, CASPOFUNGIN ACETATE, CINACALCET HCL, CLINIMIX E/DEXTROSE (2.75/5), CLINIMIX E/DEXTROSE (4.25/10), CLINIMIX E/DEXTROSE (4.25/5), CLINIMIX E/DEXTROSE (5/15), CLINIMIX E/DEXTROSE (5/20), CLINIMIX E/DEXTROSE (8/10), CLINIMIX E/DEXTROSE (8/14), CLINIMIX/DEXTROSE (4.25/10), CLINIMIX/DEXTROSE (4.25/5), CLINIMIX/DEXTROSE (5/15), CLINIMIX/DEXTROSE (5/20), CLINIMIX/DEXTROSE (6/5), CLINIMIX/DEXTROSE (8/10), CLINIMIX/DEXTROSE (8/14), CLINISOL SF, CLINOLIPID, CROMOLYN SODIUM 20 MG/2ML NEBU SOLN, CYCLOPHOSPHAMIDE 25 MG CAP, CYCLOPHOSPHAMIDE 50 MG CAP, CYCLOSPORINE 100 MG CAP, CYCLOSPORINE 25 MG CAP, CYCLOSPORINE MODIFIED, DOXERCALCIFEROL 0.5 MCG CAP, DOXERCALCIFEROL 1 MCG CAP, DOXERCALCIFEROL 2.5 MCG CAP, DRONABINOL, EMEND 125 MG/5ML RECON SUSP, ENGERIX-B, ENVARSUS XR, EVEROLIMUS 0.25 MG TAB, EVEROLIMUS 0.5 MG TAB, EVEROLIMUS 0.75 MG TAB, EVEROLIMUS 1 MG TAB, FREAMINE III, GENGRAF, GRANISETRON HCL 1 MG TAB, HEPARIN SODIUM (PORCINE) 1000 UNIT/ML SOLUTION, HEPARIN SODIUM (PORCINE) 10000 UNIT/ML SOLUTION, HEPARIN SODIUM (PORCINE) 20000 UNIT/ML SOLUTION, HEPARIN SODIUM (PORCINE) 5000 UNIT/ML SOLUTION, HEPATAMINE, HERCEPTIN HYLECTA, INTRALIPID, INTRON A, IPRATROPIUM BROMIDE 0.02 % SOLUTION, IPRATROPIUM-ALBUTEROL, LEVALBUTEROL HCL 0.31 MG/3ML NEBU SOLN, LEVALBUTEROL HCL 0.63 MG/3ML NEBU SOLN, LEVALBUTEROL HCL 1.25 MG/0.5ML NEBU SOLN, LEVALBUTEROL HCL 1.25 MG/3ML NEBU SOLN, LEVOCARNITINE 1 GM/10ML SOLUTION, LEVOCARNITINE 330 MG TAB, LEVOCARNITINE SF, MYCOPHENOLATE MOFETIL 200 MG/ML RECON SUSP, MYCOPHENOLATE MOFETIL 250 MG CAP, MYCOPHENOLATE MOFETIL 500 MG TAB, MYCOPHENOLATE SODIUM, NUTRILIPID, ONDANSETRON, ONDANSETRON HCL 24 MG TAB, ONDANSETRON HCL 4 MG TAB, ONDANSETRON HCL 4 MG/5ML SOLUTION, ONDANSETRON HCL 8 MG TAB, OXALIPLATIN 200 MG/40ML SOLUTION, PACLITAXEL 100 MG/16.7ML CONC, PARICALCITOL 1 MCG CAP, PARICALCITOL 2 MCG CAP, PARICALCITOL 4 MCG CAP, PENTAMIDINE ISETHIONATE, PLENAMINE, PREHEVBRIO, PREMASOL, PROCALAMINE,

PROGRAF 0.2 MG PACKET, PROGRAF 1 MG PACKET, PROSOL, PULMOZYME, RECOMBIVAX HB, RIABNI, RITUXAN 100 MG/10ML SOLUTION, SIROLIMUS 0.5 MG TAB, SIROLIMUS 1 MG TAB, SIROLIMUS 1 MG/ML SOLUTION, SIROLIMUS 2 MG TAB, TACROLIMUS 0.5 MG CAP, TACROLIMUS 1 MG CAP, TACROLIMUS 5 MG CAP, TOBRAMYCIN 300 MG/5ML NEBU SOLN, TRAVASOL, TROPHAMINE, VARUBI (180 MG DOSE)

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.

PEGFILGRASTIM AGENTS

MEDICATION(S)
FULPHILA, NEULASTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Adjunctive tx of Febrile neutropenia and has not received prophylactic therapy with Pegfilgrastim agents and has high risk for infection-associated complications by any of the following: Expected prolonged (greater than 10 day) and profound (less than 0.1 x 10 to the power of 9/L) neutropenia, Age greater than 65 years, Pneumonia or other clinically documented infections, Hypotension and multi organ dysfunction (sepsis syndrome), Invasive fungal infection, Prior episode of febrile neutropenia, Hospitalized at the time of the development of fever. Primary prophylaxis of FN in patients who have a risk of FN of 20% or greater based on chemotherapy regimens. OR when the risk of developing FN is greater than or equal to 10% and less than 20% based on chemotherapy in patients who have risk factors for FN including any of the following: age greater than 65 years, Poor performance status (ECOG status 3-4) or HIV infection (in particular, those with low CD4 counts (less than or eq 450/µL) but chemotherapy still indicated (Lyman 2014), Prior radiation therapy (within previous 1 year) (Terbuch 2018) (Fujiwara 2017) (Shigeta 2015), Bone marrow involvement by tumor producing cytopenias, persistent neutropenia (ANC less than 1500mm3), poor renal function (GFR less than 60mL/min) , liver dysfunction (liver function tests at least 2x upper limit of normal or bilirubin gr than 2.0 mg/dL) (Lyman 2014) (Aagaard 2018), recent surgery performed as part of cancer management within previous 30 days (not to include a procedure such as port placement, drain placement, IVC filter, etc) (Lyman 2014, Aagaard 2018). History of active infection within previous 60 days(Lyman 2014, Aagaard 2018). Current open wound and chemotherapy cannot be delayed (Lyman 2014, Aagaard 2018).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Individual with nonmyeloid malignancy is using for Secondary Prophylaxis for patients who experienced a neutropenic complication from a prior cycle of chemotherapy (for which primary prophylaxis was not received), in which a reduced dose may compromise disease-free or overall survival or treatment outcome. For use after accidental or intentional total body radiation of myelosuppressive doses (greater than 2 Grays [Gy]) (such as Hematopoietic Syndrome of Acute Radiation Syndrome). For dose dense therapy (treatment given more frequently, such as every two weeks instead of every three weeks) for adjuvant treatment of breast cancer. After a hematopoietic progenitor stem cell transplant (HPCT/HSCT) to promote myeloid reconstitution OR when engraftment is delayed or has failed.

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
Individual with relapsed or refractory myeloid/lymphoid neoplasms (MLNs) OR unresectable locally advanced, or metastatic cholangiocarcinoma AND using as monotherapy AND has confirmed disease progression (written or verbal) after one or more prior lines of systemic therapy. Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

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
Individual has HER2-positive breast cancer confirmed (verbal or written) by EITHER immunohistochemistry (IHC) of 3+ OR positive In situ hybridization (ISH).

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 (200 MG DAILY DOSE), PIQRAY (250 MG DAILY DOSE), PIQRAY (300 MG DAILY DOSE)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

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

PRALUENT

MEDICATION(S)
PRALUENT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For (A) Heterozygous Familial Hypercholesterolemia (HeFH) confirmed by: 1.Presence of a mutation in LDLR, apolipoprotein B (ApoB), PCSK9 or ARH adaptor protein gene (LDLRAP1) gene OR 2. World Health Organization (WHO)/Dutch Lipid Network Criteria with score of gtr than 8 points OR (B) History of Clinical Atherosclerotic Cardiovascular Disease (ASCVD), including one of the following: 1.Acute coronary syndromes 2.Coronary Artery Disease (CAD) 3. History of myocardial infarction (MI) 3.Stable or unstable angina 4.Coronary or other arterial revascularization 5.Stroke 6.Transient ischemic attack (TIA) 7.Peripheral arterial disease (PAD). OR (C) Primary hyperlipidemia alone or in combination with other lipid lowering agents. OR (D) using prophylactically for Established CVD. For (E). Homozygous Familial Hypercholesterolemia (HoFH) confirmed by: 1.Presence of two (2) mutant alleles at the LDLR, apoB, PCSK9 or ARH adaptor gene locus OR 2.untreated LDL-C concentration greater than 500 mg/dL (13 mmol/L) or treated LDL-C greater than or equal to 300 mg/dL (7.76 mmol/L) AND one of the following: i.Cutaneous or tendonous xanthoma before age of 10 years OR ii.Untreated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents (greater than190 mg/dL).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA

For initial request, individual meets one of the following: (A) Individual is a on high intensity statin therapy, or statin therapy at the maximum tolerated dose, where high intensity statin is defined as atorvastatin 40 mg or higher OR rosuvastatin 20 mg or higher OR (B) Individual is statin intolerant OR (C) Individual has a condition that is a contraindication for statin therapy including active liver disease, unexplained persistent elevation of serum hepatic, or pregnancy or (D) Statin associated rhabdomyolysis after a trial of one statin. Individual also has had a trial and titration of a Repatha (evolocumab) and has achieved suboptimal lipid lowering response despite at least 90 days of Repatha (evolocumab) therapy. For continuation, Individual continues to receive concomitant maximally tolerated statin (unless contraindication or individual is statin intolerant) AND there is confirmation (verbal or written attestation) of LDL reduction.

PART B PREREQUISITE

N/A

PROLIA

MEDICATION(S)
PROLIA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial requests, Osteoporosis is defined as a BMD T-Score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to a young-adult reference population OR a clinical diagnosis based on history of a low trauma fracture (fragility fracture). Glucocorticoid-induced osteoporosis defined as a bone mineral density (BMD) T score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to a young-adult reference population OR a clinical diagnosis based on history of a low trauma fracture (fragility fracture) and is initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5mg or greater of prednisone and expected to remain on glucocorticoids for a least 6 months.

AGE RESTRICTION
For Osteoporosis 18 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For Initial use: For osteoporosis/ glucocorticoid-induced osteoporosis treatment, individual has had at least ONE osteoporotic (minimal trauma) fracture OR has two or more risk factors for osteoporotic fracture OR Individual has failed or is intolerant to or has a medical contraindication to other available osteoporosis therapies (such as, bisphosphonates). For male receiving androgen deprivation therapy

for non- metastatic prostate cancer, individual has had at least ONE osteoporotic (minimal trauma) fracture OR has one or more additional risk factors for osteoporotic fracture. Individual is a postmenopausal (natural or induced) female receiving adjuvant aromatase inhibitor therapy for the treatment of breast cancer. For continuation requests, there is confirmation of clinically significant response to therapy (including but not limited to confirmation of no new fractures or reduction of fractures, or no worsening vertebral fractures, or no clinically significant adverse reaction) AND IF individual has been on therapy greater than or equal to 24 months of treatment, a repeat BMD demonstrates a stable or increase in BMD.

PART B PREREQUISITE

N/A

PROMACTA

MEDICATION(S)
PROMACTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
For initial therapy: 1) Diagnosis of chronic immune (idiopathic) thrombocytopenia (ITP) AND individual has platelet count of less than 30 x 109/L or active bleeding (ASH, 2011. Hicks et al., 2014) AND has had a prior trial and insufficient response to one of the following: a) corticosteroids OR b) immunoglobulins [for example, intravenous, anti-D] or c) splenectomy OR 2) Diagnosis of severe aplastic anemia AND individual has a platelet count of less than or equal to 30 x 109/L (Olnes et al., 2012.Desmond et al., 2014) AND individual has had a prior trial and insufficient response to an immunosuppressive therapy [such as, anti-thymocte globulin (ATG)] OR 3) individual is using as first-line treatment in combination with standard immunosuppressive therapy 4) Treatment of thrombocytopenia in individual with hepatitis C AND individual has thrombocytopenia that prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy. For continuation therapy, for ITP, severe aplastic anemia or therombocytopenia in individuals with Hep C,

individual has demonstrated a response to therapy as evidenced by increased platelet counts AND to maintain an adequate platelet count (50 200 x 109/L) to decrease the risk of bleeding OR for MDS, individual has demonstrated a clinically significant response to therapy, such as an increase in platelet counts, decrease in bleeding events, or reduction in need for platelet transfusions .

PART B PREREQUISITE

N/A

PROTOPIC

MEDICATION(S)
TACROLIMUS 0.03 % OINTMENT, TACROLIMUS 0.1 % OINTMENT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Individual had a trial of and inadequate response or intolerance to one topical prescription strength corticosteroid.

PART B PREREQUISITE
N/A

PURIXAN

MEDICATION(S)
PURIXAN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

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

QUININE

MEDICATION(S)
QUININE SULFATE 324 MG CAP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Treatment or prevention for nocturnal recumbancy leg muscle cramps or related conditions such as but not limited to: Leg cramps, muscle cramps, myoclonus, Periodic Movements of Sleep, Periodic Limb Movements of Sleep (PLMS), Restless Leg Syndrome (RLS).

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual has been diagnosed with uncomplicated malaria caused by one of the following: Plasmodium falciparum known or suspected to be resistant to chloroquine (CDC) OR chloroquine-resistant Plasmodium vivax (CDC) OR an unidentified plasmodial species known or suspected to be resistant to chloroquine (CDC) OR Chloroquine-resistant Plasmodium ovale (CDC) OR Chloroquine-sensitive Plasmodium malariae (CDC) OR Chloroquine-sensitive Plasmodium knowlesi (CDC) OR Chloroquine-sensitive Plasmodium falciparum, Plasmodium vivax or Plasmodium ovale AND one of the following (CDC): (i.) Individual is pregnant OR (ii.) Chloroquine and hydroxychloroquine are not available. Individual is using as interim treatment for severe malaria until intravenous artesunate is available (CDC) or using as follow-on treatment after intravenous artesunate.

PART B PREREQUISITE

N/A

RANEXA

MEDICATION(S)
RANOLAZINE ER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/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 dx chronic angina, individual has had a trial and inadequate response or intolerance to one of the following formulary agents (ACCF/AHA 2012): (a) Beta-blocker OR (b) Calcium-channel blocker OR (c) Long-acting nitrate.

PART B PREREQUISITE
N/A

RAVICTI

MEDICATION(S)
RAVICTI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Initial requests, Individual has had a trial and inadequate response or intolerance to sodium phenylbutyrate (Buphenyl) OR Individual has any of the following: (a) Congestive heart failure or (b) Severe renal insufficiency or (c) A clinical state where there is sodium retention with edema. For continuation requests, the confirmation of clinically significant improvement or stabilization in plasma ammonia level.

PART B PREREQUISITE
N/A

RECLAST

MEDICATION(S)
ZOLEDRONIC ACID 5 MG/100ML SOLUTION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

REGRANEX

MEDICATION(S)
REGRANEX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

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 months

OTHER CRITERIA
Individual is using as adjunctive therapy with good ulcer care practices including, but not limited to sharp debridement of the ulcer

PART B PREREQUISITE
N/A

RELISTOR

MEDICATION(S)
RELISTOR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/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 non-cancer pain related OIC, Individual must have a previous trial of or insufficient response to polyethylene glycol (generic MiraLax) (AGA 2013) AND a trial and inadequate response or intolerance to a preferred agent (Movantik/Amitiza) OR the preferred agent (Movantik/Amitiza) is not acceptable due to concomitant clinical situations, warnings or contraindications, such as but not limited to the following: Individual has disruption to the blood-brain barrier and may be at increased risk for opioid withdrawal and/or reduced analgesia (Movantik) OR Individual is taking strong CYP3A4 inhibitors and may be at increased risk for opioid withdrawal and/or reduced analgesia (Movantik). For OIC with advanced illness, individual is receiving palliative care AND must have a previous trial of or insufficient response to polyethylene glycol (generic MiraLax) (AGA 2013).

PART B PREREQUISITE

N/A

REPATHA

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For (A) Homozygous Familial Hypercholesterolemia (HoFH) confirmed by: 1. Presence of two (2) mutant alleles at the LDLR, apoB, PCSK9 or ARH adaptor gene locus OR 2. Untreated LDL-C concentration greater than 500 mg/dL (13 mmol/L) or treated LDL-C greater than or equal to 300 mg/dL (7.76 mmol/L) AND one of the following: i.Cutaneous or tendonous xanthoma before age of 10 years OR ii.Untreated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents (greater than190 mg/dL) OR (B) Heterozygous Familial Hypercholesterolemia (HeFH) with diagnosis confirmed by: 1. Presence of a mutation in LDLR, apolipoprotein B (ApoB), PCSK9 or ARH adaptor protein (LDLRAP1) gene locus OR 2. World Health Organization (WHO)/Dutch Lipid Network Criteria with score of gtr than 8 points OR (C) History of Clinical Atherosclerotic Cardiovascular Disease (ASCVD), including one of the following: 1. Acute coronary syndromes 2. Coronary Artery Disease (CAD) 3. History of myocardial infarction (MI) 3. Stable or unstable angina 4. Coronary or other arterial revascularization 5. Stroke 6. Transient ischemic attack (TIA) 7. Peripheral arterial disease (PAD) OR (D) Primary hyperlipidemia alone or in combination with other lipid lowering agents. OR (E) using prophylactically for Established CVD.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA

For initial HoFH request, individual meets ONE of the following: (A) Individual is on high intensity statin therapy, or statin therapy at the maximum tolerated dose, where high intensity statin is defined as atorvastatin 40 mg or higher OR rosuvastatin 20 mg or higher OR (B) Individual is statin intolerant OR (C) Statin associated rhabdomyolysis after a trial of a statin OR (D) Individual has a contraindication for statin therapy including active liver disease, unexplained persistent elevation of serum hepatic transaminases, or pregnancy AND Individual is on ezetimibe in addition to statin therapy (applies to individuals on statin therapy only). For initial HeFH or ASCVD requests, individual meets ONE of the following: (A) Individual is a on high intensity statin therapy, or statin therapy at the maximum tolerated dose, where high intensity statin is defined as atorvastatin 40 mg or higher OR rosuvastatin 20 mg or higher OR (B) Individual is statin intolerant OR (C) Statin associated rhabdomyolysis after a trial of a statin OR (D) Individual has a contraindication for statin therapy including active liver disease, unexplained persistent elevation of serum hepatic transaminases, or pregnancy AND Individual is on ezetimibe in addition to statin therapy (applies to individuals on statin therapy only). For continuation (HeFH, HoFH, ASCVD), mbr continues to receive concomitant maximally tolerated statin (unless contraindication or individual is statin intolerant) AND there is confirmation (verbal or written attestation) of LDL reduction. For continuation (established CVD or Primary Hyperlipidemia), confirmation (verbal or written attestation) of LDL reduction.

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
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

REVATIO

MEDICATION(S)
SILDENAFIL CITRATE 20 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individuals requesting for the treatment of erectile dysfunction.

REQUIRED MEDICAL INFORMATION
For initial requests, individual has diagnosis of Pulmonary Arterial Hypertension in adults World Health Organization (WHO) Group I AND Individual has the diagnosis of PAH confirmed by a right heart catheterization showing all of the following: (a) Mean pulmonary artery 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 Individual has WHO functional class II- IV symptoms.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For continuation requests of PAH for adults, there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in walk distance, dyspnea and/or functional class).

PART B PREREQUISITE

N/A

REVLIMID

MEDICATION(S)
LENALIDOMIDE, REVLIMID

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For mds, confirmed [verbal or written] deletion of 5q (del5q) cytogenetic abnormality with or without additional cytogenic abnormalities.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

RINVOQ

MEDICATION(S)
RINVOQ

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
For RA, UC, AS, NR-axSpA, and PsA, Individual is 18 years of age or older. For Atopic Dermatitis, individual is 12 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For initial use: moderate to severe RA, individual has had an inadequate response to MTX titrated to maximally tolerated dose (ACR 2021) OR if MTX is not tolerated or contraindicated, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE other conventional therapy (i.e., sulfasalazine, leflunomide, or hydroxychloroquine) AND has had a trial and inadequate response or intolerance to ONE tumor necrosis antagonist agent. For PsA, individual has had inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic DMARDS (such as MTX, sulfasalazine or leflunomide)] AND has had a trial and inadequate response or intolerance to ONE tumor necrosis factor (TNF) antagonist agent. For Atopic Dermatitis, a Biologic therapy (such as dupilumab or tralokinumab) has failed to achieve and maintain remission of low or mild disease activity state or are contraindicated AND a non-corticosteroid systemic

immunosuppressant (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil) has failed to achieve and maintain remission of low or mild disease activity state or are contraindicated. For UC, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants) AND individual has had a trial and inadequate response or intolerance to one tumor necrosis factor (TNF) antagonist agents. For AS/NR-axSpA, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)] AND has had a trial and inadequate response or intolerance to ONE tumor necrosis factor (TNF) antagonist agents. For Continuation requests, there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

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
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

AGE RESTRICTION
For metastatic non-small cell lung cancer (NSCLC), 18 years of age or older. For a diagnosis of a solid tumor, 12 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual is using as monotherapy.

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
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For metastatic castration-resistant prostate cancer (mCRPC), with a deleterious BRCA mutation (germline and/or somatic), Individual had been treated with androgen-receptor directed therapy and a taxane-based chemotherapy AND is using a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)) concurrently or have had a bilateral orchiectomy.

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
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Using Rybrevant as a single agent.

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
Individual has confirmed written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

SABRIL

MEDICATION(S)
VIGABATRIN, VIGADRONE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
For infantile spasm 1 month to 2yr old. For seizure 2 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
N/A

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
Individual has a diagnosis of multiple myeloma AND has not received treatment with isatuximab or another anti-CD38 agent such as daratumumab) AND (A) has relapsed or refractory disease following treatment with at least two prior lines of therapy including lenalidomide and a proteasome inhibitor (for example, bortezomib, carfilzomib, or ixazomib). Or (B) has relapsed or refractory disease following treatment with one to three prior lines of therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual is using in combination with pomalidomide and dexamethasone or carfilzomib and dexamethasone.

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
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

SIGNIFOR IR

MEDICATION(S)
SIGNIFOR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

SIRTURO

MEDICATION(S)
SIRTURO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
Individual has a diagnosis of pulmonary multi-drug resistant tuberculosis (MDR-TB) or pulmonary extensively drug-resistant tuberculosis (XDR-TB) AND the individual is using in combination with other anti-infectives (WHO 2019).

PART B PREREQUISITE
N/A

SKYRIZI

MEDICATION(S)
SKYRIZI, SKYRIZI (150 MG DOSE), SKYRIZI PEN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Dx of chronic moderate to severe (that is, extensive or disabling) plaque Ps with either of the following (AAD 2011): 1. Plaque Ps involving greater than three percent (3%) body surface area (BSA) OR 2. Plaque Ps involving less than or equal to three percent (3%) BSA involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia).

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
For initial use: dx of chronic moderate to severe plaque Ps, individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate). For Psoriatic Arthritis (PsA), individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, or leflunomide)]. For Crohn’s disease (CD), Individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy (such as systemic corticosteroids or immunosuppressants). For Continuation use, there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and

symptoms of disease.

PART B PREREQUISITE

N/A

SOLARAZE

MEDICATION(S)
DICLOFENAC SODIUM 3 % GEL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Dx of Actinic Keratosis

AGE RESTRICTION
18 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

SOMATULINE DEPOT

MEDICATION(S)
LANREOTIDE ACETATE, SOMATULINE DEPOT 120 MG/0.5ML SOLUTION, SOMATULINE DEPOT 90 MG/0.3ML SOLUTION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

SOMAVERT

MEDICATION(S)
SOMAVERT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Dx of acromegaly AND member has had an inadequate response to surgery and/or radiation OR Surgery and/or radiation therapy are not an option.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

SPRAVATO

MEDICATION(S)
SPRAVATO (56 MG DOSE), SPRAVATO (84 MG DOSE)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial 3 months, continuation 1 year. MDD with acute suicidal ideation or behavior: 1 year

OTHER CRITERIA
For initial use, individual is using for the tx of depressive sx with major depressive disorder (MDD) with acute suicidal ideation or behavior AND has a dx of MDD without psychotic features according to DSM-5 (Fu 2020, Ionescu 2020) AND is judged to be at risk for suicide by a clinician based on consideration of suicidal behavior, expressed suicidal ideation or overall clinical assessment consistent with significant continuing risk of suicide AND will use Spravato in addition to antidepressant therapy. Individual has been diagnosed with moderate to severe major depressive disorder AND had an inadequate response to the maximum tolerated dose of two antidepressant therapies during the current major depressive episode (MDE) as defined by less than 50% reduction in symptom severity using a standard rating scale that reliably measures depressive symptoms AND will use Spravato in addition to antidepressant therapy. For continuation, individual has had at least a 50% reduction in symptoms of treatment resistant moderate to severe depression compared to baseline using a standard rating scale

that reliably measures depressive symptoms AND will use Spravato in addition to antidepressant therapy.

PART B PREREQUISITE

N/A

SPRITAM

MEDICATION(S)
SPRITAM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual has a diagnosis of partial onset seizures OR primary generalized tonic-clonic seizures AND weighs more than 20 kg. Individual is using as adjunctive therapy for juvenile myoclonic epilepsy or primary generalized tonic-clonic seizure.

AGE RESTRICTION
Partial onset seizures: 4 years old. Juvenile myoclonic epilepsy: 12 years old. Primary generalized tonic-clonic seizures: 6 years old.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

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
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

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/0.5ML SOLN PRSYR, STELARA 45 MG/0.5ML SOLUTION, STELARA 90 MG/ML SOLN PRSYR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of moderate to severe plaque psoriasis with either of the following: Patient has greater than 3% of body surface area with plaque psoriasis OR Less than or equal to 3% of body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia).

AGE RESTRICTION
Individual is 18 years of age or older. For Plaque Psoriasis (Ps), Psoriatic Arthritis (PsA), age 6 and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For initial use: chronic plaque psoriasis, individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or any ONE systemic therapy (for example acitretin, methotrexate, cyclosporine). For psoriatic arthritis, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy ([nonbiologic DMARDS] such as methotrexate, sulfasalazine, or leflunomide). For Crohns disease, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy (such systemic

corticosteroids, or immunosuppressants). For Ulcerative Colitis, individual has had an inadequate response to, is intolerant of, or has a ONE contraindication to conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants). For Continuation use, there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

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
Written or verbal attestation is provided for confirmation of mutations or disease progression where applicable based on use/diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For gastrointestinal stromal tumors (GIST), individual has had progression after monotherapy with imatinib and sunitinib

PART B PREREQUISITE
N/A

STROMECTOL

MEDICATION(S)
IVERMECTIN 3 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
For the treatment or prophylaxis of COVID-19.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

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

SYMLIN

MEDICATION(S)
SYMLINPEN 120, SYMLINPEN 60

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Type 1 or type 2 diabetes AND taking mealtime insulin therapy AND has failed to achieve glucose control AND HBA1C is less than or equal to 9.

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

SYNAREL NASAL SOLUTION

MEDICATION(S)
SYNAREL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Precocious puberty, defined as the beginning of secondary sexual maturation characteristics before age 8 in girls and before age 9 in boys.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Endometriosis: 6 months, all other indications: 1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

SYNRIBO

MEDICATION(S)
SYNRIBO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

TABRECTA

MEDICATION(S)
TABRECTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For recurrent, advanced or metastatic non-small cell lung cancer (NSCLC), Individual has mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors with test results confirmed AND individual has not received treatment with another MET exon 14 skipping-targeted agent, such as crizotinib. For metastatic NSCLC, individual has MET exon 14 skipping positive tumors. For advanced or metastatic NSCLC, individual has high level MET amplification (greater than or equal to 10 gene copies) (Wolf 2020).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual is using Tabrecta (capmatinib) as monotherapy.

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
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

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
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

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
Written or verbal attestation provided to confirm deleterious or suspected deleterious germline BRCA-mutation (gBRCAm) and human epidermal growth factor receptor 2-negative (HER2) breast cancer.

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

TARGRETIN

MEDICATION(S)
BEXAROTENE, TARGRETIN 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

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

TASMAR

MEDICATION(S)
TOLCAPONE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

TAZORAC

MEDICATION(S)
TAZAROTENE 0.05 % GEL, TAZAROTENE 0.1 % CREAM, TAZAROTENE 0.1 % GEL, TAZORAC 0.05 % CREAM, TAZORAC 0.05 % GEL, TAZORAC 0.1 % GEL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
May not be approved for cosmetic purposes such as, but not limited to the following: Cosmetic purposes, Photoaging, Wrinkles, Hyperpigmentation, Sun damage, or Melasma.

REQUIRED MEDICAL INFORMATION
For psoriasis, individual has up to 20% of body surface area involvement.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For psoriasis, individual has had a prior trial and inadequate response to either of the following (AAD 2009): Any two (2) topical corticosteroids or any one (1) topical corticosteroids plus calcipotriene. For psoriasis use greater than 1 year, efficacy must be documented for continued use. Documentation may include chart notes, consultation notes.

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
For Epithelioid Sarcoma, individual has a histologically confirmed (written or verbal) diagnosis and has a current ECOG performance status of 0-2. For follicular lymphoma, ECOG performance status of 0-2. Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

TECENTRIQ

MEDICATION(S)
TECENTRIQ

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual has received treatment with another anti-PD-1 agent or anti-PD-L1 inhibitor and Individual is receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.

REQUIRED MEDICAL INFORMATION
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2.

PART B PREREQUISITE
N/A

TECFIDERA

MEDICATION(S)
TECFIDERA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL 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
For MM, current Eastern Cooperative Group (ECOG) performance status of 0-1 AND No prior treatment with any B cell maturation antigen (BCMA) targeted therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

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
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For recurrent, advanced, or metastatic Non-Small Cell Lung Cancer (NSCLC), individual is using as monotherapy AND has not received treatment with another MET exon 14 skipping-targeted agent.

PART B PREREQUISITE
N/A

TESTOSTERONE INJ

MEDICATION(S)
TESTOSTERONE CYPIONATE 100 MG/ML SOLUTION, TESTOSTERONE CYPIONATE 200 MG/ML SOLUTION, TESTOSTERONE ENANTHATE 200 MG/ML SOLUTION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Prior to starting testosterone therapy, an initial and a repeat (at least 24 hours apart) morning total testosterone level is provided to confirm a low testosterone serum level indicating one of the following: (1) Individual is 70 years of age or younger with a serum testosterone level of less than 300 ng/dL OR (2) Individual is over 70 years of age with a serum testosterone level of less than 200 ng/dL.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For initial use of replacement therapy, Individual has a dx of (1) primary hypogonadism (congenital or acquired) such as but not limited to: Cryptorchidism OR Bilateral torsion OR Vanishing testis syndrome OR orchitis OR Orchiectomy OR Klinefelter Syndrome OR Chemotherapy OR Toxic damage from alcohol or heavy metals OR idiopathic primary hypogonadism OR age related/late onset hypogonadism. Or (2) Hypogonadotropic hypogonadism (congenital or acquired), such as but not limited to: Idiopathic luteinizing hormone-releasing hormone (LHRH deficiency) OR Pituitary-hypothalamic injury AND Individual presents with symptoms associated with hypogonadism, such as

but not limited to, at least one of the following: (a) Reduced sexual desire (libido) and activity or (b) Decreased spontaneous erections or (c) Breast discomfort/gynecomastia or (d) Loss of body (axillary and pubic) hair, reduced need for shaving or (e) Very small (especially less than 5 mL) or shrinking testes or (f) Inability to father children or low/zero sperm count or (g) Height loss, low trauma fracture, low bone mineral density or (h)Hot flushes, sweats or (i) Other less specific signs and symptoms including decreased energy, depressed mood/dysthymia, irritability, sleep disturbance, poor concentration/memory, diminished physical or work performance. For Continuation of Testosterone Inj agents for replacement therapy, (a) Individual met all diagnostic criteria for initial therapy and (b) Individual has had serum testosterone level measured in the previous 180 days and (c) Individual has obtained clinical benefits as noted by symptom improvement. For treatment of delayed puberty when ALL the criteria below are met: Individual is using to stimulate puberty and has documented (verbal or written) few to no signs of puberty. For tx of breast cancer when the following are met: Female 1-5 years post-menopause and Individual is using secondarily for advanced inoperable metastatic (skeletal) breast cancer OR Premenopausal female who has benefited from oophorectomy and is considered to have a hormone responsive tumor. For tx of HIV-infected male adults with low testosterone and HIV-associated weight loss and wasting. For transgender individuals who meet ALL the following criteria: Individual has a diagnosis of gender dysphoria/incongruence or gender identity disorder and goal of treatment is female-to-male gender reassignment.

PART B PREREQUISITE

N/A

THALOMID

MEDICATION(S)
THALOMID

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

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
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

TOPICAL ANDROGENS

MEDICATION(S)
TESTOSTERONE 1.62 % GEL, TESTOSTERONE 10 MG/ACT (2%) GEL, TESTOSTERONE 12.5 MG/ACT (1%) GEL, TESTOSTERONE 20.25 MG/1.25GM (1.62%) GEL, TESTOSTERONE 20.25 MG/ACT (1.62%) GEL, TESTOSTERONE 25 MG/2.5GM (1%) GEL, TESTOSTERONE 30 MG/ACT SOLUTION, TESTOSTERONE 40.5 MG/2.5GM (1.62%) GEL, TESTOSTERONE 50 MG/5GM (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
18 years of age or older. For transgender use, individual is 16 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For Initial use: Individual has a dx of (1) primary hypogonadism (congenital or acquired) [for example, Cryptorchidism OR Bilateral torsion OR orchitis OR Vanishing testis syndrome OR Orchiectomy OR Klinefelter Syndrome OR Chemotherapy OR Toxic damage from alcohol or heavy metals OR idiopathic primary hypogonadism]. Or (2) Hypogonadotropic hypogonadism (congenital or acquired) [for example, Idiopathic luteinizing hormone-releasing hormone (LHRH deficiency), OR Pituitary-hypothalamic injury.] Individual is transgender AND is using for a diagnosis of gender Dysphoria or gender Identity Disorder AND Goal of treatment is female-to-male gender reassignment. For continuation use, Individual meets

all criteria for initial therapy AND has had serum testosterone level measured in the previous 180 days AND Individual has obtained clinical benefits as noted by symptom improvement.

PART B PREREQUISITE

N/A

TOPICAL TRETINOIN AGENTS

MEDICATION(S)
AVITA, TRETINOIN 0.01 % GEL, TRETINOIN 0.025 % CREAM, TRETINOIN 0.025 % GEL, TRETINOIN 0.05 % CREAM, TRETINOIN 0.1 % CREAM, TRETINOIN MICROSPHERE, TRETINOIN MICROSPHERE PUMP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Topical tretinoin agents may not be approved for cosmetic purposes such as, but not limited to the following: Photoaging, Wrinkles, Hyperpigmentation, Sun damage, Melasma.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

TRACLEER

MEDICATION(S)
BOSENTAN, TRACLEER 32 MG TAB SOL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial therapy, PAH confirmed by a right heart catheterization showing all of the following: (a) Mean pulmonary artery 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.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual has Pulmonary Arterial Hypertension (WHO Group I), and WHO Functional Class II-IV symptoms. For continuation therapy, there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in walk distance, dyspnea and/or functional class)

PART B PREREQUISITE
N/A

TRELSTAR LINE

MEDICATION(S)
TRELSTAR MIXJECT 11.25 MG RECON SUSP, TRELSTAR MIXJECT 3.75 MG RECON SUSP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Prostate cancer: Clinically localized disease with intermediate (T2b to T2c cancer, Gleason score of 7/Gleason grade group 2-3, or prostate specific antigen (PSA) value of 10-20 ng/mL) OR higher risk of recurrence as neoadjuvant therapy with radiation therapy or cryosurgery OR Following radical prostatectomy as adjuvant therapy when lymph node metastases are present OR Locally advanced disease OR Other advanced, recurrent, or metastatic disease.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

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
Individual has (A) recurrent or metastatic, histologically confirmed triple-negative Breast Cancer (lack of estrogen- and progesterone-receptor expression and no overexpression of HER2) AND has confirmation of disease progression (written or verbal) after two prior therapies. Or (B) locally advanced or metastatic Urothelial Cancer AND has confirmation (written or verbal) of disease progression after platinum-containing chemotherapy and either an anti-PD-1 or anti-PD-L1 agent.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

TRUSELTIQ

MEDICATION(S)
TRUSELTIQ (100MG DAILY DOSE), TRUSELTIQ (125MG DAILY DOSE), TRUSELTIQ (50MG DAILY DOSE), TRUSELTIQ (75MG DAILY DOSE)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual is using as monotherapy AND has confirmed (written or verbal) disease progression after one or more prior lines of systemic therapy.

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
HER2-positive breast cancer confirmed (verbal or written) by one of the following: Immunohistochemistry (IHC) is 3+ or In situ hypridization (ISH) positive.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

TURALIO

MEDICATION(S)
TURALIO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

TYKERB

MEDICATION(S)
LAPATINIB DITOSYLATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Cancer has been confirmed HER2 positive. HER 2 overexpression confirmed (written or verbal) by one of the following: (a) Immunohistochemistry (IHC) 3+ or (b) In situ hybridization (ISH) positive.

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
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual has had a trial/inadequate response or intolerance to 2 oral triptans (AHS 2019) OR Individual has one of the following CV or non-coronary vascular contraindications to use of triptans: Ischemic coronary artery disease (CAD) including angina pectoris, history of MI, documented silent ischemia, coronary artery vasospasm (including Prinzmetal’s angina), history of stroke or TIA, PVD, ischemic bowel disease, or uncontrolled hypertension.

PART B PREREQUISITE
N/A

UCERIS

MEDICATION(S)
BUDESONIDE ER

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 of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

UPTRAVI

MEDICATION(S)
UPTRAVI 1000 MCG TAB, UPTRAVI 1200 MCG TAB, UPTRAVI 1400 MCG TAB, UPTRAVI 1600 MCG TAB, UPTRAVI 200 & 800 MCG TAB THPK, UPTRAVI 200 MCG TAB, UPTRAVI 400 MCG TAB, UPTRAVI 600 MCG TAB, UPTRAVI 800 MCG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Pulmonary Arterial Hypertension, individual has the diagnosis of PAH confirmed by a right heart catheterization showing all of the following: (a) Mean pulmonary artery 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.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For continuation therapy, there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in walk distance, dyspnea and/or functional class).

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

VANCOCIN

MEDICATION(S)
VANCOMYCIN HCL 125 MG CAP, VANCOMYCIN HCL 250 MG CAP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual is being treated for enterocolitis caused by Staphylococcal aureus including methicillin-resistant strains. Individual is being treated for clostridium Clostridiodes difficile-associated.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

VELCADE

MEDICATION(S)
BORTEZOMIB 3.5 MG RECON SOLN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

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
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnostic Criteria for PAH: right heart catheterization which shows a mean pulmonary artery pressure (mPAP) greater than or equal to 25mmhg at rest, a pulmonary capillary wedge pressure (PCWP), mean pulmonary arterial wedge pressure (PAWP), left atrial pressure or left ventricular end diastolic pressure (LVEDP) less than or equal to 15mmhg AND a pulmonary vascular resistance (PVR) greater than 3 wood units. Criteria for Vasodilator Response: a favorable response is defined as a fall in mPAP of at least 10mmhg to an absolute mPAP of less than 40mmhg without a decrease in cardiac output, when challenged with inhaled nitric oxide, intravenous epoprostenol or intravenous adenosine or inhaled iloprost (Badesch 2007, McLaughlin 2009, Simonneau 2019).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Initial requests for Ventavis, patient must meet all of the following: meets diagnostic criteria for PAH AND demonstrates an unfavorable acute response to vasodilators AND Individual has New York Heart Association (NYHA) functional class III, or IV symptoms: AND World health Organization (WHO) Group I PAH (idiopathic PAH, PAH associated with connective tissue disorders, PAH associated with

congenital heart defects, and all Group 1 subtypes). For continuation, there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in walk distance, dyspnea and/or functional class).

PART B PREREQUISITE

N/A

VERZENIO

MEDICATION(S)
VERZENIO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

VFEND

MEDICATION(S)
VORICONAZOLE 200 MG RECON SOLN, VORICONAZOLE 200 MG TAB, VORICONAZOLE 40 MG/ML RECON SUSP, VORICONAZOLE 50 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual is currently transitioning from inpatient treatment (hospital/medical facility) to an outpatient (home) setting and requires continued therapy for an organism susceptible to Vfend (voriconazole). Or mbr is using for a FDA approved use or supported by CMS approved compendia.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

VIBERZI

MEDICATION(S)
VIBERZI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual is using for the treatment of irritable bowel syndrome with diarrhea (IBS-D) AND has had a trial and inadequate response or intolerance to two of the following medications or has a contraindication to all of the following medications: 1. Loperamide OR 2. Antispasmodics (such as dicyclomine) OR 3. Tricyclic antidepressants (AGA 2014).

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
Written or verbal attestation to confirm genetic test results show the tumor has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For Vitrakvi (larotrectinib) oral solution requests, individual is unable to swallow the oral capsule dose form due to a clinical condition, but not limited to the following: (a) Dysphagia OR (b) individual’s age.

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
genetic mutations test result is confirmed by written or verbal attestation.

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
Individual is 18 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

VOTRIENT

MEDICATION(S)
VOTRIENT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

WAKIX

MEDICATION(S)
WAKIX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Narcolepsy type 1 confirmed by the following (ICSD-3): (1) Daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months and at least one of the following: (a) Clear cataplexy (defined as more than one episode of generally brief [less than 2 min]) usually bilaterally symmetrical, sudden loss of muscle tone with retained consciousness) AND (b) Multiple Sleep Latency Test (MSLT) with one of the following: (i) Mean sleep latency of less than 8 minutes with evidence of two sleep-onset rapid eye movement periods (SOREMPs) OR (ii) At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG) OR (c) Cerebrospinal fluid hypocretin-1 deficiency (less than 100 pg/mL or less than one-third of the normative values with the same standardized assay). Narcolepsy type 2 confirmed by the following (ICSD-3): (1) Daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months AND (2) Multiple sleep latency test (MSLT) with one of the following: (a) MSLT of less than 8 minutes and evidence of two sleep-onset rapid eye movement periods (SOREMPs) (ICSD-3, 2014) OR (b) At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG) AND (3) The absence of cataplexy AND (4) Exclusion of alternative causes of excessive daytime sleepiness by history, physical exam, and PSG.

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

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
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Using Welireg (belzutifan) as monotherapy.

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
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

XENAZINE

MEDICATION(S)
TETRABENAZINE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

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
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial: 3 months. Continuation: 1 year

OTHER CRITERIA
For initial therapy: Individual is using in combination with somatostatin analog (SSA) therapy (such as but not limited to, lanreotide (Somatuline Depot), octreotide (Sandostatin)) AND individual has had an inadequate response on a stable dose of SSA monotherapy for at least 3 months. For continuation therapy requests: Individual has previously met the initiation criteria AND if improvements are confirmed by the provider (written or verbal) after 12 weeks of treatment with Xermelo (telotristat ethyl) when added to SSA therapy AND Individual does not report severe constipation or severe persistent or worsening abdominal pain.

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
Skeletally mature adolescent is defined by at least one mature long bone [for example, closed epiphyseal growth plate of the humerus]. Hypercalcemia of malignancy is defined as an albumin corrected serum calcium level greater than 12.5 mg/dL (3.1 mmol/L).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For Hypercalcemia of malignancy, Refractory to recent (within the last 30 days) treatment with intravenous bisphosphonate therapy (for example, pamidronate, zoledronic acid.

PART B PREREQUISITE
N/A

XIFAXAN - HE

MEDICATION(S)
XIFAXAN 550 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For the treatment of small intestinal bacterial overgrowth (ACG 2020).

PART B PREREQUISITE
N/A

XIFAXAN 200MG

MEDICATION(S)
XIFAXAN 200 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
30 Days

OTHER CRITERIA
For 200mg strength, travelers diarrhea (TD), individual has already been started on the requested agent and needs to complete treatment OR Individual has had a trial and inadequate response or intolerance to one of the following medications or has contraindications to all of the following medications (CDC, 2020): (1)Generic Fluoroquinolone OR(2)Azithromycin.

PART B PREREQUISITE
N/A

XOLAIR

MEDICATION(S)
XOLAIR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual has Moderate to Severe Persistent Asthma AND has a positive skin test or in vitro reactivity to a perennial aeroallergen, AND individual has a pretreatment FEV1 less than 80% predicted AND IgE level is equal to or greater than 30 IU/ml. For nasal polyps, individual had an inadequate response to nasal corticosteroids as add-on maintenance treatment AND individual has a serum IgE level greater than or equal to 30 IU/mL.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
Initial Treatment: For moderate to severe persistent asthma, individual has had a minimum of 3 month trial and inadequate response or intolerance to ONE combination controller therapy (high dose of inhaled corticosteroids plus long-acting beta-2 agonists, Leukotriene modifiers, theophylline or oral corticosteroids)(GINA 2021). Continued treatment beyond 12 months is allowed when treatment has resulted in clinical improvement as documented by one or more of the following: Decreased utilization of rescue medications OR Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids) OR

Increase in percent predicted FEV1 from pretreatment baseline OR Reduction in reported asthma-related symptoms, such as, but not limited to, wheezing, shortness of breath, coughing, fatigue, sleep disturbance, or asthmatic symptoms upon awakening. For chronic idiopathic urticaria, individual has had trial and inadequate response or intolerance to ONE potent antihistamine (AAAAI/ACAAI 2014). For continued use for CIU, treatment has resulted in confirmed (written or verbal) clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to itch severity and hive count). For initial request for nasal polyps, the presence of nasal polyps have been confirmed by one of the following (AAO-HNS2015): a) anterior rhinoscopy b) nasal endoscopy OR c) computed tomography AND individual has had trial and inadequate response to maintenance intranasal corticosteroids AND individual is refractory to or is ineligible or intolerant to the following (AAAAI/ACAAI 2014): a) systemic corticosteroids OR b) sinonasal surgery. For nasal polyps continuation requests, treatment with Xolair has resulted in confirmed clinically significant improvement in clinical signs and symptoms of disease (including but not limited to improvement in nasal congestion or reduced polyp size) AND individual continues to use Xolair in combo with maintenance intranasal corticosteroids

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
Individual has confirmed FMS-like tyrosine kinase 3 (FLT3) mutation (written or verbal attestation is acceptable).

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

XPOVIO

MEDICATION(S)
XPOVIO (100 MG ONCE WEEKLY), XPOVIO (40 MG ONCE WEEKLY), XPOVIO (40 MG TWICE WEEKLY), XPOVIO (60 MG ONCE WEEKLY), XPOVIO (60 MG TWICE WEEKLY), XPOVIO (80 MG ONCE WEEKLY), XPOVIO (80 MG TWICE WEEKLY)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For (DLBCL), Individual must not have DLBCL with mucosa-associated lymphoid tissue (MALT) lymphoma, composite lymphoma (Hodgkins and non-Hodgkins lymphoma), primary mediastinal (thymic) large B-cell lymphoma (PMBL), or known central nervous system (CNS) lymphoma (NCT02227251).

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
Individual is concomitantly receiving a gonadotropin-releasing hormone (GnRH) analog or has had a bilateral orchiectomy.

PART B PREREQUISITE
N/A

ZARXIO

MEDICATION(S)
ZARXIO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Febrile neutropenic Individuals who are at high risk for infection-associated complications by any of the following: Expected prolonged (greater than 10 day) and profound (less than 0.1 x 10 to the power of 9/L) neutropenia, Age greater than 65 years, Pneumonia or other clinically documented infections, Hypotension and multi organ dysfunction (sepsis syndrome), Invasive fungal infection, Prior episode of febrile neutropenia, Hospitalized at the time of the development of fever. Primary prophylaxis of FN in patients who have a risk of FN of 20% or greater based on chemotherapy regimens. OR when the risk of developing FN is greater than or equal to 10% and less than 20% based on chemotherapy in patients who have risk factors for FN including any of the following: age greater than 65 years, Poor performance status (ECOG status 3-4) or HIV infection (in particular, those with low CD4 counts (less than or eq 450/µL) but chemotherapy still indicated (Lyman 2014), Prior radiation therapy (within previous 1 year) (Terbuch 2018) (Fujiwara 2017) (Shigeta 2015), Bone marrow involvement by tumor producing cytopenias, persistent neutropenia (ANC less than 1500mm3), poor renal function (GFR less than 60mL/min) , liver dysfunction (liver function tests at least 2x upper limit of normal or bilirubin gr than 2.0 mg/dL) (Lyman 2014) (Aagaard 2018), recent surgery performed as part of cancer management within previous 30 days (not to include a procedure such as port placement, drain placement, IVC filter, etc) (Lyman 2014, Aagaard 2018). History of active infection within previous 60 days(Lyman 2014, Aagaard 2018). Current open wound and chemotherapy cannot be delayed (Lyman 2014, Aagaard 2018).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Secondary Prophylaxis for patients who experienced a neutropenic complication from a prior cycle of chemotherapy (for which primary prophylaxis was not received), in which a reduced dose may compromise disease-free or overall survival or treatment outcome. Using for adjunctive tx for FN and has been prophylactic therapy with GCSF agent or has not received prophylactic therapy with a GCSF and who are at high risk for infection-associated complications. Use in individuals with acute myeloid leukemia (AML) shortly after the completion of induction or repeat induction chemotherapy, or after the completion of consolidation chemotherapy for AML. For tx of moderate to severe aplastic anemia. Tx of severe neutropenia in individuals with hairy cell leukemia. For myelodysplastic syndromes (MDS) with severe neutropenia (absolute neutrophil count (ANC) less than or equal to 500 mm3 or experiencing recurrent infection. For dose dense therapy (treatment given more frequently, such as every two weeks instead of every three weeks) for adjuvant treatment of breast cancer. For chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic individuals with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia. For tx of (non-chemotherapy) drug-induced neutropenia. For tx of low neutrophil counts in individuals with glycogen storage disease type 1b. For tx of neutropenia associated with human immunodeficiency virus (HIV) infection and antiretroviral therapy. In individuals receiving radiation therapy in the absence of chemotherapy if prolonged delays secondary to neutropenia are expected. After accidental or intentional total body radiation of myleosuppressive doses (greater than 2 Grays [Gy] (such as Hematopoietic Syndrome of Acute Radiation Syndrome). After hematopoietic progenitor stem cell transplant (HPCT/HSCT) to promote myeloid reconstitution or when engraftment is delayed or has failed. To mobilize progenitor cells into peripheral blood for collection by leukapheresis, as an adjunct to peripheral blood/hematopoietic stem cell transplantation (PBSCT/PHSCT). Use as an alternate or adjunct to donor leukocyte infusions (DLI) in individuals with leukemic relapse after an allogeneic hematopoietic stem cell transplant.

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
Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

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
Individual has confirmed (written or verbal attestation is acceptable) BRAF mutation.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ZEPZELCA

MEDICATION(S)
ZEPZELCA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual has confirmation (verbal or written) of disease progression on or after platinum-based chemotherapy AND has a current ECOG performance of 0-2.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual is using as a single agent for subsequent therapy.

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

ZOMETA

MEDICATION(S)
ZOLEDRONIC ACID 4 MG/100ML SOLUTION, ZOLEDRONIC ACID 4 MG/5ML CONC

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Bone metastases documented on imaging or bone pain associated with imaging-documented metastases from breast, prostate, lung, kidney, thyroid, or other solid tumors.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
For Breast cancer, prevention of bone loss secondary to adjuvant hormone therapy OR for early stage, premenopausal breast cancer, prevention of bone loss secondary to ovarian dysfunction induced by adjuvant chemotherapy therapy OR Hypercalcemia of malignancy, treatment or Multiple myeloma OR Prevention of osteoporosis during androgen deprivation therapy in prostate cancer.

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
Initial: 6 months. Continuation: 1 Year.

OTHER CRITERIA
For continuation, Individual has achieved and sustained continuing clinical benefit (e.g., complete response, partial response, or stable disease) AND Results are confirmed (written or verbal attestation is acceptable).

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

ZYTIGA

MEDICATION(S)
ABIRATERONE ACETATE 250 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Individual is concomitantly receiving a gonadotropin-releasing hormone (GnRH) analog or has had a bilateral orchiectomy.

PART B PREREQUISITE
N/A

ZYVOX

MEDICATION(S)
LINEZOLID 100 MG/5ML RECON SUSP, LINEZOLID 600 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Confirmed vancomycin-resistant enterococcus faecium (VRE) infection. Confirmed methicillin-resistant S. aureus (MRSA) infection AND individual has had a trial and inadequate response or intolerance to an alternative antibiotic that the microorganism is susceptible to (examples of alternative antibiotics may include, but are not limited to: vancomycin, TMP-SMX, clindamycin, doxycycline, tetracycline (IDSA 2011). Isolates of MRSA have a vancomycin minimum inhibitory concentration (MIC) of greater than 2 (IDSA 2011).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
30 days. 1 year for MDR-TB, XDR-TB,

OTHER CRITERIA
If Individual started treatment with Zyvox in the hospital and requires continued outpatient therapy for an organism susceptible to linezolid. For diagnosis of pulmonary multidrug-resistant tuberculosis (MDR-TB) or pulmonary extensively drug-resistant tuberculosis (XDR-TB) (WHO 2019), linezolid will be used in combination with other anti-infectives (WHO 2019).

PART B PREREQUISITE

N/A