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
N/A

REQUIRED MEDICAL INFORMATION
For Pulmonary Arterial Hypertension, individual has the diagnosis of PAH confirmed by a right heart catheterization showing all of the following: (a) Mean pulmonary artery pressure (mPAP) greater than or equal to 25 mm Hg at rest (b) Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg (c) Pulmonary vascular resistance (PVR) greater than 3 Wood units. AND Individual has WHO functional class II- IV symptoms. For CTEPH confirmed by a right-heart catheterization showing a mPAP greater than 25 mm Hg caused by thromboemboli in the pulmonary arterial system (ACCF/AHA 2009).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For 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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial: 3 months. Continuation: 1 year

OTHER CRITERIA
For initial requests: (I) Individual has a diagnosis of one of the following: (a) Episodic migraine OR (b) Chronic migraine AND (II) Individual is using for migraine prophylaxis. And (III) Individual has had a trial of and inadequate response or intolerance to 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.

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
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

ALPHA1-PROTEINASE INHIBITOR

MEDICATION(S)

PROLASTIN-C 1000 MG RECON SOLN

PENDING CMS APPROVAL

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-DEXTROAMPHET ER, AMPHETAMINE-DEXTROAMPHETAMINE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

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

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

AMPYRA

MEDICATION(S)
DALFAMPRIDINE ER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial approval 12 weeks, renewal 1 year

OTHER CRITERIA
N/A

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
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

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

ASPARLAS

MEDICATION(S)
ASPARLAS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual has a history of serious hypersensitivity reactions, including anaphylaxis, to pegylated L-asparaginase therapy OR History of serious thrombosis with prior L-asparaginase therapy OR History of serious pancreatitis with prior L-asparaginase therapy OR History of serious hemorrhagic events with prior L-asparaginase therapy OR Severe hepatic impairment.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Ages 1 month to 21 years old

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
N/A

REQUIRED MEDICAL INFORMATION
Individual is using for 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
Individual had a trial and inadequate response (including but not limited to confirmed clinical relapse, new or enlarged lesions on MRI or confirmed disability progression) or intolerance with ONE of the following agents: Avonex (interferon beta-1a) OR Plegridy (interferon beta-1a) OR Betaseron (interferon beta-1b) OR MSB Tecfidera OR MSB Copaxone.

AURYXIA

MEDICATION(S)
AURYXIA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual has a diagnosis of an iron overload syndrome (for example, hemochromatosis) or has a diagnosis of iron deficiency anemia associated with chronic kidney disease (CKD) stages 3, 4, or 5 and is not on dialysis [Not Part D].

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
N/A

AUSTEDO

MEDICATION(S)

AUSTEDO

PENDING CMS APPROVAL

AYVAKIT

MEDICATION(S)

AYVAKIT

PENDING CMS APPROVAL

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 200 MG TAB, BANZEL 400 MG TAB, 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

BENLYSTA

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For initial treatment of SLE, individual has a Clinical diagnosis of SLE per the American College of Rheumatology [ACR] criteria AND Unequivocally positive ANA (anti-nuclear antibody) titer greater than or equal to 1:80 or anti-dsDNA (double stranded DNA antibody) greater than or equal to 30 IU/mL AND SLE is active as documented by a SELENA-SLEDAI score greater than or equal to 6 while on current treatment regimen AND There is no evidence of severe lupus nephritis (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 of SLE, 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 lupus nephritis AND there is no evidence of active central nervous system lupus. For the

treatment of active lupus nephritis, individual is receiving standard therapy.

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

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 10 MG TAB, BRIVIACT 10 MG/ML SOLUTION, BRIVIACT 100 MG TAB, BRIVIACT 25 MG TAB, BRIVIACT 50 MG TAB, BRIVIACT 75 MG TAB

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

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 3 GM/TSP POWDER, SODIUM PHENYLBUTYRATE 500 MG TAB

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Using as adjunctive therapy for chronic management of hyperammonemia

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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
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

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
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
7 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

CHANTIX

MEDICATION(S)

APO-VARENICLINE, 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 is confirmed (written or verbal) by a C4 level below the lower limit of normal (as defined by laboratory testing) and ANY of the following: 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
Individual is 6 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual has a history of moderate or severe attacks and is using as prophylaxis 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
N/A

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
N/A

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

PENDING CMS APPROVAL

COTELLIC

MEDICATION(S)
COTELLIC

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

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

CYRAMZA

MEDICATION(S)
CYRAMZA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

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

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

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

DALIRESP

MEDICATION(S)
DALIRESP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

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

DANYELZA

MEDICATION(S)
DANYELZA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual is using in combination with GM-CSF.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

DARZALEX

MEDICATION(S)

DARZALEX 400 MG/20ML SOLUTION, DARZALEX FASPRO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Has received treatment with daratumumab or another anti-CD38 agent

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

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).

DIFICID

MEDICATION(S)
DIFICID

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual has had a trial and inadequate response or intolerance to or has a contraindication to a course of oral vancomycin.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
30 Days

OTHER CRITERIA
N/A

DUEXIS

MEDICATION(S)
DUEXIS, IBUPROFEN-FAMOTIDINE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
Individual has had a trial and inadequate response or intolerance to one (1) oral generic prescription Non-Steroidal Anti-Inflammatory Drugs (NSAID) AND has had a trial and inadequate response or intolerance to one (1) of the following (Lanza 2009): (a) Preferred proton pump inhibitor (PPI) OR (b) Generic misoprostol OR (c) Generic histamine-2 receptor antagonist (H2RA) AND Individual has had an adequate response (pain relief and appropriate gastro protection) with a trial of ibuprofen and famotidine used at the same time AND Documentation (written or verbal attestation) has been provided for why the combination agent is clinically necessary and not for convenience.

DURAGESIC PATCH

MEDICATION(S)
FENTANYL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Individual is 2 years of age or older

PRESCRIBER RESTRICTION
N/A

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

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

opioid analgesic to another long-acting opioid analgesic OR (c) already receiving at least 60 mg/day of oral morphine, 30 mg/day of oral oxycodone, 8 mg/day of oral hydromorphone, or an equianalgesic dose of another opioid. For continued use, 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.

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.

ELIGARD_GNRH

MEDICATION(S)
ELIGARD

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

EMGALITY

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Episodic migraine defined as at least 4 and fewer than 15 migraine days per month and fewer than 15 headache 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. Continuation: 1 year

OTHER CRITERIA

For Initial requests: (I) Individual has a diagnosis of one of the following: (a) Episodic migraine OR (b) Chronic migraine AND (c) is using for migraine prophylaxis AND (d) has had a trial of and inadequate response or intolerance to 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.

EMSAM

MEDICATION(S)
EMSAM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

ENBREL

MEDICATION(S)
ENBREL, ENBREL MINI, ENBREL SURECLICK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

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

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For Initial use: moderate to severe Ankylosing Spondylitis, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapies: (such as sulfasalazine) (ACR 2019). For Moderate to severe Chronic Plaque Psoriasis, individual has had inadequate response to, is intolerant of, or has a contraindication to phototherapy OR ONE other systemic therapies (such as, methotrexate, acitretin, or cyclosporine). For moderate to severe Rheumatoid Arthritis, individual has had an inadequate response to, 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 2019). For moderate to severe Psoriatic Arthritis, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine or leflunomide)] (AAD 2019). For Continuation use: there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

ENHERTU

MEDICATION(S)
ENHERTU

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

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

EPCLUSA

MEDICATION(S)
SOFOSBUVIR-VELPATASVIR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

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

EPIDIOLEX

MEDICATION(S)

EPIDIOLEX

PENDING CMS APPROVAL

EPOGEN AND PROCRIT

MEDICATION(S)
PROCRIT, RETACRIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Baseline 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 is adequate as defined by one of the following: transferrin saturation at least 20% or ferritin at least 80 ng/mL or bone marrow demonstrates adequate iron stores. For MDS, endogenous 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

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

OTHER CRITERIA

N/A

ERAXIS

MEDICATION(S)
ERAXIS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

ERIVEDGE

MEDICATION(S)
ERIVEDGE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

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

ERLEADA

MEDICATION(S)
ERLEADA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual is concomitantly receiving a gonadotropin-releasing hormone (GnRH) analog [e.g. Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)] OR Has had a bilateral orchiectomy.

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
Initial use for Diagnosis of idiopathic pulmonary fibrosis (IPF) is confirmed (written or verbal) by: Exclusion of other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity AND High resolution computed tomography (HRCT) with or without lung tissue sampling. Individual has 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
For continued use, there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to decreased frequency of exacerbations, slowed rate of FVC decline or improvement in respiratory symptom burden).

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

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

FASENRA

MEDICATION(S)
FASENRA, FASENRA PEN

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 or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
For Initial use, individual has had a 3 month trial and inadequate response or intolerance to combination controller therapy (high dose inhaled corticosteroids plus long acting beta2 agonists, leukotriene modifiers, theophylline or oral corticosteroids) (ERS/ATS, 2013) AND has experienced two or more asthma exacerbations in the prior 12 months requiring use of a systemic corticosteroid or temporary increase in the individuals usual maintenance dosage of oral corticosteroids (ERS/ATS, 2013) AND has a blood eosinophil count (in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease, and known or suspected parasitic infection) greater than or equal to 150 cells/microliter (150 cells/mm3) at initiation of therapy. For Continuation use, treatment has resulted in clinical improvement as confirmed by one or more of the following: (a) decreased utilization of rescue medications OR (b) decreased frequency of exacerbations (defined as worsening of asthma that requires an increase in inhaled corticosteroid dose or treatment with systemic

corticosteroids) OR (c) increase in percent predicted FEV1 from pretreatment baseline OR (d) reduction in reported asthma-related symptoms, such as asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing.

FENTORA

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

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

FERRIPROX

MEDICATION(S)

DEFERIPRONE, FERRIPROX 100 MG/ML SOLUTION, FERRIPROX 1000 MG TAB, FERRIPROX TWICE-A-DAY

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

FETZIMA

MEDICATION(S)
FETZIMA, FETZIMA TITRATION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For MDD, individual has had a trial of TWO of the following: Desvenlafaxine, fluoxetine, fluvoxamine, escitalopram, citalopram, paroxetine, sertraline, mirtazapine, venlafaxine, or bupropion.

FINTEPLA

MEDICATION(S)
FINTEPLA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual is using for weight loss/reduction.

REQUIRED MEDICAL INFORMATION
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, SAJAZIR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Prophylaxis for HAE attacks.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

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

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)

PENDING CMS APPROVAL

FOTIVDA

MEDICATION(S)
FOTIVDA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

GALAFOLD

MEDICATION(S)
GALAFOLD

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 Fabry disease as confirmed with either Documentation (written or verbal attestation is acceptable) of complete deficiency or less than 5% of mean normal alpha-galactosidase A (a-Gal A) enzyme activity in leukocytes, dried blood spots or serum (plasma) analysis OR Documented (written or verbal attestation is acceptable) galactosidase alpha (GLA) gene mutation by gene sequencing. Individual has an amendable GLA gene variant based on the human embryonic kidney-293 assay.

AGE RESTRICTION
N/A

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.

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 stable on parenteral nutrition/intravenous (PN/IV) support, defined as the inability to significantly reduce PN/IV support, for at least 3 months AND requires PN at least 3 times per week.

GAVRETO

MEDICATION(S)
GAVRETO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

GAZYVA

MEDICATION(S)
GAZYVA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

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

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

GILENYA

MEDICATION(S)
GILENYA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

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
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

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)

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

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

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

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

HRM AGE AU

MEDICATION(S)

ASCOMP-CODEINE, BENZTROPINE MESYLATE 0.5 MG TAB, BENZTROPINE MESYLATE 1 MG TAB, BENZTROPINE MESYLATE 2 MG TAB, BIJUVA, BUTALBITAL-ACETAMINOPHEN 50-325 MG TAB, BUTALBITAL-APAP-CAFF-COD, BUTALBITAL-APAP-CAFFEINE, BUTALBITAL-ASA-CAFF-CODEINE, CARBINOXAMINE MALEATE 4 MG/5ML SOLUTION, CARISOPRODOL-ASPIRIN-CODEINE, CHLORZOXAZONE 500 MG TAB, CLEMASTINE FUMARATE 2.68 MG TAB, CLIMARA PRO, CYCLOBENZAPRINE HCL 10 MG TAB, CYCLOBENZAPRINE HCL 5 MG TAB, CYCLOBENZAPRINE HCL 7.5 MG TAB, CYPROHEPTADINE HCL 2 MG/5ML SYRUP, DIGITEK 250 MCG TAB, DIGOX 250 MCG TAB, DIGOXIN 250 MCG TAB, DIPYRIDAMOLE 25 MG TAB, DIPYRIDAMOLE 50 MG TAB, DIPYRIDAMOLE 75 MG TAB, DISOPYRAMIDE PHOSPHATE, ERGOLOID MESYLATES 1 MG TAB, ESGIC 50-325-40 MG CAP, ESTRADIOL 0.5 MG TAB, ESTRADIOL 1 MG TAB, ESTRADIOL 2 MG TAB, INDOMETHACIN 25 MG CAP, INDOMETHACIN 50 MG CAP, INDOMETHACIN ER, KETOROLAC TROMETHAMINE 10 MG TAB, MEGESTROL ACETATE 625 MG/5ML SUSPENSION, MEPERIDINE HCL 100 MG TAB, MEPERIDINE HCL 100 MG/ML SOLUTION, MEPERIDINE HCL 25 MG/ML SOLUTION, MEPERIDINE HCL 50 MG TAB, MEPERIDINE HCL 50 MG/5ML SOLUTION, MEPERIDINE HCL 50 MG/ML SOLUTION, MEPROBAMATE, METHYLDOPA, METHYLDOPA-HYDROCHLOROTHIAZIDE, NIFEDIPINE 10 MG CAP, NIFEDIPINE 20 MG CAP, PENTAZOCINE-NALOXONE HCL, PHENADOZ 25 MG SUPPOS, 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, PROMETHAZINE HCL 12.5 MG SUPPOS, PROMETHAZINE HCL 12.5 MG TAB, PROMETHAZINE HCL 25 MG SUPPOS, PROMETHAZINE HCL 25 MG TAB, PROMETHAZINE HCL 50 MG TAB, PROMETHAZINE HCL 6.25 MG/5ML SOLUTION, PROMETHAZINE HCL 6.25 MG/5ML SYRUP, PROMETHEGAN, TENCON, TRIHEXYPHENIDYL HCL 0.4 MG/ML SOLUTION, ZEBUTAL

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

PENDING CMS APPROVAL

HUMIRA

MEDICATION(S)

HUMIRA 10 MG/0.1ML PREF SY KT, HUMIRA 20 MG/0.2ML PREF SY KT, HUMIRA 40 MG/0.4ML PREF SY KT, HUMIRA 40 MG/0.8ML PREF SY KT, HUMIRA 80 MG/0.8ML PEN KIT, HUMIRA PEDIATRIC CROHNS START, HUMIRA PEN, HUMIRA PEN-CD/UC/HS STARTER, HUMIRA PEN-PS/UV/ADOL HS START, HUMIRA PEN-PSOR/UVEIT STARTER

PENDING CMS APPROVAL

HUMULIN U500

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

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

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

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

IMLYGIC

MEDICATION(S)
IMLYGIC

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
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
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For Continuation of treatment with Increlex (mecasermin), 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

PENDING CMS APPROVAL

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 PEN, AVONEX PREFILLED, BETASERON, PLEGRIDY, PLEGRIDY STARTER PACK 63 & 94 MCG/0.5ML SOLN PEN

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

INTUNIV

MEDICATION(S)
GUANFACINE HCL ER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
Individual is 6 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

IRESSA

MEDICATION(S)
IRESSA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
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 1 GM/10ML SOLUTION, OCTAGAM 1 GM/20ML SOLUTION, OCTAGAM 10 GM/100ML SOLUTION, OCTAGAM 10 GM/200ML SOLUTION, OCTAGAM 2 GM/20ML SOLUTION, OCTAGAM 20 GM/200ML SOLUTION, OCTAGAM 5 GM/50ML SOLUTION

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

conditions.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Tx of primary (PI) when hx of recurrent (SI) req ABX tx AND lack of/inadeq response to immunization AND no evidence of renal (nephrotic synd) and GI as causes of HGG AND INIT pre-tx total serum IgG below the lower limit of age adj lab ref range or more than 2SD below adj mean. hyperimmunoadj mean AND hx of recurrent SI requiring ABX therapy AND lack of/inadeq response to immunization OR Use for ONE: A) B-cell CLL w/ hx of 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 recur bacterial or clinically severe INFECT and HGG with total IgG less than 400mg/dL C) HIV infected children to prevent opportunistic bacterial infection w/HGG (IgG less than 400mg/dL) or recurrent INFECT D) PARVO B19 chronic INFECT and severe anemia assoc w/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/cPRA) levels to human leukocyte antigens or in mbr w/hx of high levels of donor-specific ab OR Transplant recipients at risk of CMV 3) Transplant recipients exp AB-mediated rejection w/ donor-specific AB OR for tx of AI DZ: A) ITP w/either active bleed or platelet count less than 30,000 mcL B) Fetal alloimmune TCP w/AB to paternal platelet antigen in maternal serum and ONE: Previously affected PREG, family hx of maternofetal alloimmune TCP or fetal blood sample shows TCP C) Isoimmune hemolytic dx of newborn, tx of severe hyperbilirubinemia D) Dermatomyositis (DMM) or polymyositis when mbr had inadeq response/intolerance/contraindication to other tx,e.g., corticosteroids, non-steroidal immunosuppressive agents AND Dx confirmed having at least 4 sx: weak trunk/proximal extremities, high serum CK or aldolase levels, unexplainable muscle pain, electromyography findings, anti-Jo-1 AB, arthralgia/arthritis w/out joint destruction, sign of systemic inflamm, e.g.,fever/elevated C-reactive protein/high SED rate or inflamm myositis seen on muscle biopsy AND using for DMM and skin lesions present or E) AI Encephalitis (AE), eval for neoplasm associated w/AE. For CONT use of AE, is clinically sig improv in symptoms on phys exam and need is demon by clinical effect (i.e, pos response, stable on current dose, or worsening of symptoms occurs from a dose dec or inc in dose intervals, or

prev dc resulted in relapse and Cancer screening continues. For 1 MISC DX: post-exposure 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 ICP OR for Kawasaki Dz tx initiated w/in 10dys of onset and tx for more than 5dys.

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

JEMPERLI

MEDICATION(S)
JEMPERLI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual has recurrent or advanced mismatch repair deficient disease with test results confirmed (written or verbal attestation acceptable) AND has a current ECOG performance status of 0-2.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent AND is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.

JUXTAPID

MEDICATION(S)
JUXTAPID 10 MG CAP, JUXTAPID 20 MG CAP, JUXTAPID 5 MG CAP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual has had an adequate trial and titration of Repatha and achieved suboptimal lipid lowering response. For Continuation use, there is confirmation (written or verbal) of LDL-C reduction has been provided.

JYNARQUE

MEDICATION(S)
JYNARQUE 15 MG TAB, JYNARQUE 30 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual has an uncorrected abnormal blood sodium level or urinary outflow obstruction OR unable to sense or appropriately respond to thirst OR has dx of hypovolemia OR is anuric OR has underlying significant liver disease (not including uncomplicated polycystic liver disease) OR will be concurrently utilizing a strong CYP3A inhibitor (such as clarithromycin, ketoconazole, itraconazole, ritonavir, indinavir, nelfinavir, saquinavir or nefazodone)

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

KADCYLA

MEDICATION(S)
KADCYLA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

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

KALYDECO

MEDICATION(S)
KALYDECO

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

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
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

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

KUVAN

MEDICATION(S)
SAPROPTERIN DIHYDROCHLORIDE

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

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
N/A

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

LEUKINE

MEDICATION(S)
LEUKINE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individuals who are at high risk for infection-associated complications demonstrated by any of the following: Expected prolonged (greater than 10 day) and profound (less than 0.1 x 10to the power of 9/L) neutropenia, Age greater than 65 years, Pneumonia or other clinically documented infection, Hypotension and multi organ dysfunction (sepsis syndrome), Invasive fungal infection, Prior episode of febrile neutropenia, Hospitalized at the time of the development of fever.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Adjunctive tx and individual as a high risk for infection-associated complications. 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 acute myeloid leukemia and using shortly after completion of induction or repeat induction chemo of AML. For myelodysplastic syndromes (MDS) with severe neutropenia (absolute neutrophil count (ANC) less than or equal to 500mm3 or experiencing recurrent/resistant infection. For mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis and autologous transplantation. For acceleration of myeloid reconstitution

after autologous or allogenic bone marrow transplantation or peripheral blood progenitor cell transplantation. For delayed neutrophil recovery/graft failure after autologous or allogenic bone marrow transplantation. Used to increase survival in individual exposed to myelosuppressive doses of radiation such as Hematopoietic Syndrome of Acute Radiation Syndrome. For malignant melanoma. For relapsed/refractory high-risk neuroblastoma AND using in combination with Danyelza (naxitamab-gqgk) OR is using in combination with dinutuximab (Unituxin), 13-cis-retinoic acid (i.e. isotretinoin) and interleukin-2 (IL-2) (i.e. aldesleukin) AND achieved a partial response to first-line multi-agent, multi-modality therapy (i.e. induction combination chemotherapy, or myeloablative consolidation chemotherapy followed by autologous stem cell transplant).

LIDOCAINE 4

MEDICATION(S)
LIDOCAINE HCL 4 % SOLUTION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

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

LIDOCAINE 5

MEDICATION(S)
LIDOCAINE 5 % 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 is using for anesthesia of accessible mucous membranes of the oropharynx (such as back of the tongue, soft palate, side and back walls of the throat, and the tonsils) OR 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
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

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).

LUMAKRAS

MEDICATION(S)
LUMAKRAS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

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

LUPRON DEPOT

MEDICATION(S)

LUPRON DEPOT (1-MONTH), LUPRON DEPOT (3-MONTH), LUPRON DEPOT (4-MONTH), LUPRON DEPOT (6-MONTH)

PENDING CMS APPROVAL

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

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

MAVYRET

MEDICATION(S)
MAVYRET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

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

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 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
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

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)

METADATE ER, METHYLPHENIDATE HCL 10 MG CHEW TAB, METHYLPHENIDATE HCL 10 MG TAB, METHYLPHENIDATE HCL 10 MG/5ML SOLUTION, METHYLPHENIDATE HCL 2.5 MG CHEW TAB, METHYLPHENIDATE HCL 20 MG TAB, METHYLPHENIDATE HCL 5 MG CHEW TAB, METHYLPHENIDATE HCL 5 MG TAB, METHYLPHENIDATE HCL 5 MG/5ML SOLUTION, METHYLPHENIDATE HCL ER 18 MG TAB ER, METHYLPHENIDATE HCL ER 20 MG TAB ER, METHYLPHENIDATE HCL ER 27 MG TAB ER, METHYLPHENIDATE HCL ER 36 MG TAB ER, METHYLPHENIDATE HCL ER 54 MG TAB ER, METHYLPHENIDATE HCL ER (CD) 10 MG CAP ER, METHYLPHENIDATE HCL ER (CD) 20 MG CAP ER, METHYLPHENIDATE HCL ER (CD) 40 MG CAP ER, METHYLPHENIDATE HCL ER (CD) 50 MG CAP ER, METHYLPHENIDATE HCL ER (CD) 60 MG CAP ER

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

6 years of age and older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

MODAFINIL

MEDICATION(S)
MODAFINIL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA

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

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).

NAMENDA LINE

MEDICATION(S)

MEMANTINE HCL 10 MG TAB, MEMANTINE HCL 28 X 5 MG & 21 X 10 MG TAB, MEMANTINE HCL 5 MG TAB, MEMANTINE HCL ER

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

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

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

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

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)
DROXIDOPA, 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 40 MG/ML SUSPENSION, POSACONAZOLE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year.

OTHER CRITERIA

N/A

NP CSF SA AGENTS

MEDICATION(S)
NEUPOGEN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

NP IVIG

MEDICATION(S)

BIVIGAM 5 GM/50ML SOLUTION, FLEBOGAMMA DIF 10 GM/100ML SOLUTION, FLEBOGAMMA DIF 10 GM/200ML SOLUTION, FLEBOGAMMA DIF 20 GM/200ML SOLUTION, FLEBOGAMMA DIF 5 GM/50ML SOLUTION, GAMMAGARD 1 GM/10ML SOLUTION, GAMMAGARD 2.5 GM/25ML SOLUTION, GAMMAGARD S/D LESS IGA, GAMMAKED 1 GM/10ML SOLUTION, GAMMAPLEX 10 GM/100ML SOLUTION, GAMMAPLEX 10 GM/200ML SOLUTION, GAMMAPLEX 20 GM/200ML SOLUTION, GAMMAPLEX 5 GM/50ML SOLUTION, PRIVIGEN 10 GM/100ML SOLUTION, PRIVIGEN 20 GM/200ML SOLUTION, PRIVIGEN 5 GM/50ML SOLUTION

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

phys exam and cont need is shown by clinical effect. For AE, dx is confirmed by specific autoab assoc with AE and Clinical present inc neuro symptoms (i.e, memory deficits, seizures, movement disorders, speech disturbances, behav changes, or psych symptoms) and Alternative etiologies of encephalitis syndrome have been ruled out, such as infectious etiologies, other neurological disorders, or other AI conditions.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

NP IG allowed if F/I to 1 PF IG (Gammunex/C, Octagam) OR PF Ig is not FDA/Off-label approved or due to clinical condition such as but not limited to: Renal insuff/impairmt, Non-O blood type, Severe IgA def, DM/pre-DM, CVD, Hyper-prolinemia, HyperNA, hi-risk of thrombosis, doc HS manifested by severe systemic/allergic or anaphylactic rxn to any ingred not also present NP agent OR if SCIG-only dose forms, may be approved for difficult vein access that precludes use of any IVIG or hx of serious rxn to IVIG expected to be avoided by using SCIG or hx of incon serum levels with IG. Tx of primary (PI) when hx of recurrent (SI) req ABX tx AND lack of/inadeq resp to immunization (IMMUN) AND no evidence of renal (nephrotic synd) and GI as causes of HGG AND INIT pre-tx total serum IgG below the lower limit of age adj lab ref range or more than 2SD below adj mean. hyperimmunoadj mean AND hx of recur SI requiring ABX therapy AND lack of/inadeq response to IMMUN OR Use for ONE: A) B-cell CLL w/ hx of recurrent bacterial or active INFECT not responding to antimicrobial tx and HGG w/ total IgG less than 500mg/dL B)MM with hx of recur bacterial or clinically severe INFECT and HGG with total IgG less than 400mg/dL C) HIV infected children to prevent opportunistic bacterial infection w/HGG (IgG less than 400mg/dL) or recurrent INFECT D) PARVO B19 chronic INFECT and severe anemia assoc w/BMS OR using in context of transplant for ONE: 1) hematopoietic stem cell transplant 2) Solid organ transplantation including prior desensit for transplantation for suppres of panel reactive anti-HLA antibody (AB) in ppl with high panel reactive AB (PRA/cPRA) levels to human leukocyte antigens or in mbr w/hx of high levels of donor-specific ab OR Transplant recipients at risk of CMV 3) Transplant recipients exp AB-mediated rejection w/ donor-specific AB OR for tx of AI DZ: A) ITP w/either active bleed or platelet count less than 30,000 mcL B) Fetal alloimmune TCP w/AB to paternal platelet antigen in maternal serum and ONE: Prev affected PREG, family hx of maternofetal alloimmune TCP or fetal blood shows TCP C) Isoimmune hemolytic dx of newborn, tx of severe HBR

D) DMM or polymyositis when mbr had F/C/I to other tx,e.g., corticosteroids, non-steroidal ISx agents AND Dx confirmed having at least 4 sx: weak trunk/proximal extremities, high serum CK or aldolase levels, unexplainable muscle pain, electromyography findings, anti-Jo-1 AB, arthralgia/arthritis w/out joint destruction, sign of systemic inflamm, e.g.,fever/elevated C-reactive protein/high SED rate or inflamm myositis seen on muscle biopsy AND using for DMM and skin lesions present or E) AI Encephalitis (AE), eval for neoplasm associated w/AE. For CONT use of AE, is clinically sig improv in sym on phys exam and need is demon by clinical effect (i.e, pos res, stable on dose, or worsening of sym occurs from dose dec or inc in dose intervals, or prev dc resulted in relapse and Cancer screening cont.

NP LA OPIOID

MEDICATION(S)
METHADONE HCL 10 MG TAB, METHADONE HCL 5 MG TAB, MORPHINE SULFATE ER, MORPHINE SULFATE ER BEADS, TRAMADOL HCL ER 100 MG TAB ER 24H, TRAMADOL HCL ER 200 MG TAB ER 24H, TRAMADOL HCL ER 300 MG TAB ER 24H, TRAMADOL HCL ER (BIPHASIC)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

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

noted by the following: (a) Individual is currently using a short-acting opioid analgesic, including use of opioid analgesia as an inpatient for post-surgical pain OR (b) Individual is transitioning from one long-acting opioid analgesic to another long-acting opioid analgesic. For continued use, 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 LA OPIOID ABUSE DETERRENT

MEDICATION(S)
BUPRENORPHINE 7.5 MCG/HR PATCH WK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

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. AND If an abuse deterrent formulation is needed [such as but not limited to Embeda ER, Hysingla ER, Targiniq ER, Troxyca ER, Xtampza ER and Zohydro ER], and individual has a history of substance abuse disorder OR individual's family member or household resident has active substance abuse disorder or a history of substance abuse disorder OR If is there is concern for abuse or dependence with pure opioid agents. 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 TZD

MEDICATION(S)
AVANDIA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Individual has had a trial and inadequate response or intolerance to metformin OR Individual has a contraindication to metformin therapy [such as but not limited to, renal insufficiency (eGFR is less than 45mL/minute/1.73m2)] AND Individual has had a trial with ONE of the following: dipeptidyl peptidase-4 (DPP-4), glucagon-like peptide-1 (GLP-1), or a sodium-glucose co-transporter-2 (SGLT2) inhibitor.

NUBEQA

MEDICATION(S)
NUBEQA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual has a diagnosis of non-metastatic castration resistant prostate cancer (nmCRPC) AND One of the following: (a) individual is concomitantly receiving a gonadotropin-releasing hormone (GnRH) analog [e.g. Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (Degarelix] OR (b) Has had a bilateral orchiectomy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

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 3) 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 AND 4) mbr is on concurrent oral corticosteroid therapy (Wechsler, 2017). 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)].

NUPLAZID

MEDICATION(S)
NUPLAZID

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial:3 months, Maintenance: 1 Year

OTHER CRITERIA
Initial therapy: Individual has a diagnosis of Parkinsons disease AND Symptoms of psychosis developed after the PD diagnosis AND Symptoms of psychosis include at least one of the following: (1) Visual hallucinations, (2) Auditory hallucination OR (3) Delusions AND Symptoms have been present for at least one month AND Individual has experienced symptoms at least once weekly. Psychiatric symptoms cannot be attributed to disorders such as schizophrenia, schizoaffective disorder, delusional disorder, or mood disorder with psychotic features, or a general medical condition including delirium. For continued therapy, the individual has had a reduction in symptoms of psychosis compared to baseline.

OCTREOTIDE LINE

MEDICATION(S)
OCTREOTIDE ACETATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

ODOMZO

MEDICATION(S)
ODOMZO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

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

OFEV

MEDICATION(S)
OFEV

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Initial: dx of idiopathic pulmonary fibrosis (IPF) is confirmed (verbal or written) by: Exclusion of other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity AND High resolution computed tomography (HRCT) with or without lung tissue sampling. Individual has 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) 2 of the following: (1) FVC decline greater than or equal to 5% and less than 10% or (2) Worsening respiratory symptoms or (3) Increased fibrosis on HRCT AND 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

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

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

OPSUMIT

MEDICATION(S)
OPSUMIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

PENDING CMS APPROVAL

ORGOVYX

MEDICATION(S)
ORGOVYX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

ORKAMBI

MEDICATION(S)
ORKAMBI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
Individual is 2 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

OTEZLA

MEDICATION(S)
OTEZLA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For plaque psoriasis (Ps) involves greater than 3% body surface area (BSA) or involves less than 3% BSA involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia).

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For Psoriatic Arthritis (PsA), Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic DMARDS (such as methotrexate, sulfasalazine, leflunomide)]. For plaque psoriasis (Ps), Individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine or methotrexate). For Behcet’s disease, Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [such as topical or systemic corticosteroid, immunosuppressants, colchicine, or NSAIDs].

OXANDRIN

MEDICATION(S)

OXANDROLONE 10 MG TAB, OXANDROLONE 2.5 MG TAB

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PADCEV

MEDICATION(S)
PADCEV

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual has diagnosis of locally advanced or metastatic urothelial cancer AND using as a single agent for 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)

ACETYLCYSTEINE 10 % SOLUTION, ACETYLCYSTEINE 20 % SOLUTION, ACYCLOVIR SODIUM, ALBUTEROL SULFATE (2.5 MG/3ML) 0.083% NEBU SOLN, ALBUTEROL SULFATE (5 MG/ML) 0.5% NEBU SOLN, ALBUTEROL SULFATE 0.63 MG/3ML NEBU SOLN, ALBUTEROL SULFATE 1.25 MG/3ML NEBU SOLN, ALBUTEROL SULFATE 2.5 MG/0.5ML NEBU SOLN, AMBISOME, AMINOSYN-PF 7 % SOLUTION, AMPHOTERICIN B 50 MG RECON SOLN, APREPITANT, ARFORMOTEROL TARTRATE, ARIKAYCE, ASTAGRAF XL, AZASAN, AZATHIOPRINE 50 MG TAB, BROVANA, BUDESONIDE 0.25 MG/2ML SUSPENSION, BUDESONIDE 0.5 MG/2ML SUSPENSION, BUDESONIDE 1 MG/2ML SUSPENSION, CALCITRIOL 0.25 MCG CAP, CALCITRIOL 0.5 MCG CAP, CALCITRIOL 1 MCG/ML SOLUTION, CASPOFUNGIN ACETATE, CINACALCET HCL, CLINIMIX E/DEXTROSE (2.75/5), CLINIMIX E/DEXTROSE (4.25/10), CLINIMIX E/DEXTROSE (4.25/5), CLINIMIX E/DEXTROSE (5/15), CLINIMIX E/DEXTROSE (5/20), CLINIMIX E/DEXTROSE (8/10), CLINIMIX E/DEXTROSE (8/14), CLINIMIX/DEXTROSE (4.25/10), CLINIMIX/DEXTROSE (4.25/5), CLINIMIX/DEXTROSE (5/15), CLINIMIX/DEXTROSE (5/20), CLINIMIX/DEXTROSE (6/5), CLINIMIX/DEXTROSE (8/10), CLINIMIX/DEXTROSE (8/14), CLINISOL SF, CLINOLIPID, CROMOLYN SODIUM 20 MG/2ML NEBU SOLN, CYCLOPHOSPHAMIDE 25 MG CAP, CYCLOPHOSPHAMIDE 50 MG CAP, CYCLOSPORINE 100 MG CAP, CYCLOSPORINE 25 MG CAP, CYCLOSPORINE MODIFIED, DOXERCALCIFEROL 0.5 MCG CAP, DOXERCALCIFEROL 1 MCG CAP, DOXERCALCIFEROL 2.5 MCG CAP, DRONABINOL, ENGERIX-B 10 MCG/0.5ML SUSPENSION, ENGERIX-B 20 MCG/ML SUSPENSION, ENVARSUS XR, EVEROLIMUS 0.25 MG TAB, EVEROLIMUS 0.5 MG TAB, EVEROLIMUS 0.75 MG TAB, FREAMINE HBC, FREAMINE III, GENGRAF, GRANISETRON HCL 1 MG TAB, HEPARIN SODIUM (PORCINE) 1000 UNIT/ML SOLUTION, HEPARIN SODIUM (PORCINE) 10000 UNIT/ML SOLUTION, HEPARIN SODIUM (PORCINE) 20000 UNIT/ML SOLUTION, HEPARIN SODIUM (PORCINE) 5000 UNIT/ML SOLUTION, HEPATAMINE, HERCEPTIN HYLECTA, INTRALIPID 20 % EMULSION, INTRON A, IPRATROPIUM BROMIDE 0.02 % SOLUTION, IPRATROPIUM-ALBUTEROL, LEVALBUTEROL HCL 0.31 MG/3ML NEBU SOLN, LEVALBUTEROL HCL 0.63 MG/3ML NEBU SOLN, LEVALBUTEROL HCL 1.25 MG/0.5ML NEBU SOLN, LEVALBUTEROL HCL 1.25 MG/3ML NEBU SOLN, LEVOCARNITINE 1 GM/10ML SOLUTION, LEVOCARNITINE 330 MG TAB, LEVOCARNITINE SF, MYCOPHENOLATE MOFETIL 200 MG/ML RECON SUSP, MYCOPHENOLATE MOFETIL 250 MG CAP, MYCOPHENOLATE MOFETIL 500 MG TAB, MYCOPHENOLATE SODIUM, NUTRILIPID, ONDANSETRON, ONDANSETRON HCL 24 MG TAB, ONDANSETRON HCL 4 MG TAB, ONDANSETRON HCL 4 MG/5ML SOLUTION, ONDANSETRON HCL 8 MG TAB, OXALIPLATIN 200 MG/40ML SOLUTION, PACLITAXEL 100 MG/16.67ML CONC, PARICALCITOL 1 MCG CAP, PARICALCITOL 2 MCG CAP, PARICALCITOL 4 MCG CAP, PENTAMIDINE ISETHIONATE,

PLENAMINE, POLIVY, PREMASOL, PROCALAMINE, PROGRAF 0.2 MG PACKET, PROGRAF 1 MG PACKET, PROSOL, PULMOZYME, RECOMBIVAX HB, RIABNI, RITUXAN 100 MG/10ML SOLUTION, SIROLIMUS 0.5 MG TAB, SIROLIMUS 1 MG TAB, SIROLIMUS 1 MG/ML SOLUTION, SIROLIMUS 2 MG TAB, SYNDROS, TACROLIMUS 0.5 MG CAP, TACROLIMUS 1 MG CAP, TACROLIMUS 5 MG CAP, TOBRAMYCIN 300 MG/5ML NEBU SOLN, TRAVASOL, TROPHAMINE 10 % SOLUTION, VANCOMYCIN HCL 100 GM RECON SOLN, VANCOMYCIN HCL 750 MG RECON SOLN, VARUBI (180 MG DOSE), ZORTRESS 1 MG TAB

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)
NEULASTA, UDENYCA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

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

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
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

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
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA

For initial request, individual meets one of the following: (A) Individual is a on high intensity statin therapy, or statin therapy at the maximum tolerated dose, where high intensity statin is defined as atorvastatin 40 mg or higher OR rosuvastatin 20 mg or higher OR (B) Individual is statin intolerant OR (C) Individual has a condition that is a contraindication for statin therapy including active liver disease, unexplained persistent elevation of serum hepatic, or pregnancy or (D) Statin associated rhabdomyolysis after a trial of one statin AND Individual is on ezetimibe (applies to individuals on statin therapy only). 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

PENDING CMS APPROVAL

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

QUININE

MEDICATION(S)
QUININE SULFATE 324 MG CAP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

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

RANEXA

MEDICATION(S)
RANOLAZINE ER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For dx chronic angina, individual has had a trial and inadequate response or intolerance to one of the following (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
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual has had a trial 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.

REGRANEX

MEDICATION(S)
REGRANEX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 months

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

REPATHA

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For (A). Homozygous Familial Hypercholesterolemia (HoFH) confirmed by: 1.Presence of two (2) mutant alleles at the LDLR, apoB, PCSK9 or ARH adaptor gene locus OR 2.untreated LDL-C concentration greater than 500 mg/dL (13 mmol/L) or treated LDL-C greater than or equal to 300 mg/dL (7.76 mmol/L) AND one of the following: i.Cutaneous or tendonous xanthoma before age of 10 years OR ii.Untreated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents (greater than190 mg/dL) OR (B). Heterozygous Familial Hypercholesterolemia (HeFH) with diagnosis confirmed by: 1.Presence of a mutation in LDLR, apolipoprotein B (ApoB), PCSK9 or ARH adaptor protein 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: 6 months. Continuation: 1 Year.

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
Individuals requesting for the treatment of erectile dysfunction.

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

PENDING CMS APPROVAL

ROZLYTREK

MEDICATION(S)
ROZLYTREK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

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

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual is using as monotherapy.

RUBRACA

MEDICATION(S)
RUBRACA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

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

RYBREVANT

MEDICATION(S)
RYBREVANT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Using Rybrevant as a single agent.

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

SAMSCA

MEDICATION(S)
TOLVAPTAN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Individual has an acute, urgent need to raise serum sodium OR is unable to sense/appropriately respond to thirst OR is anuric. Diagnosis of hypovolemic hyponatremia. Individual has underlying liver disease, including cirrhosis OR using to treat autosomal dominant polycystic kidney disease OR is currently receiving a strong CYP3A inhibitor (such as clarithromycin, ketoconazole, itraconazole, ritonavir. indinavir, nelfinavir, saquinavir, nefazodone and telithromycin).

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
30 Days

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 (A) has relapsed or refractory disease following treatment with at least two prior lines of therapy including lenalidomide and a proteasome inhibitor (for example, bortezomib, carfilzomib, or ixazomib). Or (B) has relapsed or refractory disease following treatment with one to three prior lines of therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

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

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

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, 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
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
For initial use: dx of chronic moderate to severe plaque Ps, individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate). For Continuation use, there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

SOLARAZE

MEDICATION(S)
DICLOFENAC SODIUM 3 % GEL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Dx of Actinic Keratosis

AGE RESTRICTION
18 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

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 10 MG RECON SOLN, SOMAVERT 15 MG RECON SOLN, SOMAVERT 20 MG RECON SOLN

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. Individual is using as adjunctive therapy for juvenile myoclonic epilepsy or primary generalized tonic-clonic seizure.

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

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
Individual is 18 years of age or older. For Plaque Psoriasis, age 6 and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

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

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

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)

SUNITINIB MALATE, 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

SYMDEKO

MEDICATION(S)
SYMDEKO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
6 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
Individual has a diagnosis of cystic fibrosis (CF) AND has a confirmed mutation-positive result in the cystic fibrosis transmembrane conductance regulator (CFTR) gene and the mutation type is provided and responsive to Symdeko.

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

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

N/A

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

TAKHZYRO

MEDICATION(S)
TAKHZYRO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
12 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

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

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, ECOG performance status of 0-2. Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

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
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

TEGSEDI

MEDICATION(S)
TEGSEDI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual has a baseline platelet count greater than or equal to 100 x 10 9/L AND urinary protein to creatinine ratio (UPCR) less than 1000 mg/g AND Individual has a TTR mutation confirmed by genotyping.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual has diagnosis of hereditary transthyretin (hATTR) amyloidosis or familial amyloid polyneuropathy (FAP) AND associated mild to moderate polyneuropathy. For Continuation, there is documentation (written or verbal attestation) of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improved ambulation, improvement in neurologic symptom burden, improvement in activities of daily living) AND most recent platelet count was within the past month and was greater than or equal to 100 x 109/L AND most recent urinary protein to creatinine ratio (UPCR) was within the past month and was less than 1000 mg/g.

TEPMETKO

MEDICATION(S)
TEPMETKO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

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

TESTOSTERONE INJ

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

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

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

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
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

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 25 MG/2.5GM (1%) GEL, TESTOSTERONE 30 MG/ACT SOLUTION, TESTOSTERONE 40.5 MG/2.5GM (1.62%) GEL, TESTOSTERONE 50 MG/5GM (1%) GEL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
18 years of age or older. For transgender use, individual is 16 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
For Initial use: Individual has a dx of (1) primary hypogonadism (congenital or acquired) [for example, Cryptorchidism OR Bilateral torsion OR orchitis OR Vanishing testis syndrome OR Orchiectomy OR Klinefelter Syndrome OR Chemotherapy OR Toxic damage from alcohol or heavy metals OR idiopathic primary hypogonadism]. Or (2) Hypogonadotropic hypogonadism (congenital or acquired) [for example, Idiopathic luteinizing hormone-releasing hormone (LHRH deficiency), OR Pituitary-hypothalamic injury.] Individual is transgender AND is using for a diagnosis of gender Dysphoria or gender Identity Disorder AND Goal of treatment is female-to-male gender reassignment. For continuation use, Individual meets all criteria for initial therapy AND has had serum testosterone level measured in the previous 180 days

AND Individual has obtained clinical benefits as noted by symptom improvement.

TOPICAL ONYCHOMYCOSIS

MEDICATION(S)
JUBLIA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual has a confirmed fungal infection (i.e. physical exam). And has confirmed laboratory evidence of one of the following: (1) Trichophyton rubrum OR (2) Trichophyton mentagrophytes.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
Individual has had a trial of and inadequate response or intolerance to oral itraconazole and terbinafine. Or has a, contraindication, drug interaction or concomitant clinical condition (such as but not limited history of liver disease or concerns over hepatotoxicity, history of CHF) which make use of oral itraconazole and terbinafine unacceptable OR Individual has used requested medication within the previous 6 months.

TOPICAL TRETINOIN AGENTS

MEDICATION(S)

AVITA, TRETINOIN 0.01 % GEL, TRETINOIN 0.025 % CREAM, TRETINOIN 0.025 % GEL, TRETINOIN 0.05 % CREAM, TRETINOIN 0.05 % GEL, 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

TRACLEER

MEDICATION(S)
BOSENTAN, TRACLEER 32 MG TAB SOL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
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.

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
N/A

TRUSELTIQ

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

PA INDICATION INDICATOR
N/A

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

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

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

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/Bonsity (teriparatide) (7) Teriparatide OR (8) 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 meets 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. Or (c) Individual is at very high risk for fracture as defined by one or more of the following (AACE/ACE 2020): Recent fracture (within the past 12 months), Fractures while on approved osteoporosis therapy, Multiple fractures, Fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoids), Very low T-score (less than -3.0), High risk for falls or history of injurious falls, Very high fracture probability by FRAX (fracture risk assessment tool) (e.g. major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or other validated fracture risk algorithm.

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

UBRELVY

MEDICATION(S)
UBRELVY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Using a strong CYP3A4 inhibitor (such as ketoconazole, itraconazole, clarithromycin).

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

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

UCERIS

MEDICATION(S)
BUDESONIDE ER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
N/A

UKONIQ

MEDICATION(S)
UKONIQ

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

UPTRAVI

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Pulmonary Arterial Hypertension, individual has the diagnosis of PAH confirmed by a right heart catheterization showing all of the following: (a) Mean pulmonary artery pressure (mPAP) greater than or equal to 25 mm Hg at rest (b) Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg (c) Pulmonary vascular resistance (PVR) greater than 3 Wood units.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 YEAR.

OTHER CRITERIA
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, VANCOMYCIN HCL 250 MG/5ML RECON SOLN

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

VELCADE

MEDICATION(S)
BORTEZOMIB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

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

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

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

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
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

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

XERMELO

MEDICATION(S)

XERMELO

PENDING CMS APPROVAL

XGEVA

MEDICATION(S)
XGEVA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

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

XIFAXAN - HE

MEDICATION(S)
XIFAXAN 550 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Individual is 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

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

XIFAXAN 200MG

MEDICATION(S)

XIFAXAN 200 MG TAB

PENDING CMS APPROVAL

XOLAIR

MEDICATION(S)
XOLAIR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial: 6 months. Continuation: 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 (high dose of inhaled corticosteroids plus long acting beta-2 agonists, Leukotriene modifiers, theophylline or oral corticosteroids)(GINA 2019). Continued treatment beyond 12 months is allowed when treatment has resulted in clinical improvement as documented by one or more of the following: Decreased utilization of rescue medications OR Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids) OR Increase in percent predicted FEV1 from pretreatment baseline OR Reduction in reported asthma-related symptoms, such as, but not limited to, wheezing, shortness of breath, coughing, fatigue, sleep disturbance, or asthmatic symptoms upon awakening. For chronic idiopathic urticaria, individual has had trial and inadequate response or intolerance to ONE potent antihistamine (AAAAI/ACAAI 2014). For continued use for CIU, treatment has resulted in confirmed (written or verbal) clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to itch severity and hive count).

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

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.

XURIDEN

MEDICATION(S)
XURIDEN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

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 (ICSD-3): (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) 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 100 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: 3 months. Continuation: 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 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.

ZARXIO

MEDICATION(S)
ZARXIO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

ZAVESCA

MEDICATION(S)
MIGLUSTAT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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. For continuation use, there is confirmation (written or verbal

attestation) of clinically significant improvement in clinical signs and symptoms of disease (including but not limited to reduction of spleen volume, reduction of liver volume, resolution of anemia, resolution of thrombocytopenia, reduction in fatigue, improvement in skeletal manifestations).

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
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

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

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
Initial: 6 months. Continuation: 1 Year.

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

ZYKADIA

MEDICATION(S)
ZYKADIA 150 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

ZYNLONTA

MEDICATION(S)
ZYNLONTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Individual is using as a single agent AND has a current ECOG status of 0-2 (NCT03589469).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 Year.

OTHER CRITERIA
N/A

ZYTIGA

MEDICATION(S)
ABIRATERONE ACETATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
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
N/A

REQUIRED MEDICAL INFORMATION
Confirmed vancomycin-resistant enterococcus faecium (VRE) infection. Confirmed methicillin-resistant S. aureus (MRSA) infection AND individual has had a trial and inadequate response or intolerance to 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. 1 year for MDR-TB, XDR-TB, non-tuberculous mycobacterial infection

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).