ABRAXANE

MEDICATION(S)
ABRAXANE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/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 relapsed or refractory melanoma, individual is using as a single agent and Eastern Cooperative Oncology Group (ECOG) performance status of 0-2 following at least one prior therapy. For persistent or recurrent ovarian cancer (epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer) OR Individual is using for the treatment of persistent or recurrent ovarian cancer (epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer) in an individual with confirmed taxane (solvent-based paclitaxel or docetaxel) hypersensitivity. For recurrent, metastatic or high-risk uterine/endometrial cancer in individual with confirmed taxane (solvent-based paclitaxel or docetaxel) hypersensitivity OR individual using for treatment of solid tumors where treatment with taxane is medically appropriate and the individual has confirmed taxane (solvent-based paclitaxel or docetaxel) hypersensitivity. For NSCLC, individual has current ECOG performance status of 0-2 OR individual is suing for using for NSCLC with confirmed taxane (solvent-based paclitaxel or docetaxel)

hypersensitivity. For metastatic nonsquamous NSCLC, confirmation (written or verbal) of EGFR and ALK mutations that are negative or unknown.

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

ADEMPAS

MEDICATION(S)
ADEMPAS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Use in combination with nitrates (such as but not limited to, nitroglycerin) or nitric oxide donors (such as but not limited to, amyl nitrite) in any form OR Use in combination with phosphodiesterase (PDE) inhibitors [such as, PDE-5 inhibitors (sildenafil, tadalafil, vardenafil) or nonspecific PDE inhibitors (dipyridamole, theophylline)]. Individual has a diagnosis of pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP).

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 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.

AFINITOR

MEDICATION(S)

AFINITOR 10 MG TAB, AFINITOR DISPERZ, EVEROLIMUS 2.5 MG TAB, EVEROLIMUS 5 MG TAB, 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

AIMOVIG

MEDICATION(S)
AIMOVIG, AIMOVIG (140 MG DOSE)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual is using concomitantly with botulinum toxin for migraine prophylaxis.

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 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): (a)The following antidepressants: amitriptyline, venlafaxine 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). 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.

ALDURAZYME

MEDICATION(S)
ALDURAZYME

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis is confirmed by either of the following (Clarke 2016, Lehman 2011): (a) Documented (written or verbal attestation) deficiency in alpha-L-iduronidase enzyme activity as measured in fibroblasts or leukocytes or (b) Documented (written or verbal attestation) alpha-L-iduronidase gene mutation.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
For dx of mucopolysaccharidosis I (MPS I) AND Individual has one of the following forms of MPS I: (1) Hurler OR (2) Hurler-Scheie OR (3) Scheie with moderate to severe symptoms manifestations including any of the following: (a) Cardiac valve abnormalities (such as aortic or mitral valve regurgitation, with or without insufficiency or stenosis) or (b) Corneal clouding, open-angle glaucoma, and retinal degeneration, progressive or (c) Craniofacial or growth retardation or (d) Frequent, moderate to severe upper respiratory infections or (e) Hepatosplenomegaly or (f) Hernias (such as hiatal, inguinal, or umbilical) or (g) Neurological symptoms resulting from cervical instability or cervical spinal cord compression or (h) Skeletal and joint involvement, progressive (such as, arthropathy, back pain, joint stiffness, lumbar spondylolisthesis, lumbar spinal compression, osteopenia, or osteoporosis).

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

ALIMTA

MEDICATION(S)

ALIMTA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

ALIQOPA

MEDICATION(S)
ALIQOPA

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
Initial 1 year. Continuation 6 months.

OTHER CRITERIA
For initial use dx of relapsed follicular lymphoma, Individual has received at least two prior systemic therapies and has not had previous treatment with another PI3-kinase inhibitor previously (for example, idelalisib [Zydelig]). For continued use, confirmation (written or verbal) of continuing clinical benefit (for example, complete response, partial response, or stable disease) verified at least every 6 months that is objectively measured.

ALPHA1-PROTEINASE INHIBITOR

MEDICATION(S)
ARALAST NP, PROLASTIN-C 1000 MG/20ML SOLUTION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Alpha 1 proteinase inhibitors may not be approved for individuals with IgA antibodies.

REQUIRED MEDICAL INFORMATION
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 and one of the following: Moderate airflow obstruction is evidenced by forced expiratory volume (FEV1) of 30-65 percent of predicted value, prior to initiation of therapy OR a rapid decline in lung function as measured by a change in FEV1 greater than 120 ml/year.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
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

AMPHETAMINE SALTS

MEDICATION(S)
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

AMPYRA

MEDICATION(S)
DALFAMPRIDINE 10 MG TAB ER 12H

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual has a history of seizures, OR moderate or severe renal impairment (defined as creatinine clearance less than or equal to 50 mL/min)

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

ANADROL 50

MEDICATION(S)
ANADROL-50

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Anadrol 50 may not be used to not replace other supportive measures for anemia such as transfusion, correction of iron, folic acid, B12 or pyridoxine deficiency, antibacterial therapy, or the appropriate use of corticosteroids. Using to enhance athletic ability. Individual has a diagnosis of Carcinoma of the prostate or breast in male individuals or Carcinoma of the breast in females with Hypercalcemia. Individual has a diagnosis of nephrosis (nephrotic phase of nephritis). Individual has a diagnosis of severe hepatic dysfunction.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 months

OTHER CRITERIA
Individual has a diagnosis of a deficient red cell production-associated anemia, such as but not limited to: acquired aplastic anemia, congenital aplastic anemia, myelofibrosis, or myelotoxic drug-associated hypoplastic anemia.

APOKYN

MEDICATION(S)
APOKYN

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

ARCALYST

MEDICATION(S)
ARCALYST

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Use in combination with other IL-1 inhibitors, JAK inhibitors, or other biologic drugs (such as IL-6 inhibitors, TNF antagonists, or selective co-stimulation modulators). Tuberculosis, other active serious infections or a history of recurrent infections. Individual has not had a tuberculin skin test (TST) or Centers for Disease Control (CDC)-recommended equivalent to evaluate for latent tuberculosis prior to initiating treatment with rilonacept.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Individual is 12 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

ARZERRA

MEDICATION(S)
ARZERRA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

AUBAGIO

MEDICATION(S)
AUBAGIO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with other immunomodulatory agents (such as Gilenya, tecfidera, Tysabri, Copaxone, Extavia, Plegridy, Rebif, Avonex or Betaseron). Individual has an active acute or chronic infection at the initiation of therapy or has not had a tuberculin skin test (TST) or Centers for Disease Control (CDC)-recommended equivalent to evaluate for latent tuberculosis prior to initiation of therapy.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
Individual has been on Aubagio in the past 180 days OR individual has tried therapy with ONE of the following agents: Avonex (interferon beta-1a) OR Plegridy (interferon beta-1a) OR Betaseron (interferon beta-1b) OR Tecfidera (dimethyl fumarate) OR MSB Copaxone.

AUSTEDO

MEDICATION(S)
AUSTEDO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual is suicidal or has untreated or inadequately treated depression. Individual has hepatic impairment. Individual is currently utilizing monoamine oxidase inhibitors (MAOIs), reserpine or tetrabenazine.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
18 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
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 lasting at least 30 days. For continuation requests, Individual has experienced an improvement in symptoms deemed to be clinically significant by the provider (verbal attestation).

AVASTIN

MEDICATION(S)
AVASTIN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
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
Confirmed test results (written or verbal) for individual with a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including D842V mutation.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
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

BANZEL

MEDICATION(S)

BANZEL, 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

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

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, and locally advanced or metastatic urothelial carcinoma

AGE RESTRICTION
12 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
N/A

BELEODAQ

MEDICATION(S)
BELEODAQ

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

BENLYSTA

MEDICATION(S)
BENLYSTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial treatment, 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 There is no evidence of severe renal disease (proteinuria greater than 6 gm/day, serum creatinine greater than 2.5 mg/dl, or requiring renal dialysis) AND There is no evidence of active central nervous system lupus (e.g. psychosis and seizures) AND SLE remains active while on corticosteroid, antimalarials, and/or immunosuppressants for at least the last 30 days. For continuation of therapy, confirmation (written or verbal attestation) of previous improvement in disease activity following treatment with belimumab indicating a therapeutic response AND there is no evidence of severe renal disease AND there is no evidence of active central nervous system lupus.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
N/A

BLENREP

MEDICATION(S)
BLENREP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

BLINCYTO

MEDICATION(S)
BLINCYTO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year

OTHER CRITERIA
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

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

BRIVIACT

MEDICATION(S)
BRIVIACT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
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
18 years of age and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

BUPHENYL

MEDICATION(S)
SODIUM PHENYLBUTYRATE 500 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Management of acute hyperammonemia

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
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

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

CAPLYTA

MEDICATION(S)
CAPLYTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual is currently using a CYP3A4 inducer (such as carbamazepine, phenytoin, rifampin, St. John’s wort, bosentan, efavirenz, etravirine, modafinil, nafcillin, aprepitant, armodafinil, pioglitazone, prednisone) and cannot discontinue the medication OR Individual is using a moderate (such as amprenavir, ciprofloxacin, cyclosporine, diltiazem, erythromycin, fluconazole, fluvoxamine, verapamil) or strong (such as, clarithromycin, grapefruit juice, itraconazole, voriconazole, nefazodone, ritonavir, nelfinavir) CYP3A4 inhibitor and cannot discontinue the medication OR Individual has moderate (Child-Pugh Class B) or severe hepatic impairment (Child-Pugh Class C).

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

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

CARBAGLU

MEDICATION(S)
CARBAGLU

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

CAYSTON

MEDICATION(S)
CAYSTON

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual has a forced expiratory volume in 1 second (FEV1) of less than 25% or greater than 75% of predicted

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

CELEBREX

MEDICATION(S)

CELECOXIB 100 MG CAP, CELECOXIB 200 MG CAP, CELECOXIB 400 MG CAP, CELECOXIB 50 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

1 year

OTHER CRITERIA

Individual has failed to respond to, is intolerant of, or has a medical contraindication to ONE prescription Non-Steroidal Anti-Inflammatory Drugs (NSAID) or salicylates

CERDELGA

MEDICATION(S)
CERDELGA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Use of glucosylceramide synthase inhibitor in conjunction with one another or in conjunction with a substrate reduction therapy (SRT) agent or enzyme replacement therapy (ERT) agent. Use in an ultra-rapid metabolizers of CYP2D6. Individual has pre-existing cardiac disease or long QT syndrome. End-stage renal disease (ESRD) in CYP2D6 EM individuals. Mild, moderate or severe renal impairment or ESRD in CYP2D6 IM or PM individuals. Moderate or severe hepatic impairment in CYP2D6 EM individuals. Mild, moderate or severe hepatic impairment in CYP2D6 IM or PM individuals.

REQUIRED MEDICAL INFORMATION
Presence of type 1 Gaucher disease is confirmed by either of the following: Deficiency in Glucocerebrosidase activity in the white blood cells or skin fibroblasts, OR genotype testing indicating mutation of two alleles of the glucocerebrosidase genome. And patient has clinically significant manifestations of Type 1 gauchers disease including any of the following: (A) skeletal disease (such as but not limited to avascular necrosis, erlenmeyer flask deformity, osteopenia, or pathological fracture) OR (B) individual presents with at least 2 of the following: clinically significant hepatomegaly, clinically significant splenomegaly, hgb at least 1 gram per dl below lower limit for normal for age and sex, platelet counts less than or equal to 120,000 mm3 OR (C) individual is a CYP2D6 extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) as confirmed by a FDA-approved genotype test.

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

1 YEAR.

OTHER CRITERIA

N/A

CHANTIX

MEDICATION(S)

CHANTIX, CHANTIX CONTINUING MONTH PAK, CHANTIX STARTING MONTH PAK

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

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

CINRYZE

MEDICATION(S)
CINRYZE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
HAE to be confirmed by a C4 level below the lower limit of normal (as defined by the laboratory performing the test) and ANY of the following: 1. C1 inhibitor antigenic level below the lower limit of normal. 2. C1 inhibitor functional level below the lower limit of normal Or 3. The presence of a known HAE-causing C1-INH mutation.

AGE RESTRICTION
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 against acute attacks of hereditary angioedema 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.

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

COPAXONE

MEDICATION(S)
COPAXONE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual with primary progressive MS (PPMS). Individual with non-active secondary progressive MS (SPMS). Concurrent use with other MS Disease modifying agents (such as, Aubagio, Gilenya, Tecfidera, Tysabri, Lemtrada, Ocrevus, Copaxone/Glatopa, Extavia, Mavenclad, Mayzent, Rebif, Avonex, Plegridy or Betaseron).

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
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

CORLANOR

MEDICATION(S)
CORLANOR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual has a heart rate maintained exclusively by a pacemaker. Individual has clinically significant hypotension. Individual has severe hepatic impairment (Child-Pugh Class C).

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
(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 OR has a contraindication or intolerance to beta-blocker therapy AND is in normal sinus rhythm AND If initiating treatment with Corlanor, 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 If initiating treatment with Corlanor, individual has an elevated resting heart rate.

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).

AGE RESTRICTION
18 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
For moderate to severe Ankylosing Spondylitis (AS), individual had an inadequate response to/intolerant of or has a medical contraindication to ONE conventional therapy [such as, NSAIDs or nonbiologic DMARDS such as sulfasalazine or a tumor necrosis factor (TNF) antagonist]. 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 medical contraindication to conventional therapy [nonbiologic

DMARDs (such as methotrexate, sulfasalazine or leflunomide)] or TNF antagonist (AAD 2011).

COTELLIC

MEDICATION(S)
COTELLIC

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of unresectable or metastatic melanoma with confirmed (written or verbal attestation) BRAF V600E or V600K mutation.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Individual is using Cotellic (cobimetinib) in combination with Zelboraf (vemurafenib).

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. For NSCLC, individual has and EGFR exon 19 deletion or exon 21 (L858R) substitution mutation or ALK mutation with test results confirmed (verbal or written attestation).

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).

DALIRESP

MEDICATION(S)
DALIRESP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual has moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment.

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 with a long-acting bronchodilator.

DARZALEX

MEDICATION(S)
DARZALEX, 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

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

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).

DOXIL

MEDICATION(S)

DOXORUBICIN HCL LIPOSOMAL, LIPODOX 50

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

DUAVEE

MEDICATION(S)
DUAVEE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
May not be approved for the following: (1) If individual had a hysterectomy (2) Individual has undiagnosed abnormal uterine bleeding (3) Individual has known, suspected, or past history of breast cancer (4) Individual has known or suspected estrogen-dependent neoplasia (5) Individual has active or past history of venous thromboembolism (6) Individual has active or past history of arterial thromboembolism (7) Individual has known hepatic impairment or disease OR (8) Individual has known protein C, protein S, or antithrombin deficiency or other known thrombophilic disorders.

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.

DURAGESIC PATCH

MEDICATION(S)
FENTANYL 100 MCG/HR PATCH 72HR, FENTANYL 12 MCG/HR PATCH 72HR, FENTANYL 25 MCG/HR PATCH 72HR, FENTANYL 50 MCG/HR PATCH 72HR, FENTANYL 75 MCG/HR PATCH 72HR

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, 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.

ELAPRASE

MEDICATION(S)
ELAPRASE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documented deficiency in iduronate 2-sulfatase enzyme activity as measured in fibroblasts or leukocytes combined with normal enzyme activity level of another sulfatase OR Documented pathologic iduronate 2-sulfatase gene mutation.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Individual has symptoms attributable to MPS II such as: (a) Developmental delay or cognitive impairment or (b) Frequent infections or (c) Hearing loss or (d) Hepatosplenomegaly or (e) Hernias or (f) Impaired respiratory function or (g) Joint pain or (h) Skeletal deformities or (i) Sleep apnea or (j) Valvular heart disease.

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.

ELITEK

MEDICATION(S)
ELITEK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual is receiving treatment in a setting appropriate for providing necessary monitoring and supportive care for tumor lysis syndrome AND Individual has not received a course of Elitek therapy in the past.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
30 DAYS.

OTHER CRITERIA
Individual has been diagnosed with leukemia, lymphoma or other hematologic malignancy with risk factors for tumor lysis syndrome AND Individual is receiving chemotherapy.

EMGALITY

MEDICATION(S)
EMGALITY, EMGALITY (300 MG DOSE)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual is using concomitantly with botulinum toxin for migraine prophylaxis

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 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). Cluster HA meeting the following IHS diagnostic criteria (ICHD3): (a) Individual has 5 or more headache attacks AND (b) has severe or very severe unilateral orbital supraorbital and/or temporal pain lasting 15 to 180 minutes if untreated AND (c) Headache accompanied by 1 or both of the following: (i) 1 or more of following sx or signs, ipsilateral to the headache: (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) Headache is not attributed to another headache disorder AND (IV) Cluster headaches are episodic per following diagnostic criteria (ICHD-3 Beta): (a) Individual has cluster headache 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, Maintenance: 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 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): (1) The following antidepressants: amitriptyline, venlafaxine 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) Mbr is using for tx of episodic cluster headaches AND has had a trial of and inadequate response or intolerance to one of the following agents for the tx of cluster HA: (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 significant by individual or prescriber. For Renewal requests of Episodic Cluster Headaches: mbr has a reduction in the overall number of cluster headache periods AND has obtained clinical benefit deemed significant by individual or prescriber.

EMPLICITI

MEDICATION(S)
EMPLICITI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

EMSAM

MEDICATION(S)
EMSAM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individuals with pheochromocytoma OR Individual is currently taking one of the following: (1) Selective serotonin reuptake inhibitors (SSRIs) (for example, fluoxetine) OR (2) Serotonin and norepinephrine reuptake inhibitors (SNRIs) (for example, venlafaxine) OR (3) Tricyclic antidepressants (clomipramine or imipramine) OR (4) Opiate analgesics (meperidine, tramadol, methadone, pentazocine) OR (5) Dextromethorphan OR (6) Carbamazepine.

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

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 except for Initial high dose tx chronic plaque psoriasis 12 wk

OTHER CRITERIA
For 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 NSAIDs or nonbiologic DMARDs) (ACR 2015). For Moderate to severe Chronic Plaque Psoriasis, individual has had inadequate response to, is intolerant of, or has a medical 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, is intolerant of, or has a contraindication to ONE conventional therapy [nonbiologic DMARDs (such as methotrexate,

sulfasalazine, leflunomide or hydroxychloroquine)] (ACR 2015). 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 2011). 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 2011).

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 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
Individual is using Enhertu as monotherapy.

ENTRESTO

MEDICATION(S)
ENTRESTO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual has a left ventricular ejection fraction less than or equal to 40%.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
N/A

EPCLUSA

MEDICATION(S)
EPCLUSA, 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.

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 or tuberous sclerosis complex, Individual has responded inadequately to previous antiepileptic drugs.

EPOGEN AND PROCRIT

MEDICATION(S)
PROCRIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Hemoglobin (Hgb) levels are less than 10.0 g/dL, prior to initiation of therapy (unless otherwise specified) AND prior to initiation of therapy, (baseline) evaluation of the individual iron status reveals, transferrin saturation at least 20% or ferritin at least 80 ng/mL or bone marrow demonstrates adequate iron stores. For MDS, endogenous erythropoietin level is less than 500 mU/ml. For anemia related to zidovudine in HIV-infected patients when the dose of zidovudine is less than or equal to 4200 mg per week, endogenous erythropoietin level is less than or equal 500 mU/ml. Reduction of Allogeneic Blood Transfusion in Pre-Operative Surgery Patients: Patient's hgb is greater than 10.0 and less than or equal to 13.0 g/dL, individual is scheduled to undergo elective, noncardiac, nonvascular surgery, individual is at high risk for perioperative transfusions with significant, anticipated blood loss, individual is unable or unwilling to donate autologous blood. 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.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

12 weeks.

OTHER CRITERIA

For continued use of epoetin alfa may only be approved beyond 12 weeks if the hemoglobin does not exceed 11.0 g/dL AND iron stores (including transferrin saturation and ferritin) are adequately maintained and monitored periodically during therapy.

ERAXIS

MEDICATION(S)

ERAXIS 100 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

ERBITUX

MEDICATION(S)
ERBITUX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Erbitux is used in combination with other anti-VEGF agents (e.g., bevacizumab). Erbitux is used in more than one line of therapy.

REQUIRED MEDICAL INFORMATION
For stage IV, kras wild type colon, rectal, colorectal, small bowel, appendix, or anal adenocarcinoma when used as a single agent or as part of combination therapy. AND Extended RAS gene mutation testing is confirmed (written or verbal) and the tumor is determined to be RAS wild-type. For squamous cell carcinoma of the Head and/or Neck cancer, Erbitux is used in combination with radiation therapy, for the treatment of locally or regionally advanced disease. Or as a single agent for the treatment of patients with recurrent or metastatic disease for whom prior platinum-based therapy has failed. Or in combination with platinum-based therapy with 5-FU (fluorouracil) as first-line treatment for individuals with recurrent locoregional disease or metastatic SCCHN. OR as a single agent or in combination therapy with or without radiation therapy for any of the following indications, unresectable locoregional recurrence or second primary in individuals who have received prior radiation therapy OR resectable locoregional recurrence in individuals who have not received prior radiation therapy OR distant metastases.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA

N/A

ERIVEDGE

MEDICATION(S)
ERIVEDGE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
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.

ERLEADA

MEDICATION(S)

ERLEADA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year.

OTHER CRITERIA

N/A

ERWINASE

MEDICATION(S)
ERWINAZE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
History of serious thrombosis with prior L-asparaginase therapy. History of pancreatitis with prior L-asparaginase therapy. History of serious hemorrhagic events with prior L-asparaginase therapy.

REQUIRED MEDICAL INFORMATION
Individual is using Erwinase as a component of a multi-agent chemotherapeutic regimen AND is using for Acute lymphoblastic lymphoma or acute lymphocytic leukemia (ALL) or Extranodal natural killer T-cell lymphoma, nasal type (ENKL). Individual has developed a documented systemic allergic reaction or anaphylaxis to prior treatment with Oncaspar (Pegaspargase).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

ESBRIET

MEDICATION(S)
ESBRIET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
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 surgical lung biopsy. Individual has documented (written or verbal) pulmonary function tests within prior 60 days with 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
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

FABRAZYME

MEDICATION(S)
FABRAZYME

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of Fabry disease is confirmed with either of the following: (a) Documentation of complete deficiency or less than 5% of mean normal alpha-galactosidase A enzyme activity in leukocytes, dried blood spots or serum (plasma) analysis or (b) Documented galactosidase alpha gene mutation by gene sequencing.

AGE RESTRICTION
Individual is 8 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Individual has one or more symptoms or physical findings attributable to Fabry disease (ACMG), such as, but not limited to: (a) Burning pain in the extremities (Acroparesthesias) or (b) Cutaneous vascular lesions (Angiokeratomas) or (c) Corneal verticillata (whorls) or (d) Decreased sweating (anhidrosis or hypohidrosis) or (e) Personal or family history of exercise, heat, or cold intolerance or (f) Personal or family history of kidney failure.

FARYDAK

MEDICATION(S)
FARYDAK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

FASLODEX

MEDICATION(S)
FASLODEX, FULVESTRANT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

FETZIMA

MEDICATION(S)
FETZIMA, FETZIMA TITRATION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
May not be approved for treatment of fibromyalgia

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 ER, desvenlafaxine Fumerate ER, fluoxetine, fluvoxamine, escitalopram, citalopram, paroxetine, sertraline, mirtazapine, immediate-release venlafaxine, extended-release venlafaxine or bupropion.

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 OR using within 14 days of taking a monoamine oxidase inhibitor (MAOI).

REQUIRED MEDICAL INFORMATION
N/A

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).

FIRAZYR

MEDICATION(S)
ICATIBANT ACETATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Prophylaxis for HAE attacks.

REQUIRED MEDICAL INFORMATION
HAE to be confirmed by a C4 level below the lower limit of normal (as defined by the laboratory performing the test) and either a C1 inhibitor antigenic level below the lower limit of normal or a C1 inhibitor functional level below the lower limit of normaL.

AGE RESTRICTION
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.

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

FORTEO

MEDICATION(S)
FORTEO, TERIPARATIDE (RECOMBINANT)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual is using Forteo (teriparatide) in combination with any of the following: Prolia (denosumab), Bisphosphonates, Evista (raloxifene), Miacalcin/Fortical (calcitonin nasal spray), Recalst (zolendronic acid), Evenity (romosozumab-aqqg), or Tymlos (abalaoparatide).

REQUIRED MEDICAL INFORMATION
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
2 years. Requests to continue therapy beyond 24 months (2 years) should not be approved.

OTHER CRITERIA
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. Individual has utilized Forteo (teriparatide) AND abaloparatide [Tymlos] for a combined total duration of less than 24 months in their lifetime.

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 diagnosis of Short Bowel Syndrome (SBS) individual has been dependent on parenteral nutrition/intravenous (PN/IV) support, For at least 3 months AND requires PN at least 3 times per week.

GAUCHERS

MEDICATION(S)
CEREZYME, VPRIV

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Use of enzyme replacement therapy (ERT) agents in conjunction with one another or in conjunction with a substrate reduction therapy (SRT) agent. Use of ERT agents for the treatment of type 2 gaucher disease.

REQUIRED MEDICAL INFORMATION
Type 1 Gaucher is confirmed by either (Weinreb 2004, Wang 2011): Deficiency in Glucocerebrosidase activity as measured in white blood cells or skin fibroblasts OR genotype tests indicating mutation of two alleles of the glucocerebrosidase genome. And indiv has clinically significant manifestations of gauchers (Andersson 2005, Weinreb 2004) including for type 1,3: [Adults] skeletal disease (such as but not limited to avascular necrosis, Erlenmeyer flask deformity, osteopenia or pathological fracture) OR presents with 2 or more of the following: clinically significant hepatomegaly/splenomegaly, hgb at least 1 gm/dl below lower limit for normal for age and sex, platelet counts less than or equal to 120,000 mm3. [Children] clinical manifestations such as but not limited to hepatomegaly, splenomegaly, anemia, thrombocytopenia, skeletal disease or growth failure (Andersson 2005) OR Type 3 gauchers is confirmed by genotype testing indicating mutation of 2 alleles of the glucocerebrosidase genome (Kaplan 2013, Wang 2011) And has clinically significant manifestations of gauchers listed above in type 1 AND Neurological findings are consistent with type 3 gaucher disease based on neurological evaluation including brain imaging[MRI or CT and EEG].

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

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 and has not received treatment with another RET arrangement positive-targeted agent such as cabozntinib, vandetanib or selpercatinib (NCT03037385).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

GAZYVA

MEDICATION(S)
GAZYVA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
Gazyva may be approved for treatment of chronic lymphocytic leukemia/small lymphocytic lymphoma for any of the following: a) first-line in individuals without del (17p) mutation when used in combination with chlorambucil or bendamustine 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.

GILENYA

MEDICATION(S)
GILENYA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with other MS disease modifying agents (such as, Aubagio, Tecfidera, Tysabri, Ocrevus, Copaxone/Glotopa, Extavia, Rebif, Avonex, Plegridy, Betaseron). Individual has history or presence of Mobitz Type II second- or third-degree atrioventricular (AV) block or sick sinus syndrome, unless individual has a functioning pacemaker. Individual has a baseline QTc interval greater than or equal to 500 ms. Individual is being treated with Class Ia (such as quinidine, procainamide, or disopyramide) or Class III [such as amiodarone, Multaq (dronedarone), Tikosyn (dofetilide), or sotalol] anti-arrhythmic drugs. Individual has had a recent (within the past 6 months) occurrence of one of the following: Myocardial infarction, Unstable angina, Stroke, Transient ischemic attack (TIA), Decompensated heart failure requiring hospitalization, Class III/IV heart failure or individual has an active acute or chronic infection at the initiation of therapy.

REQUIRED MEDICAL INFORMATION
I. Individual has had a trial and inadequate response or intolerance to one of the following: Avonex (interferon beta-1a), Plegridy (interferon beta-1-a), Betaseron (interferon beta-1b), Tecfidera (dimethyl fumarate), MSB Copaxone OR II. Individual has high disease activity despite treatment with a disease modifying drug (including Aubagio, Avonex, Plegridy, Rebif, Betaseron, Lemtrada, Mavenclad, Mayzent, Ocrevus, Copaxone/Glatopa, Tecfidera and Tysabri) 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, Plegridy, Rebif, Betaseron, Lemtrada, Mavenclad, Mayzent, Ocrevus, Copaxone/Glatopa, Tecfidera and Tysabri) 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.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 YEAR.

OTHER CRITERIA

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
Test results confirmed for individuals with metastatic non-small cell lung cancer (NSCLC) with non-resistant epidermal growth factor receptor (EGFR) mutation.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
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
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

GLEOSTINE

MEDICATION(S)

GLEOSTINE 10 MG CAP, GLEOSTINE 100 MG CAP, GLEOSTINE 40 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

1 year

OTHER CRITERIA

N/A

HALAVEN

MEDICATION(S)
HALAVEN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
Halaven is used as a single agent and in a single line of therapy for recurrent or metastatic breast cancer. Member has previously received at least two chemotherapeutic regimens for locally recurrent or metastatic disease. Individual is using in combination with trastuzumab (or trastuzumab biosimilars) in the treatment of locally recurrent or metastatic HER2+ breast cancer with: (a) Symptomatic visceral disease OR (b) Either hormone receptor-negative disease or hormone receptor-positive and endocrine refractory disease. For soft tissue sarcoma, agent is used as a single agent in a single line of therapy and has previously received at least 2 chemotherapeutic regimens for locally recurrent or metastatic disease.

HARVONI

MEDICATION(S)
HARVONI

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.

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).

HETLIOZ

MEDICATION(S)
HETLIOZ

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

HP ACTHAR

MEDICATION(S)

ACTHAR

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 West Syndrome, infant or child less than 2 years of age.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

3 MONTHS.

OTHER CRITERIA

N/A

HRM AGE

MEDICATION(S)

AMITRIPTYLINE HCL 10 MG TAB, AMITRIPTYLINE HCL 100 MG TAB, AMITRIPTYLINE HCL 150 MG TAB, AMITRIPTYLINE HCL 25 MG TAB, AMITRIPTYLINE HCL 50 MG TAB, AMITRIPTYLINE HCL 75 MG TAB, AMOXAPINE, 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, NORTRIPTYLINE HCL 10 MG CAP, NORTRIPTYLINE HCL 10 MG/5ML SOLUTION, NORTRIPTYLINE HCL 25 MG CAP, NORTRIPTYLINE HCL 50 MG CAP, NORTRIPTYLINE HCL 75 MG CAP, PHENOBARBITAL 100 MG TAB, PHENOBARBITAL 15 MG TAB, PHENOBARBITAL 16.2 MG TAB, PHENOBARBITAL 20 MG/5ML ELIXIR, PHENOBARBITAL 20 MG/5ML SOLUTION, 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

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/5ML SOLUTION, CARISOPRODOL 350 MG TAB, CLEMASTINE FUMARATE 2.68 MG TAB, CYCLOBENZAPRINE HCL 10 MG TAB, CYCLOBENZAPRINE HCL 5 MG TAB, CYCLOBENZAPRINE HCL 7.5 MG TAB, CYPROHEPTADINE HCL 4 MG TAB, DIGITEK 250 MCG TAB, DIGOX 250 MCG TAB, DIGOXIN 250 MCG TAB, ERGOLOID MESYLATES 1 MG TAB, ESTRADIOL 0.025 MG/24HR PATCH WK, ESTRADIOL 0.0375 MG/24HR PATCH WK, ESTRADIOL 0.05 MG/24HR PATCH WK, ESTRADIOL 0.06 MG/24HR PATCH WK, ESTRADIOL 0.075 MG/24HR PATCH WK, ESTRADIOL 0.1 MG/24HR PATCH WK, ESTRADIOL 0.5 MG TAB, ESTRADIOL 1 MG TAB, ESTRADIOL 2 MG TAB, GLYBURIDE 1.25 MG TAB, GLYBURIDE 2.5 MG TAB, GLYBURIDE 5 MG TAB, HYDROXYZINE HCL 10 MG TAB, HYDROXYZINE HCL 25 MG TAB, HYDROXYZINE HCL 50 MG TAB, HYDROXYZINE PAMOATE 25 MG CAP, HYDROXYZINE PAMOATE 50 MG CAP, INDOMETHACIN 25 MG CAP, INDOMETHACIN 50 MG CAP, INDOMETHACIN 75 MG CAP ER, LANOXIN 250 MCG TAB, MENEST 0.3 MG TAB, MENEST 0.625 MG TAB, MENEST 1.25 MG TAB, METHOCARBAMOL 500 MG TAB, METHOCARBAMOL 750 MG TAB, 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 TAB, PROMETHAZINE HCL 25 MG TAB, PROMETHAZINE HCL 50 MG TAB, TRIHEXYPHENIDYL HCL, ZOLPIDEM TARTRATE 10 MG TAB, ZOLPIDEM TARTRATE 5 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

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

HUMAN GROWTH HORMONE

MEDICATION(S)
NORDITROPIN FLEXPRO, OMNITROPE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Use of GH tx when applicable criteria have not been met may not be approved for, but not limited to, the following: Renal transplant, Anabolic tx, except for AIDS, provided to counteract acute or chronic catabolic illness (e.g. surgery, trauma, cancer,chronic hemodialysis) producing catabolic (protein wasting) changes in both adult and ped. Anabolic tx to enhance body mass or strength for professional, recreational or social reasons, Constitutional delay of growth and development. Cystic fibrosis, GH Tx in combo with GnRH agonist (Lupron-leuprolide) as a Tx of precocious puberty. Hypophosphatemic rickets, osteogenesis imperfecta, osteoporosis, Short Stature associated with GH insensitivity (Laron Syndrome). Therapy in older adults with normally occurring decrease in GH, who are not congenitally GH deficient and who have no evidence of organic pituitary dz (this is referred to as age-related GH deficiency). Tx of CHF, burn patients, fibromyalgia, glucocorticoid-induced growth failure. Tx of HIV lipodystrophy (fat redistribution syndrome), also referred to as altered body habitus (e.g. buffalo hump), associated with antiviral therapy in HIV-infected patients. Tx of intrauterine growth restriction (IUGR)or Russell-Silver Syndrome that does not result in SGA. Tx of obesity. Other etiologies of SS where GH has not been shown to be associated with an increase in final height, including but not limited to achondrodoplasia and other skeletal dysplasias. 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: Reconstructive GH tx may be approved 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: individ evaluated AND growth rate remains above 2.5cm/year (does not apply to children with prior documented hypopituitarism)(Grimberg2016). GH may be approved for Adolescents with childhood onset GHD who have completed linear growth. Treatment with GH in other populations approved when: Individual has AIDS wasting syndrome, defined as greater than 10% of baseline wt loss that cannot be explained by a concurrent illness other than HIV infection AND is being tx with antiviral therapy AND continues tx until above definition is no longer met OR individual dx with short bowel syndrome AND is receiving specialized nutritional support.

HUMIRA

MEDICATION(S)
HUMIRA, HUMIRA PEDIATRIC CROHNS START, HUMIRA PEN, HUMIRA PEN-CD/UC/HS STARTER, 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, non-infectious Uveitis, Hidradenitis Suppurativa (HS) and Crohns disease. Patient must be at least 2 years old for JIA and non-infectious uveitis. Individual must be at least 6 years of age for Crohns disease. Individual must be at least 12 years old for HS.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
For moderate to severe RA, individual has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE conventional therapy [nonbologic DMARDs (such as methotrexate, sulfasalazine, leflunomide, or hydroxylchloroquine)] (ACR 2015). For moderate to severe Psoriatic

Arthritis, individual has had an inadequate response to, is intolerant of, has medical 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 medical contraindication to ONE conventional therapy (e.g. 5-ASA products, sulfasalazine, systemic corticosteroids, or immunosuppressants). For chronic moderate to severe plaque psoriasis, individual has had an inadequate response to, is intolerant of, or has a medical 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 medical 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 medical 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 medical 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 medical contraindication to conventional therapy (such as oral antibiotics).

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
For use as a continuous subcutaneous infusion.

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.

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

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

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

ILARIS

MEDICATION(S)
ILARIS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Tuberculosis, invasive fungal infection, other active serious infection, or a history of recurrent infection. Individual who have not had a tuberculin skin test or a CDC-recommended equivalent to evaluate for latent tuberculosis prior to initiating Ilaris (canakinumab). Using Ilaris in combination with other biologic disease-modifying antirheumatic drugs (DMARDs), such as, tumor necrosis factor (TNF) antagonists, IL-1R antagonists, Janus kinase inhibitors (for example, tofacitinib citrate), selective co-stimulation modulators or IL-6 receptor antagonists.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
For cryopyrin-associated periodic syndromes age 4 years and older and for systemic juvenile idiopathic arthritis 2 years of age and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
FFor SIJA, individual has had an inadequate response to, intolerant of, or has a medical contraindication to ONE corticosteroids or nonsteroidal anti-inflammatory drugs (NSAIDs) AND may be used alone or in combination with corticosteroids, methotrexate or NSAIDs. For FMF, individual has active type 1 FMF disease with genetic confirmation of the diagnosis (MEFV gene exon 10 mutation) and confirmed recurrent, active disease (that is, at least one flare per month) and has failed to respond

to, or is intolerant of colchicine therapy. For HIDS/MKD, individual has HIDS with genetic confirmation of the diagnosis by deoxyribonucleic acid (DNA) analysis or enzymatic studies (that is, mutations in the MVK gene or markedly reduced mevalonate kinase activity) and confirmed prior history of greater than or equal to three febrile acute flares within a 6-month period when not receiving prophylactic treatment. For TRAPS, genetic confirmation of the diagnosis (TNFRSF1A gene mutation) and has chronic or recurrent disease activity defined as six flares in a 12-month period.

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

IMFINZI

MEDICATION(S)
IMFINZI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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

REQUIRED MEDICAL INFORMATION
For locally advanced or metastatic urothelial carcinoma, Inoperable or metastatic transitional-cell urothelial carcinoma histologically or cytologically confirmed. For locally advanced, unresectable non-small cell lung cancer, histologically or cytologically confirmed stage III and current Eastern Cooperative Oncology Group performance status 0-2.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
Individual has inoperable or metastatic urothelial carcinoma AND Either the disease has progressed during or following platinum-containing therapy OR disease has progressed within 12 months of neoadjuvant or adjuvant treatment with platinum-containing therapy. For locally advanced, unresectable non-small cell lung cancer (NSCLC), disease has not progressed after definitive chemoradioation and disease has progressed or individual has reached a maximum of 12 months of treatment. For extensive stage Small Cell Lung Cancer, Individual is using as first line therapy in combination with etoposide and either cisplatin or carboplatin for four (4) cycles (followed by

maintenance Imfinzi monotherapy)

IMLYGIC

MEDICATION(S)
IMLYGIC

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual is immunocompromised. Individual is pregnant.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual has diagnosis of unresectable melanoma AND is using as intralesional treatment for one of the following: a) Stage III disease with clinical or satellite/in-transit metastases b) Local satellite recurrence of disease c) in-transit recurrence of disease.

INCRELEX

MEDICATION(S)
INCRELEX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual has suspected or known malignancy. Individual has closed. Individual has of secondary IGF-1 deficiency (for example, due to GH deficiency, untreated malnutrition, untreated hypothyroidism).

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), Growth velocity is greater than or equal to 2cm (greater than equal to 2.0 cm) total growth in 1 year AND Final adult height has not been reached.

INGREZZA

MEDICATION(S)
INGREZZA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Has congenital long QT-syndrome or arrhythmia associated with a prolonged QT interval. Individual is currently using a strong CYP 3A4 inducer (examples, rifampin, carbamazepine, phenytoin, St. Johns wort). Individual is currently using a monoamine oxidase inhibitor (MAOI) (examples, isocarboxazid, phenelzine, selegiline)

REQUIRED MEDICAL INFORMATION
Tardive dyskinesia confirmed by the following (DSM-5): A) At least 60 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 used in treatment of nausea and gastroparesis [such as prochlorperazine, promethazine, metoclopramide] AND B) Presence of involuntary athetoid or choreiform movements lasting at least 30 days.

AGE RESTRICTION
18 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Requests for continuation of therapy may be approved for individuals who meet the following criteria: Individual has experienced an improvement in symptoms deemed to be clinically significant by the provider.

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

INQOVI

MEDICATION(S)
INQOVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
N/A

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

INTERFERONS FOR MS

MEDICATION(S)
AVONEX, AVONEX PEN, AVONEX PREFILLED, BETASERON

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with other MS disease modifying agents (such as Aubagio, Avonex, Bafiertam, Betaseron, Copaxone/Glatiramer/Glatopa, Extavia, Gilenya, Lemtrada, Mavenclad, Mayzent, Ocrevus, Plegridy, Rebif, Tecfidera, and Tysabri, Vumerity and Zeposia).

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

INTUNIV

MEDICATION(S)

GUANFACINE HCL 1 MG TAB ER 24H, GUANFACINE HCL 2 MG TAB ER 24H, GUANFACINE HCL 3 MG TAB ER 24H, GUANFACINE HCL 4 MG TAB ER 24H

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

ISTODAX

MEDICATION(S)

ISTODAX (OVERFILL), ROMIDEPSIN

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

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: clotrimazole, ketoconazole, econazole, or nystatin.

IVIG

MEDICATION(S)
GAMUNEX-C, OCTAGAM 1 GM/20ML SOLUTION, OCTAGAM 2 GM/20ML SOLUTION, OCTAGAM 2.5 GM/50ML SOLUTION, OCTAGAM 25 GM/500ML SOLUTION, OCTAGAM 30 GM/300ML SOLUTION, OCTAGAM 5 GM/100ML SOLUTION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Hyperimmunoglobulinemia E synd when dx is evidenced by high level of serum IgE. Autoimmune mucocutaneous blistering dx when mbr had inadeq response/intolerance/contraindication to other tx such as corticosteroids,immunosuppressants. For autoimmune 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 electromyography (SFE) or presence of antibodies (AB) directed against voltage-gated Ca channels B) Myasthenia Gravis (MG) and dx confirmed by presence of AB against the acetylcholine receptor or muscle specific tyrosine kinase or characteristic ED findings using RNS or SFE AND using for worsening sx or exacerbation or short-term therapy as immunosuppressive tx is taking effect or MAINT therapy of MG when mbr had inadeq response/intolerance/contraindication to other tx such as steroids, immunosuppressants C) Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), as INIT trial up to 12wks when muscle weakness or sensory dysfx is caused by neuropathy in more than 1 limb and nerve conduction studies or diagnostic criteria confirm evidence of demyelinating neuropathy and other polyneuropathies. For cont use of CIDP, clinically sig improvement in neurological sx on exam and cont need is shown by attempts on annual basis to titrate dose or interval of therapy result in sx worsening. As INIT exam(up to 12wks), clinical presentation w/electrodiagnostic test confirm MMN. For MMN cont use, mbr had improvement in strength and fx and need shown by attempts annually to titrate dose or interval therapy results in worse sx.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

Tx of primary humoral immunprimaryodeficiency (PI) when hx of recurrent sinopulmonary infection (SI) req ABX tx AND lack of/inadeq response to immunization AND no evidence of renal (nephrotic synd) and GI as causes of hypogammaglobulinemia (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 recurrent bacterial or active INFECT not responding to antimicrobial therapy and HGG w/ total IgG less than 500mg/dL B)Multiple myeloma with hx of recurrent bacterial or clinically severe INFECT and HGG with total IgG less than 500mg/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/bone marrow suppression OR using in context of transplant for ONE: 1) hematopoietic stem cell transplant 2) Solid organ transplantation including prior desensitization for transplantation for suppression of panel reactive anti-HLA antibody (AB) in ppl with high panel reactive AB (PRA) levels to human leukocyte antigens OR Transplant recipients at risk of CMV 3) Transplant recipients experiencing AB-mediated rejection w/ donor-specific AB OR for tx of ONE autoimmune 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, 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. For 1 MISC DX: post-exposure prophylaxis 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 immunity in PREG or severely immunocompromised ppl OR for Kawasaki Dz tx initiated w/in 10dys of onset and tx for more than 5dys.

IXEMPRA

MEDICATION(S)
IXEMPRA KIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
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

JEVTANA

MEDICATION(S)
JEVTANA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/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 hormone-refractory metastatic prostate cancer, individual has a Eastern Cooperative Oncology Group (ECOG) performance status is 0-2.

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), based on the presence of the following (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) One 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
18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Individual has had an adequate trial and titration of Repatha and achieved suboptimal lipid lowering response.

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 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 in a single line of therapy. 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).

KALYDECO

MEDICATION(S)
KALYDECO 150 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Using Kalydeco (ivacaftor) monotherapy, without concurrent use of lumacaftor or tezacaftor, for the F508del mutation in the CFTR gene.

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

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 immunosuppressant.

REQUIRED MEDICAL INFORMATION
Current ECOG (Eastern Cooperative Oncology Group) performance status of 0-2.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
For melanoma, confirmed (verbal or written) presence of unresectable or metastatic melanoma tx is 1st line in untreated dz or 2nd line in confirmed (verbal or written) dz progression while receiving or since completing most recent therapy. For adv melanoma w/lymph node, resected high risk stage III. For colorectal cancer, monotherapy, primary tx as single agent for unresectable metachronous metastases (defective mismatch repair/high microsatellite instability [dMMR/MSIH] only) 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. 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, no sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK)

translocations. For 1st line adv/metastatic nonsquamous NSCLC, used in combo w/pemetrexed and carboplatin, cytologically confirmed stage IIIb or IV, no sensitizing EFGR mutation or ALK translocations. For 1st line metastatic squamous NSCLC, used in combo with carboplatin and paclitaxel or nab-paclitaxel and cytologically confirmed stage IV and has not undergone prev systemic tx for dz. For CONT/MAINT of recurrent/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 recurrent/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 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 small cell lung cancer, used as single agent and confirmed dz relapse w/in 6mon after complete or partial response or stable dz with initial tx or primary progressive dz 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.

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

KORLYM

MEDICATION(S)
KORLYM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
History of unexplained vaginal bleeding. Current endometrial hyperplasia with atypia or endometrial carcinoma. Diagnosis of severe hepatic impairment (Child Pugh Class C). Concomitant use with any of the following: (1) Long term systemic corticosteroids for serious medical conditions or illnesses OR (2) Simvastatin or lovastatin OR (3) CYP3A substrates with narrow therapeutic ranges (such as but not limited to cyclosporine, fentanyl, sirolimus, tacrolimus) OR (4) Agents or co-morbid conditions which prolong the QT interval

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
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.

KOSELUGO

MEDICATION(S)
KOSELUGO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
2 years old or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
N/A

KUVAN

MEDICATION(S)
KUVAN 100 MG TAB SOL, SAPROPTERIN DIHYDROCHLORIDE 100 MG TAB SOL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
If blood phenylalanine levels do not decrease from baseline at a dose of 10mg/kg/day administered for up to one month. The dose may be increased up to 20mg/kg/day. Individuals are non-responders if phenylalanine levels do not decrease after 1 month and tx should be discontinued

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial 8 weeks, 1 year for continuation

OTHER CRITERIA
N/A

KYPROLIS

MEDICATION(S)
KYPROLIS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/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 (for primary treatment) and being used in combination with lenalidomide plus dexamethasone. For the treatment of Waldenstrom’s macroglbulinemia when the following criteria are met: (a) Used as a primary agent, in combination with rituximab (or rituximab biosimilar) and dexamethasone OR (b) Used for relapsed disease when the primary therapy of carfilzomib, rituximab (or rituximab biosimilar) and dexamethasone was given and relapse is greater than 12 months after therapy.

LARTRUVO

MEDICATION(S)
LARTRUVO

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 histologically confirmed (verbal or written) diagnosis of late stage soft tissue sarcoma (locally advanced or metastatic) not previously treated with an anthracycline and is using in combination with doxorubicin and after at least 8 cycles with doxorubicin or earlier discontinuation of doxorubicin due to toxicity, and then if so chosen, continuing olaratumab as monotherapy in the absence of unacceptable toxicities until disease progression and unable to use Radiotherapy or surgery as a treatment option and Individual's current Eastern Cooperative Oncology Group (ECOG) performance status is 0-2.

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

LETAIRIS

MEDICATION(S)
AMBRISENTAN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual has idiopathic pulmonary fibrosis (IPF).

REQUIRED MEDICAL INFORMATION
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
N/A

LEVOLEUCOVORIN

MEDICATION(S)

KHAPZORY, LEVOLEUCOVORIN CALCIUM 50 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

LIBTAYO

MEDICATION(S)
LIBTAYO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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

REQUIRED MEDICAL INFORMATION
Individual has current ECOG performance status of 0-2

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
N/A

LIDOCAINE TOPICAL

MEDICATION(S)

LIDOCAINE 5 % OINTMENT, LIDOCAINE HCL 4 % SOLUTION, LIDOCAINE PAK

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/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 local analgesia OR Individual is using for relief of pain and itching due to minor cuts, minor scrapes, minor skin irritations, minor burns, and insect bites.

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

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

LORBRENA

MEDICATION(S)
LORBRENA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
N/A

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 1or 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
18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Individual has a documented trial of, an inadequate response or intolerance TWO (2) of the following medications: (a) Loperimide (b) antispasmodics (for example, dicyclomine), or (c) tricyclic antidepressants (AGA 2014).

LUMIZYME

MEDICATION(S)
LUMIZYME

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For infantile-onset Pompe disease, dx is confirmed with acid alpha-glucosidase deficiency (GAA) activity in skin fibroblasts of less than 1% of the normal mean or by GAA gene sequencing AND presence of symptoms (for example respiratory and/or skeletal muscle weakness) of infantile-onset Pompe disease AND evidence of hypertrophic cardiomyopathy. For non-infantile onset (late-onset) Pompe disease, dx is confirmed by GAA enzyme assay which shows reduced enzyme activity less than 40% of the lab specific normal mean value AND confirmed by a second GAA enzyme activity assay in a separate sample (from purified lymphocytes, fibroblasts or muscle) or by GAA gene sequencing AND forced vital capacity (FVC) 30 -79% of predicted value while in the sitting position AND ability to walk 40 meters on a 6-minute walk test (assistive devices permitted) AND muscle weakness in the lower extremities.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

LUMOXITI

MEDICATION(S)
LUMOXITI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individuals with severe renal impairment (CrCl less than 29 mL/min).

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
N/A

LUPRON DEPOT

MEDICATION(S)
LUPRON DEPOT (1-MONTH), LUPRON DEPOT-PED (1-MONTH) 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 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 (not to continue beyond 6 months) OR Dysfunctional uterine bleeding 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 documented anemia (Letheby et al. 2001). 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. 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, except for Endometriosis:6months, Uterine Fibroids:3months

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).

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

LYNPARZA

MEDICATION(S)
LYNPARZA 100 MG TAB, LYNPARZA 150 MG TAB

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

MAKENA

MEDICATION(S)
HYDROXYPROGESTERONE CAPROATE 1.25 GM/5ML SOLUTION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Women with multiple gestations.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 months

OTHER CRITERIA
Therapy initiated between 16 weeks, 0 days and 20 weeks, 6 days of gestation and Singleton pregnancy and absence of preterm labor within the current pregnancy and individual is between 16 and 36 weeks of gestation with a singleton pregnancy. Prior history of a preterm singleton delivery before 37 weeks gestation due to either spontaneous preterm labor or premature rupture of membranes.

MEGACE SUSPENSION HRM

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

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.

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

MEKTOVI

MEDICATION(S)
MEKTOVI

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 is acceptable).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
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

METHYLPHENIDATE

MEDICATION(S)

METHYLPHENIDATE HCL 10 MG TAB, METHYLPHENIDATE HCL 20 MG TAB, METHYLPHENIDATE HCL 5 MG TAB

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

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 110 pg/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 2009): (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).

MONJUVI

MEDICATION(S)
MONJUVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/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 diagnosis of relapsed or refractory diffuse large B-cell lymphoma and is using in one of the following ways: (1) in combination with lenalidomide for a maximum of 12 cycles of chemotherapy without disease progression or unacceptable toxicity OR (2) as monotherapy until disease progression or unacceptable toxicity after previously completing 12 cycles in combination with lenalidomide without disease progression/unacceptable toxicity AND Individual has received one to three prior lines of therapy and one prior therapy line must have included a CD20-targeted therapy (e.g. rituximab) AND individual is not eligible for high dose chemotherapy (HDC) with autologous stem-cell transplantation (ASCT).

MOZOBIL

MEDICATION(S)
MOZOBIL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Using as a mobilizing agent for an allogeneic stem cell donor (NCCN, ASBMT 2014), mobilizer of leukemic cells or as a component of a conditioning regimen prior to an allogeneic hematopoietic stem cell transplant.

REQUIRED MEDICAL INFORMATION
Using in combination with granulocyte colony stimulating factor (G-CSF) (such as Neupogen, Nivestym, Zarxio or Granix) and after stem cell mobilization and collection, a subsequent autologous hematopoietic stem cell transplant is anticipated.

AGE RESTRICTION
18 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 months

OTHER CRITERIA
Individual may use a maximum of up to four consecutive doses of plerixafor (Mozobil) injections per cycle for up to 2 cycles.

MYLOTARG

MEDICATION(S)
MYLOTARG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Relapsed or refractory CD33-positive AML: 2 years and older. For newly diagnosed CD33-positive AML: 1 month and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
N/A

NAGLAZYME

MEDICATION(S)
NAGLAZYME

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Mucopolysaccharidosis VI is confirmed: (a) with an increase in dermatan sulfate in the urine and (b) Decrease in the activity of N-acetylgalactosamine-4-sulfatase (arylsulfatase B) enzyme as measured in fibroblasts or leukocytes combined with normal enzyme activity level of another sulfatase OR (c) N-acetylgalactosamine-4-sulfatase (arylsulfatase B) gene mutation confirmed (written or verbal attestation).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

NAMENDA LINE

MEDICATION(S)

MEMANTINE HCL 10 MG TAB, MEMANTINE HCL 10 MG/5ML SOLUTION, MEMANTINE HCL 2 MG/ML SOLUTION, MEMANTINE HCL 5 MG TAB, MEMANTINE HCL 14 MG CAP ER 24H, MEMANTINE HCL 21 MG CAP ER 24H, MEMANTINE HCL 28 MG CAP ER 24H, MEMANTINE HCL 7 MG CAP ER 24H

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.

NATPARA

MEDICATION(S)
NATPARA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Serum corrected total calcium levels maintained within therapeutic range on calcium supplements and active vitamin D forms alone OR serum corrected total calcium level of less than or equal to 7.5 mg/dL at initiation of therapy. Individual is using to treat hypoparathyroidism caused by a gene mutation in the calcium-sensing receptor OR using to treat acute (duration of less than 6 months, Bilezikian et al. 2011) postoperative hypoparathyroidism OR Individual is at increased risk for osteosarcoma (such as but not limited to, concomitant Pagets disease of bone, open epiphyses, prior history of skeletal external beam or implant radiation therapy).

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
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.

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

NEXAVAR

MEDICATION(S)
NEXAVAR

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

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.

NORTHERA

MEDICATION(S)
NORTHERA

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 (resulting in inadequate response, therapeutic failure or intolerance) of at least one prior pharmacologic therapy (which may include midodrine or fludrocortisone) for treatment of symptoms of NOH.

NOXAFIL

MEDICATION(S)

NOXAFIL 100 MG TAB DR, NOXAFIL 40 MG/ML SUSPENSION

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year.

OTHER CRITERIA

N/A

NP INTERFERON FOR MS

MEDICATION(S)
EXTAVIA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with other MS disease modifying agents (such as Aubagio, Avonex, Bafiertam, Betaseron, Copaxone/Glatiramer/Glatopa, Extavia, Gilenya, Lemtrada, Mavenclad, Mayzent, Ocrevus, Plegridy, Rebif, Tecfidera, and Tysabri, Vumerity and Zeposia).

REQUIRED MEDICAL INFORMATION
Individual has a diagnosis relapsing MS (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
Individual has been on Extavia or Rebif in the past 180 days OR member has tried therapy with ONE of the following agents: Avonex (interferon beta-1a) OR Plegridy (interferon beta-1a) OR Betaseron (interferon beta-1b) OR Tecfidera (dimethyl fumarate) OR MSB Copaxone.

NP LA OPIOID

MEDICATION(S)
METHADONE HCL 10 MG TAB, METHADONE HCL 5 MG TAB, MORPHINE SULFATE 100 MG TAB ER, MORPHINE SULFATE 15 MG TAB ER, MORPHINE SULFATE 200 MG TAB ER, MORPHINE SULFATE 30 MG TAB ER, MORPHINE SULFATE 60 MG TAB 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
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, 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 AND has one of the following: Diagnosis of cancer related pain and/or is actively undergoing cancer therapy (provide cancer diagnosis) OR diagnosis of terminal illness and is receiving palliative/end-of-life care (provide terminal diagnosis) OR has pain severe enough to require daily, around-the-clock, long term opioid treatment (provide diagnosis).

NP TOPICAL ANDROGENS

MEDICATION(S)
TESTOSTERONE 25 MG/2.5GM (1%) 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
Individual has had a trial of androgel 1.62% AND Individual has a dx of one: (1) primary hypogonadism (congenital or acquired) (for example, bilateral torsion, cryptorchidism, chemotherapy, Klinefleter Syndrome, orchitis, orchiectomy, toxic damage from alcohol or heavy metals, vanishing testis syndrome, idiopathic primary hypogonadism, age-related hypogonadism [also referred to as late-onset hypogonadism]) OR (2) Hypogonadotropic hypogonadism (also called secondary hypogonadism) (congenital or acquired) [for example, idiopathic gonadotropin or luteinizing hormone-relapsing hormone (LHRH) deficiency, pituitary-hypothalamic injury] OR (3) 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.

NUBEQA

MEDICATION(S)
NUBEQA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

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.

AGE RESTRICTION
For eosinophilic asthma: 6 years old or older. For eosinophilic granulomatosis with polyangitis (EGPA): 18 years old or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
For severe eosinophilic asthma, individual has had a 3 month trial/inadequate response to combination controller therapy (high dose inhaled corticosteroids plus LA beta2-agonist, leukotriene modifiers, theophylline or oral corticosteroids) (ERS/ATS 2013) AND has experienced 2 or more asthma exacerbations in the prior 12 months requiring use of a systemic corticosteroid or temporary increase in

the individuals usual maintenance of oral corticosteroids (ERS/ATS 2013). For Continuation Therapy after 12 months in individuals with severe eosinophilic asthma: Treatment has resulted in clinical improvement as confirmed by either i) Decreased utilization of rescue medications OR ii) A decreased frequency of exacerbation (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroid) OR iii) An increase in percent predicted FEV1 from pretreatment baseline OR iv) A reduction in reported asthma-related symptoms, such as, to wheezing, shortness of breath, coughing, fatigue, sleep disturbance or asthmatic symptoms upon awakening. For individuals with relapsing or refractory eosinophilic granulomatosis with polyangiitis for 6 months or greater and 1) a history or presence of asthma and 2) blood eosinophil level of greater than or equal to 10% of leucocytes or an absolute eosinophil count of greater than 1000 cells per cubic millimeter (in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease and known or suspected parasitic infection) and 2) the presence of 2 or more features of eosinophilic granulomatosis with polyangiitis (such as, biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration or eosinophil-rich granulomatosis inflammation, 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. For Continuation Therapy after 12 months in individuals with eosinophilic granulomatosis with polyangiitis when treatment has resulted in clinical improvement as confirmed by the achievement of remission at some point during tx, defines as the following: Birmingham Vasculitis Activity Score, version 3, of zero on scale from 0 to 63 and receipt of prednisolone or prednisone at dose of 4mg or less per day.

NUEDEXTA

MEDICATION(S)
NUEDEXTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with any of the following: (i.) Agents containing quinidine, quinine, or mefloquine OR (ii.) Agents that both prolong the QT interval and are metabolized by CYP2D6 (for example, thioridazine, pimozide) OR Concomitant monoamine oxidase inhibitor (MAOI) use or use in the preceding 14 days OR Individual has any of the following cardiovascular conditions: (i.)Prolonged QT interval, congenital long QT syndrome, or history suggestive of torsades de pointes OR (ii.) Heart failure OR (iii.) Complete atrioventricular (AV) block without an implanted pacemaker or at high-risk of a complete AV block.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
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 2014, Pioro et al. 2010), multiple sclerosis (AAN 2016, Pioro et al, 2010), stroke (2016 AHA/ASA)].

NULOJIX

MEDICATION(S)
NULOJIX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

NUPLAZID

MEDICATION(S)
NUPLAZID 10 MG TAB, NUPLAZID 34 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
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.

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
Individual has (A) diagnosis of carcinoid tumors for any of the following: Metastatic carcinoid tumors OR Carcinoid syndrome to suppress or inhibit severe diarrhea and flushing episodes associated with the disease OR Prophylactic administration prior to biopsy in an individual with a suspected functioning carcinoid tumor OR Prophylactic administration prior to induction of anesthesia in an individual with a functional carcinoid tumor OR Prophylactic administration to a surgical procedure in an individual with a functional carcinoid tumor. OR (B) Diagnosis of Bleeding gastroesophageal varices when GE varices are associated with liver disease AND octreotide acetate is used in combination with endoscopic therapy or alone if endoscopic therapy is not available. OR (C) Chemotherapy or radiation-induced diarrhea that is unresponsive to conventional antidiarrheal medications (for example, diphenoxylate and atropine or loperamide) OR (D) Malignant bowel obstruction to manage GI symptoms (such as nausea, vomiting or pain). OR (E) central nervous system meningiomas that are surgically

inaccessible, recurrent, or progressive and is not a candidate for further radiation therapy OR (F) thymic carcinoma or thymoma with or without prednisone OR (G) Using for rapid relief of symptoms or for breakthrough symptoms in individuals taking long-acting octreotide acetate when any of the criteria are met for the above uses OR (H) Neuroendocrine Tumors: (i) Management of unresectable locoregional disease or distant metastasis or (ii) As treatment of the profuse watery diarrhea associated with VIPomas or (iii) Treatment of underlying hypergastrinemic Zollinger-Ellison syndrome or (iv) Prophylactic treatment prior to surgery for gastrinoma.

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 OR has a diagnosis of advanced BCC with nodal or distant metastases disease involvement (NCCN 2B). For continued treatment, individual does not show evidence of progressive disease while on sonidegib therapy.

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 dx of idiopathic pulmonary fibrosis (IPF) is confirmed (verbal or written) 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 surgical lung tissue sampling. Individual has documented (written or verbal) pulmonary function tests within prior 60 days with a 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 If initiating therapy, individual has documented (verbal or written) pulmonary function tests within prior 60 days showing 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 If initiating therapy, 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) FVC decline greater than or equal to 5% and less than 10% AND worsening respiratory symptoms or increased fibrosis on HRCT OR (c) Worsening respiratory symptoms AND increased fibrosis on HRCT AND If initiating therapy, individual has documented (written or verbal) pulmonary function tests within prior 60 days showing FVC greater than or equal to 45%.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 YEAR.

OTHER CRITERIA

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

ONUREG

MEDICATION(S)
ONUREG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

OPDIVO

MEDICATION(S)
OPDIVO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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

REQUIRED MEDICAL INFORMATION
Current ECOG performance status 0-2. For renal cell carcinoma, histologic confirmation with clear-cell component. For NSCLC, SCCHN, Urothelial carcinoma, confirmation (verbal or written) of disease progression.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
For unresectable or metastatic melanoma: used as a single agent or in combination with Yervoy, as first-line therapy for untreated melanoma OR used as a single agent or in combination with Yervoy, as second-line or subsequent therapy for disease progression while receiving or since completing most recent therapy if anti-PD-1 or anti-PD-L1 agent not previously used. For resected advanced melanoma for up to 12 months of adjuvant therapy when individual has resected state IIIB, IIIC or stage IV disease. For stage IV or recurrent NSCLC when: agent is used in combination with ipilmumab AND cytologically confirmed stage IV or recurrent NSCLC AND high tumor mutation burden (greater than or equal to 10 mutations per megabase) AND no sensitizing epidermal growth factor receptor mutations

or anaplastic lymphoma kinase translation in nonsquamous carcinoma AND individual has not received prior systemic therapy as primary therapy for advanced or metastatic NSCLC, prior adjuvant or neoadjuvant chemotherapy is permitted as long as the administration of the prior regimen occurred at least 6 months prior. For intermediate or poor risk renal cell carcinoma, agent used as single agent OR used in combination with ipilmumab for four cycles followed by nivolumab, as subsequent therapy if no checkpoint blockade (PD-1, PD-L1 or CTLA-4) antibody treatment has been previously administered. For advanced or metastatic RCC, confirmed (verbal or written) progression after one or two prior anti-angiogenic regimens for treatment of advanced or metastatic disease. For malignant pleural mesothelioma, used as subsequent therapy OR individual is ineligible for platinum-based therapy, defined as having one or more of the following risk factors for platinum-based chemotherapy toxicity: ECOG performance status equal to 2, Glomerular filtration rate less than 60ml/min, hearing loss (measured at audiometry) of 25 dB at two contiguous frequencies, or Grade 2 or greater peripheral neuropathy. For merkel cell carcinoma (MCC), used as a single agent and Presence of metastatic or recurrent locoregional MCC determined to be not amenable to definitive surgery or radiation therapy.

OPSUMIT

MEDICATION(S)
OPSUMIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual is initiating therapy and has a diagnosis of clinically significant/severe anemia or in combination with other endothelin receptor antagonist (ERA) agents, such as but not limited to Letairis (ambrisentan) or Tracleer (bosentan).

REQUIRED MEDICAL INFORMATION
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
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
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

ORKAMBI

MEDICATION(S)
ORKAMBI 100-125 MG TAB, ORKAMBI 200-125 MG TAB

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 2 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
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
Carcinoma of the prostate or breast in male individuals OR Carcinoma of the breast in females with hypercalcemia. Using to enhance athletic performance or physique. Individual has a diagnosis of nephrosis (nephrotic phase of nephritis). Individual has a diagnosis of hypercalcemia.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 months

OTHER CRITERIA
N/A

PADCEV

MEDICATION(S)
PADCEV

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individuals have moderate or severe hepatic impairment (Child-Pugh B or C) OR the criteria not met.

REQUIRED MEDICAL INFORMATION
Individual has diagnosis of locally advanced or metastatic urothelial cancer AND using as subsequent therapy after progression with anti-PD-1 and anti-PD-L1 agent AND individual has current ECOG performance status of 0 – 2.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART D VS PART B

MEDICATION(S)

ABELCET, ACETYLCYSTEINE 10 % SOLUTION, ACETYLCYSTEINE 20 % SOLUTION, ACYCLOVIR SODIUM, ADRIAMYCIN, ADRUCIL, 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 II 10 % SOLUTION, AMINOSYN II 15 % SOLUTION, AMINOSYN-PF, AMIODARONE HCL 150 MG/3ML SOLUTION, AMIODARONE HCL 450 MG/9ML SOLUTION, AMIODARONE HCL 900 MG/18ML SOLUTION, AMPHOTERICIN B 50 MG RECON SOLN, APREPITANT 125 MG CAP, APREPITANT 40 MG CAP, APREPITANT 80 MG CAP, ARRANON, ARSENIC TRIOXIDE 10 MG/10ML SOLUTION, ARSENIC TRIOXIDE 12 MG/6ML SOLUTION, ATGAM, AZATHIOPRINE 50 MG TAB, AZATHIOPRINE SODIUM, BELRAPZO, BENDAMUSTINE HCL, BENDEKA, BESPONSA, BLEOMYCIN SULFATE, BUDESONIDE 0.25 MG/2ML SUSPENSION, BUDESONIDE 0.5 MG/2ML SUSPENSION, BUDESONIDE 1 MG/2ML SUSPENSION, BUSULFAN, BUSULFEX, CALCITRIOL 0.25 MCG CAP, CALCITRIOL 0.5 MCG CAP, CARBOPLATIN, CARMUSTINE, CINACALCET HCL, CISPLATIN 100 MG/100ML SOLUTION, CISPLATIN 200 MG/200ML SOLUTION, CISPLATIN 50 MG/50ML SOLUTION, CLADRIBINE, CLINIMIX E/DEXTROSE (2.75/10), CLINIMIX E/DEXTROSE (2.75/5), CLINIMIX E/DEXTROSE (4.25/10), CLINIMIX E/DEXTROSE (4.25/25), 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 N14G30E, CLINIMIX N9G15E, CLINIMIX N9G20E, CLINIMIX/DEXTROSE (4.25/10), CLINIMIX/DEXTROSE (4.25/25), CLINIMIX/DEXTROSE (4.25/5), CLINIMIX/DEXTROSE (5/15), CLINIMIX/DEXTROSE (5/20), CLINIMIX/DEXTROSE (5/25), CLINIMIX/DEXTROSE (6/5), CLINIMIX/DEXTROSE (8/10), CLINIMIX/DEXTROSE (8/14), CLINOLIPID, CLOFARABINE, CLOLAR, CROMOLYN SODIUM 20 MG/2ML NEBU SOLN, CYCLOPHOSPHAMIDE 25 MG CAP, CYCLOPHOSPHAMIDE 50 MG CAP, CYCLOSPORINE 100 MG CAP, CYCLOSPORINE 25 MG CAP, CYCLOSPORINE 50 MG/ML SOLUTION, CYCLOSPORINE MODIFIED, CYTARABINE, CYTARABINE (PF), DACARBAZINE, DACTINOMYCIN, DAUNORUBICIN HCL, DECITABINE, DEXRAZOXANE HCL, DOCETAXEL 160 MG/16ML SOLUTION, DOCETAXEL 160 MG/8ML CONC, DOCETAXEL 20 MG/2ML SOLUTION, DOCETAXEL 20 MG/ML CONC, DOCETAXEL 200 MG/10ML CONC, DOCETAXEL 80 MG/4ML CONC, DOCETAXEL 80 MG/8ML SOLUTION, DOXERCALCIFEROL 0.5 MCG CAP, DOXORUBICIN HCL, DRONABINOL, ENGERIX-B 10 MCG/0.5ML SUSPENSION, ENGERIX-B 20 MCG/ML SUSPENSION, EPIRUBICIN HCL, ETOPOPHOS, ETOPOSIDE 1 GM/50ML SOLUTION, ETOPOSIDE 100 MG/5ML SOLUTION, ETOPOSIDE 500 MG/25ML SOLUTION, EVEROLIMUS 0.25 MG TAB, EVEROLIMUS 0.5 MG TAB, EVEROLIMUS 0.75 MG TAB, EVOMELA, FLUDARABINE PHOSPHATE, FLUOROURACIL 1

GM/20ML SOLUTION, FLUOROURACIL 2.5 GM/50ML SOLUTION, FLUOROURACIL 5 GM/100ML SOLUTION, FLUOROURACIL 500 MG/10ML SOLUTION, FOLOTYN, FREAMINE III, GANCICLOVIR SODIUM 500 MG RECON SOLN, GEMCITABINE HCL 1 GM RECON SOLN, GEMCITABINE HCL 1 GM/10ML SOLUTION, GEMCITABINE HCL 1 GM/26.3ML SOLUTION, GEMCITABINE HCL 2 GM RECON SOLN, GEMCITABINE HCL 2 GM/20ML SOLUTION, GEMCITABINE HCL 2 GM/52.6ML SOLUTION, GEMCITABINE HCL 200 MG RECON SOLN, GEMCITABINE HCL 200 MG/2ML SOLUTION, GEMCITABINE HCL 200 MG/5.26ML SOLUTION, GENGRAF, HEPARIN (PORCINE) IN NACL 12500-0.45 UT/250ML-% SOLUTION, HEPARIN (PORCINE) IN NACL 25000-0.45 UT/500ML-% SOLUTION, 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 150 MG RECON SOLN, HERCEPTIN HYLECTA, IDARUBICIN HCL, IFEX 3 GM RECON SOLN, IFOSFAMIDE, INTRALIPID, INTRON A, IPRATROPIUM BROMIDE 0.02 % SOLUTION, IPRATROPIUM-ALBUTEROL, IRINOTECAN HCL, LEUCOVORIN CALCIUM 100 MG RECON SOLN, LEUCOVORIN CALCIUM 200 MG RECON SOLN, LEUCOVORIN CALCIUM 350 MG RECON SOLN, LEUCOVORIN CALCIUM 50 MG RECON SOLN, LEUCOVORIN CALCIUM 500 MG RECON SOLN, 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, MELPHALAN HCL, MIACALCIN 200 UNIT/ML SOLUTION, MITOMYCIN 20 MG RECON SOLN, MITOMYCIN 40 MG RECON SOLN, MITOMYCIN 5 MG RECON SOLN, MITOXANTRONE HCL, MUTAMYCIN, MYCOPHENOLATE MOFETIL 200 MG/ML RECON SUSP, MYCOPHENOLATE MOFETIL 250 MG CAP, MYCOPHENOLATE MOFETIL 500 MG TAB, MYCOPHENOLATE MOFETIL HCL, MYCOPHENOLATE SODIUM, NIPENT, NITROGLYCERIN 5 MG/ML SOLUTION, NUTRILIPID, ONDANSETRON, ONDANSETRON HCL 24 MG TAB, ONDANSETRON HCL 4 MG TAB, ONDANSETRON HCL 8 MG TAB, OXALIPLATIN, PACLITAXEL 100 MG/16.67ML CONC, PACLITAXEL 100 MG/16.7ML CONC, PACLITAXEL 150 MG/25ML CONC, PACLITAXEL 30 MG/5ML CONC, PAMIDRONATE DISODIUM 6 MG/ML SOLUTION, PARAPLATIN, PARICALCITOL 1 MCG CAP, PARICALCITOL 2 MCG CAP, PARICALCITOL 4 MCG CAP, PENTAMIDINE ISETHIONATE 300 MG RECON SOLN FOR NEBULIZATION, PENTAMIDINE ISETHIONATE FOR NEBULIZATION SOLN 300 MG, POLIVY, POTELIGEO, PREMASOL 10 % SOLUTION, PROGRAF 0.2 MG PACKET, PROGRAF 1 MG PACKET, PROGRAF 5 MG/ML SOLUTION, PROLEUKIN, PULMOZYME, RECOMBIVAX HB, RITUXAN, RITUXAN HYCELA, SIMULECT, SIROLIMUS 0.5 MG TAB, SIROLIMUS 1 MG TAB, SIROLIMUS 1 MG/ML SOLUTION, SIROLIMUS 2 MG TAB, SYNTHAMIN 17, TACROLIMUS 0.5 MG CAP, TACROLIMUS 1 MG CAP, TACROLIMUS 5 MG CAP, TAXOTERE, THIOTEPA 100 MG RECON SOLN, THIOTEPA 15 MG RECON SOLN, THYMOGLOBULIN, TICE BCG, TOBRAMYCIN 300 MG/5ML NEBU SOLN,

TOPOSAR 1 GM/50ML SOLUTION, TOPOSAR 100 MG/5ML SOLUTION, TOPOTECAN HCL, TRAVASOL, TREANDA, TRISENOX, TROPHAMINE, VANCOMYCIN HCL 750 MG RECON SOLN, VINBLASTINE SULFATE, VINCASAR PFS, VINCRISTINE SULFATE, VINORELBINE TARTRATE, VYXEOS, XOPENEX, XOPENEX CONCENTRATE, YONDELIS, ZANOSAR, ZORTRESS

DETAILS

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

PEGFILGRASTIM AGENTS

MEDICATION(S)
FULPHILA, NEULASTA, NEULASTA ONPRO

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. In an individual with acute lymphocytic leukemia (ALL) after completion of the first few days of initial induction chemotherapy or first post-remission course of chemotherapy. 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.

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 is using as monotherapy AND has confirmed disease progression (written or verbal) after one or more prior lines of systemic therapy AND confirmation (written or verbal) of fibroblast growth factor receptor 2 (FGFR2) fusion or non-fusion rearrangement as detected by an FDA-approved test.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
N/A

PERJETA

MEDICATION(S)
PERJETA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
If administered after Herceptin (trastuzumab) is discontinued or as part of a regimen without Herceptin (trastuzumab). Concomitant use with other targeted biologic agents (including but not limited to erlotinib, cetuximab, panitumumab, bevacizumab, ziv-aflibercept and lapatinib).

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 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 use Perjeta will be used in combination with trastuzumab (or trastuzumab biosimilars) AND either docetaxel or paclitaxel. (Note If docetaxel or paclitaxel treatment is discontinued (for example, related to toxicity), treatment with Perjeta and trastuzumab may continue.) AND combination chemotherapy with Perjeta (pertuzumab) will be used as single line anti-HER2 chemotherapy for metastatic disease until progression OR individual has early stage, locally advanced or inflammatory breast cancer and will undergo neoadjuvant therapy (prior to surgery) or adjuvant systemic therapy AND primary tumor is larger than 2cm or individual is lymph node positive (for

neoadjuvant therapy: clinically evident by palpation or imaging) AND used in combination with trastuzumab (or trastuzumab biosimilars)and with one of the following: docetaxel with or without carboplatin or paclitaxel AND pertuzumab is used for a maximum of 18 cycles (12 month course).

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

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
Individual has confirmed (written or verbal attestation is acceptable) PIK3CA mutation using an FDA-approved test (such as the therascreen PIK3CA RGQ PCR Kit).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
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

PRALUENT

MEDICATION(S)
PRALUENT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with Juxtapid or Kynamro.

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.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial 3 month. Continuation 1 yr.

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. Individual also has had an adequate 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.

PROLIA

MEDICATION(S)
PROLIA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
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 a history of a low trauma fracture (fragility fracture) at high risk for fracture. Glucocorticoid-induced osteoporosis defined as a 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 a history of a low trauma fracture (fragility fracture) at high risk for fracture and is initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5mg or greater of prednisone and expected or 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 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 risk factors for osteoporotic fracture. Individual is a postmenopausal (natural or induced) female receiving adjuvant aromatase inhibitor therapy for the treatment of breast cancer.

PROMACTA

MEDICATION(S)
PROMACTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Using Promacta to normalize platelet counts. Use in individuals with ITP whose degree of thrombocytopenia and clinical condition (for example, platelet count greater than 30 x 109/L or active bleeding) do not increase the risk of bleeding. Use in individuals with chronic hepatitis C whose degree of thrombocytopenia does not prevent the initiation of peginterferon therapy or limits the ability to maintain an optimal peginterferon-based therapy. Used in individuals with chronic hepatitis C who are no longer on a peginterferon and ribavirin based regimen. Used concomitantly with other thrombopoietin receptor agonists such as romiplostim (Nplate). Used in individuals taking in combination with direct-acting antiviral agents used without concomitant use of a peginterferon agent for treatment of thrombocytopenia associated with chronic hepatitis C infection.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
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) dx of severe aplastic anemia AND is being used in combination with standard immunosuppressive therapy for first-line treatment. For maintenance therapy, 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.

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.

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

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

RANEXA

MEDICATION(S)
RANOLAZINE 1000 MG TAB ER 12H, RANOLAZINE 500 MG TAB ER 12H

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/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 (ACCF 2012): (a) Beta-blocker OR (b) Calcium-channel blocker OR (c) Long-acting nitrate.

RAVICTI

MEDICATION(S)
RAVICTI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Using for the management of acute hyperammonemia. Using to treat N-acetylglutamate synthase deficiency (NAGS).

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
2 months 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 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.

RELISTOR

MEDICATION(S)
RELISTOR 12 MG/0.6ML SOLUTION, RELISTOR 8 MG/0.4ML SOLUTION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual has a known or suspected mechanical gastrointestinal obstruction.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
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: (1) individual is taking a diphenylheptane opioid (e.g., methadone), where effectiveness has not been established in the treatment of OIC (Amitiza) OR (2) individual has disruption to the blood-brain barrier and may be at increased risk for opioid withdrawal and/or reduced analgesia (Movantik) OR (3) individual is taking strong CYP3A4 inhibitors and may be at increased risk for opioid withdrawal and/or reduced analgesia (Movantik).

REMICADE

MEDICATION(S)
REMICADE

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: Greater than 3% of body surface area with plaque psoriasis OR Less than or equal to 3% 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
For Crohn's Disease or Ulcerative colitis, 6 yr of age or older. For JIA, 2 yr of age or older. For all other indications 18 yr of age.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
For RA, individual has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE Conventional Therapy [nonbiological DMARDs (such as methotrexate, sulfasalazine, leflunomide, or hydroxychloroquine)] (ACR 2015). For Crohn's Disease, individual has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE conventional therapy (such as 5-ASA products, sulfasalazine, systemic corticosteroids, or immunosuppressive drugs). For moderately to severely active Ulcerative Colitis, individual has failed to respond to, is intolerant of, or has a medical contraindication to ONE conventional therapy (such as 5-ASA products,

sulfasalazine, systemic corticosteroids, or immunosuppressive drugs). For Ankylosing Spondylitis 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)] (ACR 2015)]. For Psoriatic Arthritis, individual has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE conventional therapy [nonbiological DMARDs (such as methotrexate, sulfasalazine, or leflunomide)]. For chronic plaque psoriasis, individual has had an inadequate response to, is intolerant of, or has a medical contraindication to phototherapy or ONE other systemic therapy (such as methotrexate, acetretin, or cyclosporine). For Refractory Wegener's Granulomatosis, individual is using in combination with ONE corticosteroid. For PJIA, individual has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE Conventional Therapy [nonbiologic DMARD (such as methotrexate)]. For chronic, recurrent, treatment-refractory or vision-threatening, non-infectious uveitis, individual has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE conventional therapy (such as corticosteroids or immunosuppressive drugs [for example, azathioprine, cyclosporine, or methotrexate]). For Sarcoidosis (Baughman 2006), mbr has had an inadequate response to, is intolerant of, or has a contraindication to systemic corticosteroids AND has had an inadequate response to, is intolerant of, or has a contraindication to nonbiologic DMARDs (such as methotrexate or azathioprine).

REPATHA

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with Juxtapid or Kynamro.

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 gene (LDLRAP1) gene 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 3 month. Continuation 1 yr.

OTHER CRITERIA

For initial HoFH request, individual meets 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 (applies to individuals on statin therapy only). For initial HeFH or ASCVD requests, individual meets 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. 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.

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

REVATIO

MEDICATION(S)
SILDENAFIL CITRATE 20 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Use in combination with organic nitrates, such as but not limited to, isosoribide mono/dinitrate or nitroglycerin.

REQUIRED MEDICAL INFORMATION
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
N/A

REVLIMID

MEDICATION(S)
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

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
Individual is 18 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
For moderate to severe RA, individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic DMARDS (such as methotrexate, sulfasalazine, leflunomide, or hydroxychloroquine)].

ROZLYTREK

MEDICATION(S)
ROZLYTREK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
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
For solid tumors, the individual has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation with confirmed (written or verbal) genetic test results.

RUBRACA

MEDICATION(S)
RUBRACA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For epithelial ovarian, fallopian tube, or primary peritoneal cancer, Individual has confirmed deleterious BRCA mutation (verbal or written).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

RYDAPT

MEDICATION(S)
RYDAPT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual is using as a single-agent induction therapy for the treatment of AML.

REQUIRED MEDICAL INFORMATION
Individual has confirmed (written or verbal attestation) FMS-like tyrosine kinase 3 (FLT3) mutation OR KIT816V mutation.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
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

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 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).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

SIGNIFOR IR

MEDICATION(S)
SIGNIFOR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual has a diagnosis of severe hepatic impairment (Child-Pugh C)

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

SINGULAIR

MEDICATION(S)
MONTELUKAST SODIUM 10 MG TAB, MONTELUKAST SODIUM 4 MG CHEW TAB, MONTELUKAST SODIUM 4 MG PACKET, MONTELUKAST SODIUM 5 MG CHEW 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
For dx of perennial allergic rhinitis (PAR) or seasonal allergic rhinitis (SAR), Individual has had a trial and inadequate response or intolerance to or has a contraindication to the following (AAO-HNSF 2015): (a) Intranasal steroid AND (b) Oral non-sedating or intranasal antihistamine. For dx of acute prevention of exercise-induced bronchoconstriction (EIB), Individual has had a trial and inadequate response to a short-acting beta-2 agonist (ATS 2013).

SIRTURO

MEDICATION(S)
SIRTURO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Latent infection due to Mycobacterium tuberculosis OR Drug-sensitive tuberculosis OR Extra-pulmonary tuberculosis OR Infections caused by non-tuberculosis mycobacteria.

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).

SKYRIZI

MEDICATION(S)
SKYRIZI (150 MG DOSE)

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
18 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
For 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).

SOMATULINE DEPOT

MEDICATION(S)
SOMATULINE DEPOT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

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

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
18 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial 3 months, continuation 1 year.

OTHER CRITERIA
For initial use, 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 depression compared to baseline using a standard rating scale that reliably measures depressive symptoms AND will use Spravato in addition to antidepressant therapy.

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.

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

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

STELARA

MEDICATION(S)
STELARA

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, age 6 and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
For chronic plaque psoriasis, individual has had an inadequate response to, is intolerant of, or has a medical 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 medical contraindication to ONE conventional therapy ([nonbiologic DMARDS] such as methotrexate, sulfasalazine, or leflunomide). For Crohns disease, individual has had an inadequate response to, has lost response to, is intolerant of, or has a medical contraindication to conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants) or a tumor necrosis factor (TNF) antagonist. For Ulcerative Colitis, individual has

had an inadequate response to, has lost response to, is intolerant of, or has a medical contraindication to conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants) or a tumor necrosis factor (TNF) antagonist.

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
N/A

SUTENT

MEDICATION(S)
SUTENT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

SYLATRON

MEDICATION(S)
SYLATRON

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Member is being treated for melanoma with microscopic or gross nodal involvement AND Treatment is initiated within 84 days after definitive surgical resection.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

SYMLIN

MEDICATION(S)
SYMLINPEN 120, SYMLINPEN 60

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
May not be approved if individual has any of the following: receiving drugs that stimulate gastric motility (i.e. metoclopramide), diagnosis of severe gastroparesis, hypoglycemia unawareness or recent hypoglycemia requiring assistance within past 6 months

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

AGE RESTRICTION
18 or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

SYNAGIS

MEDICATION(S)
SYNAGIS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Administration of more than 5 doses of palivizumab in one RSV season. Children who reach 24 months of age prior to the commencement of the RSV season. Treatment in children or infants with known RSV disease. Continued RSV immunoprophylaxis for children who experience breakthrough RSV hospitalization. Primary asthma prevention or to reduce subsequent episodes of wheezing. Children with surgically corrected congenital heart disease or hemodynamically insignificant heart disease (including secundum atrial septal defect, small ventricular septal defect, uncomplicated pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus) who do not otherwise meet approval criteria. Children with Down syndrome who do not otherwise meet approval criteria.

REQUIRED MEDICAL INFORMATION
Individual is using when the following are met: A) Maximum of Five (5) doses of palivizumab for infants during the first RSV season within the first year of life: Born before 29 weeks 0 days gestation (up to and including 28 weeks, 6 days) and younger than 12 months of age at the start of the RSV season OR Chronic lung disease (CLD) of prematurity (defined as birth at less than 32 weeks, 0 days gestation and a requirement for greater than 21% oxygen for at least 28 days after birth) OR Hemodynamically significant congenital heart disease (CHD) (including infants with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures and infants with moderate to severe pulmonary hypertension OR infants with anatomic pulmonary abnormalities (i.e., tracheal ring) or a neuromuscular condition that impairs the ability to clear secretions from the upper airway because of ineffective cough OR Cystic fibrosis with clinical evidence of chronic lung disease or nutritional compromise (weight for length less than tenth percentile). B) Maximum of five (5) doses of palivizumab for children younger than 24 months of age with any of the following: Profoundly immunocompromised, such as severe combined immunodeficiency, advanced acquired immunodeficiency syndrome undergoing organ or hematopoietic stem cell transplant, or an

absolute lymphocyte count of less than 100 cell/mm3 OR undergoing cardiac transplantation.of less than 100 cell/mm3 OR undergoing cardiac transplantation.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

5 Months.

OTHER CRITERIA

C) An additional dose of palivizumab may be allowed for children younger than 24 months of age who have approval for a course of treatment and who undergo cardiopulmonary bypass for surgical procedures. D) A maximum of 5 doses of palivizumab prophylaxis may be approved for children during their second RSV season with any of the following: (i) for preterm infants born at less than 32 weeks, 0 days gestation who required at least 28 days of oxygen after birth and who continue to require medical intervention within 6 months of the start of the second RSV season (including, supplemental oxygen, chronic systemic corticosteroid therapy, or diuretics) or (ii) Cystic fibrosis with severe lung disease (history of hospitalization, abnormal chest x-ray or CT scan) or weight for length less than tenth percentile.

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

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

TABRECTA

MEDICATION(S)
TABRECTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual has confirmation (written or verbal) of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors as detected by an FDA-approved test AND individual has not received treatment with another MET exon 14 skipping-targeted agent, such as crizotinib.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

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

TAFINLAR

MEDICATION(S)

TAFINLAR

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Tafinlar may not be approved for the treatment of individuals with wild type BRAF melanoma.

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year

OTHER CRITERIA

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
Individual has either: (a) EGFR (epidermal growth factor receptor) T790M mutation is confirmed (verbal or written) OR (b) EGFR exon 19 deletions or exon 21 L858R mutations is confirmed (verbal or written)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
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

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

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

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

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

TAZORAC

MEDICATION(S)
TAZAROTENE 0.1 % CREAM, 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: 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.

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, tumor is positive for EZH2 mutation as detected by an FDA approved test.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
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.

TECFIDERA

MEDICATION(S)
TECFIDERA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Using in combination with other immunomodulatory products (such as Aubagio, Gilenya, Tysabri, Copaxone/Glatiramer/Glatopa, Extavia, Rebif, Avonex, Mavenclad, Plegridy, Lemtrada, Ocrevus, or Betaseron). Individual is using to treat non-active secondary progressive multiple sclerosis.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
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
N/A

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 (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.

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

TIBSOVO

MEDICATION(S)
TIBSOVO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documented susceptible isocitrate dehydrogenase-1 (IDH1) (written or verbal attestation is acceptable)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

TOPICAL ANDROGENS

MEDICATION(S)
TESTOSTERONE 1.62 % GEL, TESTOSTERONE 20.25 MG/1.25GM (1.62%) GEL, TESTOSTERONE 20.25 MG/ACT (1.62%) GEL, TESTOSTERONE 40.5 MG/2.5GM (1.62%) 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
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.

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

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

TORISEL

MEDICATION(S)
TEMSIROLIMUS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/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 renal cell carcinoma, individual is using for either of the following (A or B): (A) As first-line therapy as a single agent (monotherapy) for (either i or ii): (i) Relapsed metastatic disease or (ii) Surgically unresectable stage IV renal carcinoma in individuals with a poor prognosis as manifested by having at least 3 of the following (1 through 6): 1. Lactate dehydrogenase greater than 1.5 times the upper limit of normal or 2. Hemoglobin less than the lower limit of normal or 3. Corrected calcium level greater than 10mg/dL (2.5mmol/liter) or 4. Interval of less than a year from original diagnosis to the start of systemic therapy or 5. Karnofsky performance status less than or equal to 70 or ECOG performance score of 2 - 4 or 6. Greater than or equal to 2 sites of metastases. OR (B) For subsequent (second-line) therapy as a single agent (monotherapy) for relapsed metastatic or for surgically unresectable stage IV disease.

TRACLEER

MEDICATION(S)
BOSENTAN, TRACLEER 32 MG TAB SOL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual is concomitantly taking cyclosporine A or glyburide.

REQUIRED MEDICAL INFORMATION
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.

TRANSMUCOSAL FENTANYL CITRATE

MEDICATION(S)
FENTANYL CITRATE 1200 MCG LOZ HANDLE, FENTANYL CITRATE 1600 MCG LOZ HANDLE, FENTANYL CITRATE 200 MCG LOZ HANDLE, FENTANYL CITRATE 400 MCG LOZ HANDLE, FENTANYL CITRATE 600 MCG LOZ HANDLE, FENTANYL CITRATE 800 MCG LOZ HANDLE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Using for the treatment of acute or postoperative pain. Using for treatment of migraine headache pain Using for non-cancer related breakthrough pain.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Individual is 16 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Individual has a diagnosis of active cancer with breakthrough cancer (such as, metastatic or locally invasive cancer for which the individual is currently seeking treatment) with breakthrough cancer pain 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 transmucosal fentanyl Citrate for cancer related breakthrough pain.

TRELSTAR LINE

MEDICATION(S)
TRELSTAR MIXJECT

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

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 recurrent or metastatic, histologically confirmed triple-negative Breast Cancer (lack of estrogen- and progesterone-receptor expression and no overexpression of HER2) AND Individual has confirmation of disease progression (written or verbal) after two prior therapies.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
N/A

TROGARZO

MEDICATION(S)
TROGARZO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual who has received immunomodulating therapy within 12 weeks of initiating treatment with Trogarzo (for example, interferon, systemic steroids or systemic chemotherapy) (NCT00784147) OR Individual is being treated for an acute infection secondary to HIV infection (NCT00784147).

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
Individual is using to treat human immunodeficiency virus (HIV) infection AND has a viral load of greater than 1000 copies/mL AND has a history of at least 6 months of antiretroviral treatment AND is receiving a failing antiretroviral regimen or has failed and is off therapy AND has confirmed resistance to at least one antiretroviral agent from three different classes as measured by resistance testing (FDA Summary, 2018) AND Individual is using in combination with other antiretroviral agents and has confirmed full viral sensitivity/susceptibility to at least one antiretroviral agent (other than Trogarzo) as determined by resistance testing.

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

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

TYKERB

MEDICATION(S)
LAPATINIB DITOSYLATE, TYKERB

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

TYMLOS

MEDICATION(S)
TYMLOS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual has utilized abaloparatide and teriparatide for a combined total lifetime duration of 2 years or longer. Individual is using Tymlos in combination with any of the following: (1) Prolia (denosumab) OR (2) Bisphosphonate OR (3) Evista (raloxifene) OR (4) Miacalcin/Fortical (calcitonin nasal spray) OR (5) Reclast (zoledronic acid) OR (6) Forteo (teriparatide) OR (7) Evenity (romosozumab-aqqg).

REQUIRED MEDICAL INFORMATION
Individual is a postmenopausal female with one of the following: (A) dx of 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 (B) clinical dx based on history of A low trauma fracture (fragility fracture) at high risk for fracture AND Individual has had one of the following: (a) refractory to a trial of bisphosphonate OR (b) individual is intolerant to or has a contraindication to bisphosphonate therapy as defined by one of the following (1 through 5): (1) Hypersensitivity to TWO bisphosphonates (one of which must be generic alendronate) OR (2) Inability to stand or sit upright for at least 30 minutes OR (3) A pre-existing gastrointestinal disorder (for example, Barrett’s esophagus, hypersecretory disorders, delayed esophageal emptying, etc.) OR (4) Uncorrected hypocalcemia OR (5) Severe renal insufficiency as defined by creatinine clearance less than 35 mL/min for alendronate agents and zoledronic agents or creatinine clearance less than 30 mL/min for risedronate and ibandronate.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

2 years. Requests to continue therapy beyond 24 months (2 years) should not be approved.

OTHER CRITERIA

N/A

TYSABRI

MEDICATION(S)
TYSABRI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Treatment of primary progressive MS or non-active secondary progressive multiple sclerosis. Currently responsive to and tolerating another treatment for MS or CD. Current or prior history of progressive multifocal leukoencephalopathy (PML). Medical condition which significantly compromises the immune system including HIV infection or AIDS, leukemia, lymphoma or organ transplantation. Concurrent use with chronic antineoplastics or immunosuppressants (for example, azathioprine) or TNF inhibitors. Concurrent use with other MS disease modifying agents (such as Aubagio, Gilenya, Tecfidera, Lemtrada, Mavenclad, Mayzent, Ocrevus, Copaxone/Glatiramer/Glatopa, Extavia, Rebif, Avonex, Plegridy, or Betaseron). Positive test results for anti- John Cunningham virus (JCV) antibodies.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
Individual is using as monotherapy for relapsing forms of multiple sclerosis (RMS) (including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease)) who have had an inadequate response to, or are unable to tolerate, alternative treatments for MS. For diagnosis of Crohns disease, Individual has an inadequate response to, or is unable to tolerate conventional CD

therapies and TNF inhibitors. For all uses, mbr is enrolled in and meets all conditions of the CD or MS Touch Prescribing Program.

UCERIS

MEDICATION(S)
BUDESONIDE 9 MG TAB ER 24H

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

UPTRAVI

MEDICATION(S)
UPTRAVI

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
Individual has pulmonary arterial hypertension (PAH) [World Health Organization (WHO) Group 1] AND individual has WHO functional class II-IV symptoms.

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

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
14 days

OTHER CRITERIA
N/A

VECTIBIX

MEDICATION(S)
VECTIBIX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual has received prior treatment with cetuximab [Note: a course of cetuximab discontinued because of an adverse reaction is not considered prior treatment] OR Panitumumab is used in combination with other anti-VEGF agents (e.g., bevacizumab) OR Panitumumab is being used for more than one line (course) of therapy.

REQUIRED MEDICAL INFORMATION
Extended RAS gene mutation testing with an FDA approved test and results confirm (written or verbal) the tumor is RAS wild-type.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
Used as a single agent or as part of combination therapy for stage IV colon, rectal, colorectal, small bowel, appendiceal, or anal adenocarcinoma.

VELCADE

MEDICATION(S)
BORTEZOMIB, VELCADE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

VEMLIDY

MEDICATION(S)
VEMLIDY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual has end stage renal disease (estimated creatinine clearance below 15 mL/min) and is not receiving chronic hemodialysis. Individual has decompensated (Child-Pugh B or C) hepatic impairment.

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

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

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, a pulmonary capillary wedge pressure (PCWP), 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.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
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).

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

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) with IV antifungal (voriconazole) to an outpatient (home) setting. 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

VIDAZA

MEDICATION(S)
AZACITIDINE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

VIRAZOLE

MEDICATION(S)
VIRAZOLE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/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 hospitalized and will receive treatment in an inpatient setting.

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
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

VOSEVI

MEDICATION(S)
VOSEVI

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 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
18 years of age or older

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. For Genotype 1, 1a Individual has had a trial of and inadequate response to Harvoni (sofosbuvir/ledipasvir) OR Individual is currently on and completing a course of therapy with Vosevi OR has one of the following: (1) Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Harvoni(sofosbuvir/ledipasvir) which is not also in Vosevi OR (2) concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens OR (3) Individual failed to

achieve a sustained viral response (SVR) or relapsed after achieving a SVR during a prior successfully completed Hepatitis C regimen containing an NS5A inhibitor. For Genotype 4 Individual has had a trial of and inadequate response to Harvoni(sofosbuvir/ledipasvir) or Epclusa(sofosbuvir/velpatasvir) OR Individual is currently on and completing a course of therapy with Vosevi OR has one of the following: (1) Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Harvoni(sofosbuvir/ledipasvir) or Epclusa(sofosbuvir/velpatasvir) which is not also in Vosevi OR (2) concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens OR (3) Individual failed to achieve a sustained viral response (SVR) or relapsed after achieving a SVR during a prior successfully completed Hepatitis C regimen containing an NS5A inhibitor.

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

XALKORI

MEDICATION(S)
XALKORI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation (written or verbal) is provided that tumor is anaplastic lymphoma kinase (ALK)-positive or c-ros oncogene 1 (ROS1) positive, or Mesenchymal-Epidermal Transition (MET) amplifications are present or Inflammatory Myofibroblastic tumor (IMT) with ALK Translocation.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
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

XGEVA

MEDICATION(S)
XGEVA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
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).

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
18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

XOLAIR

MEDICATION(S)
XOLAIR 150 MG RECON SOLN

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. Severe asthma as defined by the National Heart, Lung, and Blood Institute: Severe Persistent Asthma: symptoms throughout the day, extremely limited normal activity. Nocturnal symptoms are frequent, FEV1 or PEF is less than or equal to 60% predicted. Moderate Persistent Asthma as defined by the National Heart, Lung, and Blood Institute: Daily symptoms, daily use of inhaled short-acting beta2-agonist, somewhat limited activity, Nocturnal symptoms occur greater than 1 time per week, FEV1 or PEF is greater than 60% and less than 80% predicted, FEV1 FVC is reduced 5 percent or exacerbations requiring oral systemic corticosteroids use for more than or equal to 2 times per year.

AGE RESTRICTION
Patient is 12 years of age or older for urticaria and 6 years of age or older for moderate to severe persistent asthma.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
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 (medium to high doses of inhaled corticosteroids plus long acting beta-2 agonists, Leukotriene modifiers, theophylline or oral corticosteroids)(GINA 2018). 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).

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

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

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

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.

XYREM

MEDICATION(S)
XYREM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial tx of Narcolepsy type 1 (narcolepsy with cataplexy) 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 [less than 2 min]) usually bilaterally symmetrical, sudden loss of muscle tone with retained consciousness) AND (2) Multiple Sleep Latency Test (MSLT) showing one of the following: (a) MSLT 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 110 pg/mL or less than one-third of the normative values with the same standardized assay).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial Request 3 months, Renewal is 6 months.

OTHER CRITERIA
For initial tx, of Narcolepsy type 2 (narcolepsy without cataplexy) confirmed by the following: (1) Daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months AND (2) MSLT showing one of the following: (a) MSLT of less than 8 minutes with evidence of two

SOREMPs (ICSD-3, 2014) or (b) At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight PSG AND (3) absence of cataplexy AND (4) Exclusion of alternative causes of excessive daytime sleepiness by history, physical exam and PSG. AND (5) Mbr has had a previous trial of and inadequate response or intolerance to TWO of the following medications: (A) One of the following wakefulness promoting medications: (i) Modafinil or (ii) Nuvigil (armodafinil) AND (B) One of the following stimulants: (i) Methylphenidate (ii) Dextroamphetamine or (iii) Amphetamine/dextroamphetamine salt immediate-release OR (6) Trials of wakefulness promoting agents and stimulant agents are not acceptable due to concomitant clinical situations including but not limited to the following: (1) Cardiovascular disease or (2) Drug interactions. For Renewal of Narcolepsy type I or II, Xyrem (sodium oxybate) use has resulted in a reduction in frequency of cataplexy attacks OR use has resulted in a reduction in excessive daytime sleepiness (EDS) as measured by improvement in Epworth Sleepiness Scale (ESS) measurements or Maintenance of Wakefulness Test (MWT). For continuation, use has resulted in a reduction in frequency of cataplexy attacks compared to baseline OR use has resulted in a reduction in excessive daytime sleepiness (EDS) as measured by improvement in Epworth Sleepiness Scale (ESS) measurements or Maintenance of Wakefulness Test (MWT) compared to baseline

YERVOY

MEDICATION(S)
YERVOY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual has autoimmune disease which requires treatment with immunosuppressant drugs.

REQUIRED MEDICAL INFORMATION
For small cell lung cancer, unresectable or metastatic melanoma (cutaneous or uveal), colorectal cancer, renal cell carcinoma, or first line treatment of stage IV/recurrent NSCLC, individual has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
For the tx of unresectable or metastatic melanoma (cutaneous and uveal): Used in combo with nivolumab as: (a) First-line therapy or (b) Second-line or subsequent therapy for disease progression if nivolumab was not prev used or Ipilimumab is used as a single agent for one of the following: (a) First line therapy as a single course of 4 tx or (b) Second-line or subsequent lines of therapy as a single course of 4 treatments or (c) Retreatment, consisting of a 4-dose limit, for an individual who had no significant systemic toxicity during prior ipilimumab therapy, and whose disease progressed after being stable for greater than 6 mon following completion of a prior course of ipilimumab, and for whom no intervening therapy has been admin. OR used for the adjuvant treatment of cutaneous melanoma in mbr with pathologic involvement of regional lymph nodes of more than 1 millimeter who have

undergone complete resection, including lymphadenetomy. For the tx of small cell lung cancer (SCLC): Ipilimumab is used in combo with nivolumab as subsequent therapy for one of the following: 1) demonstrated dz relapse within 6 mon following complete or partial response or stable disease with initial tx, OR 2) no response with initial treatment, OR 3) primary progressive dz. For colorectal cancer AND meets one of the following criteria: (a) Primary tx used in combination with nivolumab for unresectable metachronous metastases (defective mismatch repair/high microsatellite instability [dMMR/MSIH] only) and previous adjuvant FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 mon or (b) Ipilimumab is used in combo with nivolumab as subsequent therapy for unresectable advanced or metastatic colorectal cancer with defective mismatch repair (dMMR) or high microsatellite instability (MSIH) mutations that has progressed following tx with fluoropyrimidine and oxaliplatin or irinotecan. For Renal cell carcinoma, when: (a) used in combination with nivolumab, for four cycles followed by single agent nivolumab as first-line therapy for previously untreated RCC or (b) used in subsequent therapy with nivolumab for four cycles followed by single agent nivolumab if no checkpoint blockade (PD-1, PD-L1, or CTLA-4) antibody tx has been previously administered and (c)Histologic confirmation of RCC with clear-cell component. For stage IV/recurrent NSCLC when: used in combo with nivolumab and Cytologically confirmed stage IV or recurrent NSCLC and High tumor mutation burden (greater than or equal to 10 mutations per megabase) and No sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) translocations in nonsquamous carcinoma and Has not received prior systemic therapy as primary therapy for advanced or metastatic NSCLC, prior adjuvant or neoadjuvant chemotherapy is permitted as long as the last administration of the prior regimen occurred at least 6 months prior.

YONSA

MEDICATION(S)
YONSA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/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.

ZALTRAP

MEDICATION(S)
ZALTRAP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
Diagnosis of metastatic anal adenocarcinoma or metastatic appendicle adenocarcinoma or metastatic colorectal/rectal/colon cancer AND used in combination with an irinotecan based regimen AND individual is resistant to or has disease progression following treatment with an oxaliplatin containing regimen AND Zaltrap will be used in a single line of therapy.

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 acute lymphocytic leukemia (ALL) after completion of the first few days of initial induction chemotherapy or first post-remission course of chemotherapy. 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.

ZAVESCA

MEDICATION(S)
MIGLUSTAT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
May not be approved for use in conjunction with Cerdelga (eliglustat) or enzyme replacement therapy (ERT) agents (Cerezyme, Elelyso or Vpriv). Severe Type 1 Gaucher disease (hemoglobin less than 9 g/dL, platelet count less than 50,000 mm3 or those at risk developing new bone complications) (Weinreb et al. 2005). Individual has severe renal impairment (less than 30 mL/min/1.73 m2). Individual has mild, moderate or severe hepatic impairment or cirrhosis.

REQUIRED MEDICAL INFORMATION
Presence of type 1 Gaucher disease is confirmed by either of the following (Weinreb et al. 2004, Wang et al. 2011): Deficiency in Glucocerebrosidase enzyme activity as measured in white blood cells or skin fibroblasts, OR genotype testing indicating mutation of two alleles of the glucocerebrosidase genome. And patient has clinically significant manifestations of gauchers disease including any of the following: skeletal disease (such as but not limited to avascular necrosis, Erlenmeyer flask deformity, osteopenia or pathological fracture) OR patient presents with at least 2 of the following: clinically significant hepatomegaly, clinically significant splenomegaly, hgb at least 1 gram per deciliter below lower limit for normal for age and sex, platelet counts less than or equal to 120,000 mm3.

AGE RESTRICTION
Individual is 18 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA

Enzyme replacement therapy with Cerezyme, ELELYSO or VPRIV is not a therapeutic option for reasons such as but limited to any of the following (Label, Weinreb et al. 2005): (a) Medically unmanageable hypersensitivity or (b) Development of therapy-limiting inhibitory antibodies or (c) Poor peripheral or central venous access.

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

ZELBORAF

MEDICATION(S)
ZELBORAF

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individuals with wild-type BRAF melanoma.

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

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

ZOMETA

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

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.

ZULRESSO

MEDICATION(S)
ZULRESSO

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
Individual is 6 months postpartum or less AND has a diagnosis of moderate to severe postpartum depression consistent with qualifying score using a standardized screening tool for depression (such as, but not limited to, Hamilton Rating Scale for Depression [HAM-D], Patient Health Questionnaire [PHQ-9], Beck Depression Inventory [BDI], Montgomery-Asberg Depression Rating Scale [MADRS], Edinburgh Postnatal Depression Scale [EPDS]).

ZYDELIG

MEDICATION(S)
ZYDELIG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
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).

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

ZYTIGA

MEDICATION(S)
ABIRATERONE ACETATE 250 MG TAB, ZYTIGA 500 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.

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
Treatment of gram-negative infections.

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 or has contraindications to an alternative antibiotic that the organism is susceptible to (depending on manifestation, severity of infection and culture or local sensitivity patterns, examples of alternative antibiotics may include, but are not limited to: vancomycin, TMP-SMX, clindamycin, doxycycline, tetracycline (Based on 2011 IDSA MRSA guideline recommendations)). Isolates of MRSA have a vancomycin minimum inhibitory concentration (MIC) of greater than 2.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
30 days

OTHER CRITERIA
Individual started treatment with Zyvox in the hospital and requires continued outpatient therapy. 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). For diagnosis of non-tuberculous mycobacterial infection (including but not limited to M. fortuitum)(ATS/IDSA 2007), linezolid will be used in combination with other anti-infectives

(ATS/IDSA 2007).