

ABRAXANE

MEDICATION(S)

ABRAXANE, PACLITAXEL PROTEIN-BOUND PART

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 melanoma, individual is using as a single agent, second line/subsequent tx and Eastern Cooperative Oncology Group (ECOG) performance status of 0-2. For persistent or recurrent ovarian cancer (epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer) OR Individual is using for the treatment of persistent or recurrent ovarian cancer (epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer) when used with carboplatin in an individual with confirmed taxane (solvent-based paclitaxel or docetaxel) hypersensitivity. For recurrent, metastatic or high-risk uterine/endometrial cancer in individual with confirmed taxane (solvent-based paclitaxel or docetaxel) hypersensitivity OR individual using for treatment of solid tumors where treatment with taxane is medically appropriate and the individual has confirmed taxane (solvent-based paclitaxel or docetaxel) hypersensitivity. For NSCLC, individual has current ECOG performance status of 0-2 OR individual is

using for NSCLC with confirmed taxane (solvent-based paclitaxel or docetaxel) hypersensitivity.

PART B PREREQUISITE

N/A

ACTEMRA

MEDICATION(S)

ACTEMRA, ACTEMRA ACTPEN

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, except for the diagnosis of JIA, PJIA. For JIA, PJIA patient is 2 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year. For the treatment of COVID: 30 days.

OTHER CRITERIA

For Initial use: rheumatoid arthritis (RA), Individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021) OR If methotrexate is not tolerated or contraindicated, individual has had an inadequate response to, is intolerant of, or has a contraindication to other conventional therapy [sulfasalazine, leflunomide, or hydroxychloroquine] AND individual has had a trial and inadequate response or intolerance to: Humira(adalimumab) OR Enbrel(etanercept). For Systemic Juvenile Idiopathic Arthritis (SJIA), agent is being used to reduce signs/symptoms or induce/maintain clinical response. Individual has failed to respond to, is tolerant of, or has a contraindication to ONE corticosteroid or nonsteroidal anti-inflammatory drug (NSAID). For Polyarticular Juvenile Idiopathic Arthritis (PJIA), Individual has had inadequate response to, is intolerant of, or has a contraindication to ONE Conventional therapy [non-biologic DMARD (such as methotrexate)] AND individual has had a

trial and inadequate response or intolerance to: Humira(adalimumab) OR Enbrel(etanercept). For any of the above indications, if the TNF agent [Enbrel(etanercept)/Humira(adalimumab)] are not acceptable due to Individual's age OR mbr has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction. Actemra may be allowed without trial of preferred TNF agents. For Multicentric Castleman Disease (MCD), agent is being used as a single agent for tx of relapsed/refractory or progressive MCD. Individual is HIV (human immunodeficiency virus) and HHV-8 (human herpes-8) negative. And individual has no concurrent clinically significant infection (for example, Hepatitis B or Hepatitis C) and has no concurrent lymphoma. For Giant Cell Arteritis, agent used in combination with a tapering course of corticosteroids (such as, prednisone) OR being used as a single agent after discontinuing corticosteroids. For chronic Antibody-mediated renal transplant rejection with the following are met (Choi 2017): mbr has chronic active antibody-mediated rejection plus donor-specific antibodies and transplant glomerulopathy AND has failed to respond to IVIG plus rituximab therapy with or without plasma exchange. For SSc-ILD, dx has been confirmed (written or verbal) through chest high resolution computed tomography (HRCT) scan showing ground glass opacification or fibrosis AND has confirmed (written or verbal) pulmonary function tests showing Forced Vital Capacity (% FVC) greater than 55% of predicted (Khanna 2020). For COVID use, individual is a hospitalized adult receiving systemic steroids and requiring oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). For Continuation use, there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

PART B PREREQUISITE

N/A

ACTIMMUNE

MEDICATION(S)

ACTIMMUNE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ACTIQ

MEDICATION(S)

ACTIQ 1200 MCG LOZ HANDLE, ACTIQ 200 MCG LOZ HANDLE, ACTIQ 400 MCG LOZ HANDLE, ACTIQ 600 MCG LOZ HANDLE, ACTIQ 800 MCG LOZ HANDLE

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 16 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 Actiq (fentanyl).

PART B PREREQUISITE

N/A

ADBRY

MEDICATION(S)

ADBRY

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For Initial use for Atopic Derm, Individual meets one of the following (A or B): (A) Failure of topical pharmacological therapy as indicated by both (1 and 2) of the following: (1) Daily treatment of topical corticosteroids of medium to higher potency for at least fourteen (14) days has failed to achieve and maintain remission of low or mild disease activity state OR (a) Topical corticosteroids are not indicated due to severe hypersensitivity reactions or concomitant clinical situations, including but not limited to (AAD 2014): (i) has lesions located in sensitive areas (including, but not limited to, face, anogenital area or skin folds) OR (ii) has steroid-induced atrophy OR (iii) History of long-term or uninterrupted topical steroid use AND (2) Daily treatment of topical calcineurin inhibitors for six (6) weeks has failed to achieve and maintain remission of low or mild disease activity state OR (a) Topical calcineurin inhibitors (TCI) are not indicated due to severe hypersensitivity reactions or concomitant clinical situations, including but not limited to (Elidel 2017, Protopic 2019): (i) History of or active malignant or pre-malignant skin conditions OR (ii) has Netherton's Syndrome or other skin diseases that can increase the risk of systemic absorption of TCI OR (iii) Individual is considered to be immunocompromised, including those on systemic immunosuppressive medications on an ongoing basis. OR (B) One of the following: (1) Phototherapy (UVB or PUVA) has failed to achieve and maintain remission of low or mild disease activity state or is contraindicated OR (2) Non-corticosteroid systemic immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil) have failed to achieve and maintain remission of low or mild disease activity state or is contraindicated.

AGE RESTRICTION

Individual is 18 years of age or older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 6 Months, Continuation: 1 year

OTHER CRITERIA

For continuation, treatment has resulted in significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to decrease in affected body surface area, pruritus, or severity of inflammation, and/or improved quality of life).

PART B PREREQUISITE

N/A

ADCIRCA

MEDICATION(S)

ADCIRCA, ALYQ, TADALAFIL (PAH), TADLIQ

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Using tadalafil-PAH formulations for the treatment of erectile dysfunction.

REQUIRED MEDICAL INFORMATION

For initial use, Individual has diagnosis of Pulmonary Arterial Hypertension World Health Organization (WHO) Group 1. Individual has the diagnosis of PAH confirmed by a right heart catheterization showing all of the following: (a) Mean pulmonary artery pressure (mPAP) greater than or equal to 25 mm Hg at rest (b) Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg (c) Pulmonary vascular resistance (PVR) greater than 3 Wood units. AND Individual has WHO functional class II- IV symptoms.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

ADEMPAS

MEDICATION(S)

ADEMPAS

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

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

PART B PREREQUISITE

N/A

AFINITOR

MEDICATION(S)

AFINITOR, AFINITOR DISPERZ, EVEROLIMUS 10 MG TAB, EVEROLIMUS 2 MG TAB SOL, EVEROLIMUS 2.5 MG TAB, EVEROLIMUS 3 MG TAB SOL, EVEROLIMUS 5 MG TAB, EVEROLIMUS 5 MG TAB SOL, EVEROLIMUS 7.5 MG TAB

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

AFREZZA

MEDICATION(S)

AFREZZA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Individual has had a physical examination including detailed medical history to identify potential lung disease.

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 diabetes mellitus and using for one of the following: 1. For type 1 diabetes, individual will be using concurrently with long-acting insulin. OR 2. For type 2 diabetes, individual has inadequate control, intolerance, or contraindication to at least 2 anti-diabetic medications and will be using concurrently with long-acting insulin.

PART B PREREQUISITE

N/A

AIMOVIG

MEDICATION(S)

AIMOVIG

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 3 months. Continuation: 1 year

OTHER CRITERIA

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

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

PART B PREREQUISITE

N/A

AJOVY

MEDICATION(S)

AJOVY

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 3 months. Continuation: 1 year

OTHER CRITERIA

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

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

PART B PREREQUISITE

N/A

ALECENSA

MEDICATION(S)

ALECENSA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ALIMTA

MEDICATION(S)

ALIMTA, PEMETREXED DISODIUM 100 MG RECON SOLN, PEMETREXED DISODIUM 500 MG RECON SOLN

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

ALPHA1-PROTEINASE INHIBITOR

MEDICATION(S)

ARALAST NP, GLASSIA, PROLASTIN-C, ZEMAIRA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

ALUNBRIG

MEDICATION(S)

ALUNBRIG

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

AMPHETAMINE LINE

MEDICATION(S)

ADZENYS XR-ODT, DYANAVEL XR

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 6 years of age or older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

AMPHETAMINE SALTS

MEDICATION(S)

AMPHET-DEXTROAMPHET 3-BEAD ER, AMPHETAMINE-DEXTROAMPHET ER, AMPHETAMINE-DEXTROAMPHETAMINE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

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

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

AMPHETAMINE SALTS - B

MEDICATION(S)

ADDERALL, ADDERALL XR, MYDAYIS

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, 6 years of age or older for extended-release. For Narcolepsy, 6 years of age or older for immediate release

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

AMPYRA

MEDICATION(S)

AMPYRA, DALFAMPRIDINE ER

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial approval 12 weeks, renewal 1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

AMVUTTRA

MEDICATION(S)

AMVUTTRA

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 initial use, member has a diagnosis of hereditary transthyretin (hATTR) amyloidosis or familial amyloid polyneuropathy (FAP) AND has associated mild to moderate polyneuropathy (NCT 03759379). For Continuation use, there is confirmation 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).

PART B PREREQUISITE

N/A

APOKYN

MEDICATION(S)

APOKYN, APOMORPHINE HCL 30 MG/3ML SOLN CART

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Erectile Dysfunction (ED) use

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 YEAR.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ARANESP

MEDICATION(S)

ARANESP (ALBUMIN FREE)

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For Initial use, Hemoglobin (Hgb) levels are less than 10 g/dL, prior to initiation of therapy (unless otherwise specified) AND the individual iron status reveals, transferrin saturation at least 20% or ferritin at least 80 ng/mL or bone marrow demonstrates adequate iron stores. For MDS, endogenous erythropoietin level is less than 500 mU/ml. For tx of anemia due to myelosuppressive chemotherapy, chemo is planned for a minimum of 2 months and the dx is non-myeloid cancer and anticipated outcome is not cure. For anemia associated with CKD ON dialysis use is to achieve and maintain hgb levels within the range of 10.0 to 11.0 g/dL. For anemia associated with CKD NOT ON dialysis use is to achieve and maintain hgb levels of 10.0g/dL. For continued use, individual demonstrates continued need for ESA treatment and has confirmation of response to treatment as evidenced by an increase in hemoglobin levels from baseline AND is using the lowest ESA dose necessary to avoid transfusions AND meets one of the following criteria: (a) Hgb level is not greater than 11.0 g/dL for CKD individuals on dialysis, or greater than 10.0 g/dL for CKD non-dialysis, unless otherwise specified (for example, pediatric individuals with CKD where target Hgb levels is within the range of 10 to 12 g/dL) OR (b) Hgb level is not greater than 11.0 g/dL for individuals using for myelosuppressive chemotherapy related anemia or myelodysplastic syndrome AND If using for myelosuppressive chemotherapy-related anemia, individual is not using beyond 6 weeks after chemotherapy has completed.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ARCALYST

MEDICATION(S)

ARCALYST

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

AUBAGIO

MEDICATION(S)

AUBAGIO, TERIFLUNOMIDE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

AURYXIA

MEDICATION(S)

AURYXIA

PA INDICATION INDICATOR

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

PART B PREREQUISITE

N/A

AUSTEDO

MEDICATION(S)

AUSTEDO, AUSTEDO XR, AUSTEDO XR PATIENT 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

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 3 months. Continuation: 1 year

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

AUVELITY

MEDICATION(S)

AUVELITY

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For MDD.

AGE RESTRICTION

Individual is 18 years of age or older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

AVASTIN

MEDICATION(S)

ALYMSYS, AVASTIN, MVASI, VEGZELMA, ZIRABEV

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

AYVAKIT

MEDICATION(S)

AYVAKIT

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis. For Advanced Systemic Mastocytosis (AdvSM), individual has a platelet count of greater than or equal to $50 \times 10^9/L$.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

AZSTARYS

MEDICATION(S)

AZSTARYS

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 6 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

BAFIERTAM

MEDICATION(S)

BAFIERTAM

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/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 relapsing multiple sclerosis (RMS) (including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease). AND has had a trial and was unable to tolerate MSB Tecfidera.

PART B PREREQUISITE

N/A

BALVERSA

MEDICATION(S)

BALVERSA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

BANZEL

MEDICATION(S)

BANZEL, RUFINAMIDE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

1 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

BARACLUDE

MEDICATION(S)

BARACLUDE, ENTECAVIR

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

2 years of age and older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

BAVENCIO

MEDICATION(S)

BAVENCIO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

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

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

Individual is 12 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

BENLYSTA

MEDICATION(S)

BENLYSTA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 6 months. Continuation: 1 Year.

OTHER CRITERIA

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

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

PART B PREREQUISITE

N/A

BEOVU

MEDICATION(S)

BEOVU 6 MG/0.05ML 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

N/A

PART B PREREQUISITE

N/A

BERINERT

MEDICATION(S)

BERINERT

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Prophylaxis for HAE attacks.

REQUIRED MEDICAL INFORMATION

Dx of HAE to be confirmed (written or verbal) by a C4 level below the lower limit of normal (as defined by laboratory testing) and either a C1 inhibitor antigenic level below the lower limit of normal (as defined by lab testing) or a C1 inhibitor functional level below the lower limit of normal (as defined by lab testing).

AGE RESTRICTION

Individual is 5 years 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 for acute HAE attacks.

PART B PREREQUISITE

N/A

BESREMI

MEDICATION(S)

BESREMI

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

18 years of age or older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

BEYFORTUS

MEDICATION(S)

BEYFORTUS

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Individual meets one of the following criteria: (A) Individual was a preterm infant born at less than 32 weeks, 0 days gestation who required at least 28 days of oxygen after birth AND continues to require medical intervention within 6 months of the start of the second RSV season (including supplemental oxygen, chronic corticosteroid therapy or diuretics) OR (B) Individual has a diagnosis of cystic fibrosis with severe lung disease (hx of hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable) or weight for length less than tenth percentile OR (C) Individual is profoundly immunocompromised (including severe combined immunodeficiency, advanced acquired immunodeficiency syndrome, undergoing organ or hematopoietic stem cell transplant, or an absolute lymphocyte count of less than 100 cells/mm³) OR (D) Individual is an American Indian OR (E) Individual is an Alaska Native.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

6 months

OTHER CRITERIA

Individual is using for the prevention of respiratory syncytial virus (RSV) AND (A) Individual is less than 8 months of age and has not previously received a dose of Beyfortus (ACIP) OR (B) Individual is 8 – 19

months of age and entering their second RSV season (ACIP).

PART B PREREQUISITE

N/A

BOSULIF

MEDICATION(S)

BOSULIF

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 YEAR.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

BOTOX-MYOBLOC-DYSPO

MEDICATION(S)

BOTOX, DYSPO, MYOBLOC, XEOMIN

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Botulinum toxin is considered cosmetic as a treatment of skin wrinkles or other cosmetic indications and is not approvable.

REQUIRED MEDICAL INFORMATION

For Cervical Dystonia (spasmodic torticollis) of mod or greater severity when: mbr is requesting initial tx AND HX of recurrent clonic and/or tonic involuntary contractions of 1 or more of the following muscles: sternocleidomastoid, splenius, trapezius and/or posterior cervical muscles AND sustained head tilt and/or abnormal posturing with limited range of motion in the neck AND duration of the condition is greater than 6 months. Subsequent injections for the tx of cervical dystonia of mod or greater severity when all the following is met: Individual is requesting subsequent injections AND response to initial tx documented in medical records. For initial use in chronic migraine, PT has 15 or more headache-days/month for more than 3 months which on at least 8 days per month has features of a migraine HA (ICHD-3) AND Individual has had trial of/inadequate response to a 2 month trial at target or usual effective dose or intolerance to 2 agents for migraine prophylaxis (at least 1 agent in any 2 of the following classes) or has contraindication to all of the following meds (AAN/AHA 2012/2015, Level A and B evidence, ICSI 2013, high quality evidence, AHS 2019): 1 of these antidepressants: amitriptyline, venlafaxine nortriptyline, duloxetine OR 1 of these beta blockers: metoprolol, propranolol, timolol (oral), nadolol, atenolol, nebivolol OR the following CCB: verapamil OR 1 of these antiepileptics: valproate sod, divalproex sod, topiramate, gabapentin.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial Chronic migraine: 6 months, Renewal: 1 Year. All others 1 Year.

OTHER CRITERIA

For Continuing tx of chronic migraine HA, mbr has completed an initial 6 month trial and has a reduction in overall number of migraine days or reduction in number of severe migraine days/month AND individual has obtained clinical benefit deemed significant by individual or prescriber including any of the following (AHS 2019): (1) 50% reduction in freq of days with HA or migraine OR (2) Significant decrease in attack duration OR (3) Significant decrease in attack severity OR (4) Improved response to acute treatment OR (5) Reduction in migraine-related disability and improvements in functioning in important areas of life OR (6) Improvements in health related quality of life and reduction in psychological stress due to migraine. Treatment of primary hyperhidrosis. Treatment of secondary hyperhidrosis. Treatment of significant drooling in patients who are unable to tolerate scopolamine. Treatment neurogenic overactive bladder (also referred to as detrusor overactivity or detrusor sphincter dyssynergia) that is inadequately controlled with anticholinergic therapy. Treatment of idiopathic overactive bladder in adults who are unresponsive to or intolerant of a trial of anticholinergic therapy. Treatment of Hirschsprung disease and associated functional obstruction caused by the inability of the internal anal sphincter to relax after prior surgical tx. For mbrs utilizing botulinum toxin concurrently with calcitonin gene-related peptide (CGRP) agents for migraine prophylaxis: A. mbr is req initial duplicate therapy AND B. has had a reduction in the overall number of migraine days or reduction in number of severe migraine days per month with the initial agent AND C. mbr continues to experience a significant number of migraine headache days or severe migraine days per month OR D. mbr is requesting continued use of both agents AND E. has had further reduction in the overall number of migraine days or reduction in number of severe migraine days per month compared to monotherapy.

PART B PREREQUISITE

N/A

BRAFTOVI

MEDICATION(S)

BRAFTOVI

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

BRIUMVI

MEDICATION(S)

BRIUMVI

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/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 relapsing multiple sclerosis (RMS) (including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease), mbr is able to ambulate without aid or rest for at least 100 meters AND If initiating therapy, mbr has experienced at least two relapses within the previous two years or one relapse within the previous year or at least one T1 gadolinium-enhancing lesion on MRI within the previous year.

PART B PREREQUISITE

N/A

BRUKINSA

MEDICATION(S)

BRUKINSA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Individual has no prior BTK inhibitor usage.

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

BUPHENYL

MEDICATION(S)

BUPHENYL, OLPRUVA (2 GM DOSE), OLPRUVA (3 GM DOSE), OLPRUVA (4 GM DOSE), OLPRUVA (5 GM DOSE), OLPRUVA (6 GM DOSE), OLPRUVA (6.67 GM DOSE), PHEBURANE, SODIUM PHENYLBUTYRATE 3 GM/TSP POWDER, SODIUM PHENYLBUTYRATE 500 MG TAB

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Using as adjunctive therapy for chronic management of hyperammonemia

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

BYLVAY

MEDICATION(S)

BYLVAY, BYLVAY (PELLETS)

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial requests, individual has serum bile acid level above the upper limit of the normal based on reference range (NCT03566238). 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

Initial 6 months, Continuation 1 year.

OTHER CRITERIA

For initial requests: Individual has a diagnosis of progressive familial intrahepatic cholestasis (PFIC) and moderate to severe pruritus due to PFIC AND individual has had a trial and inadequate response or intolerance to one systemic agent for PFIC [such as ursodeoxycholic acid, cholestyramine, rifampicin, naltrexone, or sertraline (Kremer 2014)]. For continuation requests: Individual has had a positive therapeutic response to treatment (defined as a reduction in pruritus severity from baseline) AND DOES NOT have evidence of portal HTN AND does not have evidence of hepatic decomposition (for example, variceal hemorrhage, ascites, or hepatic encephalopathy) AND individual does not have worsening or persistent fat-soluble vitamin (FSV) deficiency (includes vitamin A, D, E and K) despite adequate supplementation.

PART B PREREQUISITE

N/A

CABOMETYX

MEDICATION(S)

CABOMETYX

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

CALQUENCE

MEDICATION(S)

CALQUENCE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

CAMBIA

MEDICATION(S)

CAMBIA, DICLOFENAC POTASSIUM(MIGRAINE)

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/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 trial of and inadequate response or intolerance to up to TWO generic non-steroidal anti-inflammatory drugs (NSAIDs), one of which must be a generic diclofenac agent AND Documentation (written or verbal) has been provided which defines: (A) The inadequate response to the preferred oral NSAIDs AND (B) The medical reason Cambia (diclofenac) is clinically necessary.

PART B PREREQUISITE

N/A

CAPRELSA

MEDICATION(S)

CAPRELSA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

CARBAGLU

MEDICATION(S)

CARBAGLU, CARGLUMIC ACID

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

CAYSTON

MEDICATION(S)

CAYSTON

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

7 years of age or older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

CEQUA

MEDICATION(S)

CEQUA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Documentation (written or verbal) is provided indicating an abnormal result or response to one or more of the following dry eye disease diagnostic/assessment methods (AAO, 2018): 1) Tear break-up time (less than 10 seconds) or 2) Ocular surface dye staining using fluorescein, rose bengal, or lissamine green dyes or 3) Schirmer test (aqueous tear production of less than or equal to 10 mm of strip wetting in 5 minutes) or 4) Fluorescein clearance test/tear function index or 5) Tear osmolarity (indicating tear film instability) or 6) Tear lactoferrin concentrations in the lacrimal gland (decreased) or 7) Matrix metalloproteinase-9 (MMP-9) test.

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Individual using for moderate to severe dry eye AND has had a trial and inadequate response or intolerance to MSB Restasis OR has a known hypersensitivity to any ingredient to MSB Restasis (preferred agent) which is not also present in the requested non-preferred agent.

PART B PREREQUISITE

N/A

CERDELGA

MEDICATION(S)

CERDELGA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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).

PART B PREREQUISITE

N/A

CHANTIX

MEDICATION(S)

CHANTIX, CHANTIX CONTINUING MONTH PAK, CHANTIX STARTING MONTH PAK,
VARENICLINE TARTRATE, VARENICLINE TARTRATE (STARTER)

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

3 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

CHENODAL

MEDICATION(S)

CHENODAL

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

Individual is using for gallstone dissolution AND has a well-opacifying gallbladder with radiolucent stones AND has an increased surgical risk due to systemic disease or advanced age. For continuation, Repeat imaging studies show partial dissolution of gallstone(s).

PART B PREREQUISITE

N/A

CHOLBAM

MEDICATION(S)

CHOLBAM

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

CHORIONIC GONADOTROPIN

MEDICATION(S)

CHORIONIC GONADOTROPIN 10000 UNIT RECON SOLN, NOVAREL, PREGNYL

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Use in the following: Infertility treatments (Including use with IVF, ART), Obesity, Weight loss, Stimulation of spermatogenesis in males, Treatment of anovulation in females with infertility, Ovulation induction in females.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

6 months

OTHER CRITERIA

Individual is using for Pre-pubertal cryptorchidism not caused by anatomical obstruction in males OR Hypogonadotropic hypogonadism from pituitary deficiency in males.

PART B PREREQUISITE

N/A

CIALIS BPH

MEDICATION(S)

CIALIS 2.5 MG TAB, CIALIS 5 MG TAB, TADALAFIL 2.5 MG TAB, TADALAFIL 5 MG TAB

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 benign prostatic hyperplasia (BPH) and is using to treat the signs and symptoms of BPH.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

CIBINQO

MEDICATION(S)

CIBINQO

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 in refractory, moderate to severe atopic dermatitis, a non-corticosteroid systemic immunosuppressant (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil) has failed to achieve and maintain remission of low or mild disease activity state or are contraindicated OR a biologic therapy (such as dupilumab or tralokinumab) has failed to achieve and maintain remission of low or mild disease activity state or are contraindicated AND Individual has had a trial of and inadequate response or intolerance to Rinvoq (upadacitinib) OR The PF agent (Rinvoq (upadacitinib) is not acceptable due to individual's age. For continuation use, treatment with Cibinqo has resulted in confirmed clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to decreased pruritis, inflammation, dermatitis, or exacerbations).

PART B PREREQUISITE

N/A

CIMZIA

MEDICATION(S)

CIMZIA, CIMZIA STARTER KIT

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Individual has chronic moderate to severe (that is, extensive or disabling) 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.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

For initial use: For moderate to severe Crohn's Disease, Individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy (e.g.systemic corticosteroids, or immunosuppressants) AND Individual has had trial and inadequate response or is intolerant to Humira (adalimumab) OR Stelara (ustekinumab). For moderate to severe Rheumatoid Arthritis, Individual has had an inadequate response to, methotrexate titrated to maximally tolerated dose (ACR 2021) OR If methotrexate is not tolerated or contraindicated, individual has had an inadequate response to, is intolerant of, or has a contraindication to other ONE conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine) AND Individual has had a trial and an inadequate response or is intolerant to

Humira (adalimumab) OR Enbrel (etanercept). For moderate to severe Psoriatic Arthritis, Individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy (such as nonbiologic DMARDs) AND has had a trial and an inadequate response or is intolerant to Humira (adalimumab) OR Enbrel (etanercept) OR Cosentyx (secukinumab) OR Stelara (ustekinumab) OR Otezla (apremilast). For moderate to severe Ankylosing Spondylitis (AS), Individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy (such as NSAIDs or non-biologic DMARDs) AND has had a trial and an inadequate response or is intolerant to Humira (adalimumab) OR Enbrel (etanercept) OR Cosentyx (secukinumab). For plaque psoriasis 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) AND has had a trial of and inadequate response or intolerance to Humira (adalimumab) OR Enbrel (etanercept) OR Cosentyx (secukinumab) OR Stelara (ustekinumab) OR Skyrizi (risankizumab-rzaa) OR Otezla (apremilast). For non-radiographic axial spondyloarthritis, individual has had an inadequate response to, or has a contraindication to conventional therapy [such as NSAID or nonbiologic such as sulfasalazine]] AND has had a trial and inadequate response or intolerance to Cosentyx (secukinumab). For any of the above indications, if the PF TNF agent (Enbrel/Humira/Cosentyx/Stelara/Skyrizi/Otezla) are not acceptable due to individual's age or individual is pregnant or planning on becoming pregnant. Cimzia may be allowed without trial of preferred TNF. For Continued use, there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

PART B PREREQUISITE

N/A

CINQAIR

MEDICATION(S)

CINQAIR

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Individual has blood eosinophil counts (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 400 cells/microliter at initiation of therapy. The individual has pretreatment forced expiratory volume in one second (FEV1) less than 80% predicted AND FEV1 reversibility of at least 12% and 200mL after albuterol administration.

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial 6 months, Continuation 1 Year.

OTHER CRITERIA

For initial requests, individual must have a diagnosis of eosinophilic asthma AND individual has had a 3 month trial and inadequate response or intolerance to combination controller therapy (high dose inhaled corticosteroids plus long acting beta2-agonist, leukotriene modifiers, theophylline or oral corticosteroids) (ERS/ATS 2013) AND individual 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 dosage of oral corticosteroids (ERS/ATS 2013). For continuation Therapy:

Treatment has resulted in clinical improvement as confirmed one or more of the following: 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, but not limited to asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance or wheezing.

PART B PREREQUISITE

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.

PART B PREREQUISITE

N/A

CLINDAGEL

MEDICATION(S)

CLINDAGEL

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/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 prior trial and inadequate response of TWO formulary generic topical clindamycin 1% agents.

PART B PREREQUISITE

N/A

COMETRIQ

MEDICATION(S)

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

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

COPAXONE

MEDICATION(S)

COPAXONE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

COPIKTRA

MEDICATION(S)

COPIKTRA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 YEAR.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

CORLANOR

MEDICATION(S)

CORLANOR

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

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

PART B PREREQUISITE

N/A

COSENTYX

MEDICATION(S)

COSENTYX 150 MG/ML SOLN PRSYR, COSENTYX 75 MG/0.5ML SOLN PRSYR, COSENTYX (300 MG DOSE), COSENTYX SENSOREADY (300 MG), COSENTYX SENSOREADY PEN

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

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

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

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

PART B PREREQUISITE

N/A

COTELLIC

MEDICATION(S)

COTELLIC

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

CRESEMBA

MEDICATION(S)

CRESEMBA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/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 initiated treatment in an inpatient setting and requires continued treatment of invasive aspergillosis or mucormycosis in an outpatient setting. For invasive aspergillosis individual has an inadequate response/intolerance to or contraindication to voriconazole or liposomal amphotericin B (ATS 2011, IDSA 2008). For invasive mucormycosis individual has had an inadequate response/intolerance to or contraindication to amphotericin B (ATS 2001). Individual has human immunodeficiency virus (HIV) infection and is using to treat esophageal candidiasis refractory to oral itraconazole and/or fluconazole (AHFS).

PART B PREREQUISITE

N/A

CRINONE

MEDICATION(S)

CRINONE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Progesterone supplementation or replacement as part of an Assisted Reproductive Technology (ART) treatment for infertile women with progesterone deficiency, Progesterone supplementation/deficiency.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

CYRAMZA

MEDICATION(S)

CYRAMZA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

For urothelial cancer, 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

D.H.E INJ

MEDICATION(S)

DIHYDROERGOTAMINE MESYLATE 1 MG/ML SOLUTION

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

For migraine attacks with aura in individuals meeting the following International Headache Society (IHS) diagnostic criteria (must meet criteria A-D): A) At least 2 or more headache attacks AND B) Aura consisting of at least 1 of the following fully reversible aura sx: 1. visual symptoms (such as, flickering lights, spots or lines) OR 2. Sensory symptoms (for example, pins and needles, numbness) OR 3. Speech and/or language (for example, aphasia) OR 4. Motor (for example, weakness) OR 5. Brainstem (for example, ataxia or vertigo) OR 6. Retinal (for example, blindness) AND C) At least 3 of the following characteristics: a) At least 1 aura sx develops gradually over 5 or more minutes or b) 2 or more aura sx occur in succession or c) Each individual aura lasts 5 to 60 minutes or d) At least 1 aura sx is unilateral or e) At least 1 aura sx is positive (scintillations and pins and needles are examples of positive sx of aura) or f) The aura is accompanied or followed within 60 minutes, by headache AND D) Individuals headache is not attributed to another headache disorder (for example, transient ischemic

attack). For migraine attacks without aura in adults meeting the following IHS diagnostic criteria: 1) At least 5 or more headache attacks AND 2) Headaches lasting 4-72 hrs (untreated or unsuccessfully treated) AND 3) Headache has at least 2 or more of the following: i) Unilateral location ii) Pulsating quality iii) Moderate or severe pain intensity iv) Aggravation by or causing avoidance of routine physical activity (such as, walking or climbing stairs) AND 4) Individuals headache is accompanied by 1 or more of the following: i) Nausea, vomiting or both ii) Photophobia or phonophobia AND 5) Individuals headache is not attributed to another headache disorder (for example, transient ischemic attack). For cluster headache episodes in adults meeting the following IHS diagnostic criteria: A) At least 5 or more attacks B) Severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15 to 180 minutes if untreated AND C) Headache is accompanied by at least 1 or both of the following: 1. One or more of the following sx or signs, ipsilateral to the headache: (i) conjunctival injection and/or lacrimation (ii) nasal congestion and/or rhinorrhea (iii) eyelid edema (iv) forehead and facial sweating (v) forehead and facial flushing (vi) miosis and ptosis OR 2. A sense of restlessness or agitation AND D) Attacks have a frequency from one every other day to 8 per day for more than half of the time the disorder is active AND E) Individual's headache is not attributed to another headache disorder. DHE may also be approved: For Status migrainosus or rebound withdrawal type of headaches.

PART B PREREQUISITE

N/A

DALIRESP

MEDICATION(S)

DALIRESP, ROFLUMILAST

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

DARZALEX

MEDICATION(S)

DARZALEX, DARZALEX FASPRO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Has received treatment with daratumumab or another anti-CD38 agent

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

DAURISMO

MEDICATION(S)

DAURISMO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

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

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

DAYBUE

MEDICATION(S)

DAYBUE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

DESOXYN

MEDICATION(S)

DESOXYN, METHAMPHETAMINE HCL

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Adjunct treatment of exogenous obesity/weight loss.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Individual is 6 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Individual has a diagnosis of attention deficit hyperactivity disorder (ADHD) AND has had a trial of and insufficient response or intolerance to one of the following: (a) methylphenidate containing agent OR (b) amphetamine containing agent (such as, amphetamine/dextroamphetamine, lisdexamfetamine, or dextroamphetamine).

PART B PREREQUISITE

N/A

DIACOMIT

MEDICATION(S)

DIACOMIT

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

DIFICID

MEDICATION(S)

DIFICID

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

30 Days

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

DIMETHYL FUMARATE

MEDICATION(S)

DIMETHYL FUMARATE 120 MG CAP DR, DIMETHYL FUMARATE 240 MG CAP DR, DIMETHYL FUMARATE STARTER 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

Individual has a diagnosis of relapsing multiple sclerosis (RMS) (including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease) AND has had a trial and inadequate response or intolerance to MSB Tecfidera.

PART B PREREQUISITE

N/A

DOPTELET

MEDICATION(S)

DOPTELET

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For dx thrombocytopenia, individual has a platelet count of less than 50×10^9 /L AND has chronic liver disease and is using prior to a planned procedure.

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

For CLD, 1 year. For ITP, Initial 6 months, Continuation 1 year.

OTHER CRITERIA

For initial use for chronic immune thrombocytopenia (ITP), individual has had a prior trial and an insufficient response to one of the following: (a) Corticosteroids or (b) Immunoglobulins (for example, IVIG) or (c) Splenectomy (ASH, 2011) AND individual has a platelet count of less than 30×10^9 /L. For continued use for ITP, individual is maintaining a platelet count ($50 - 100 \times 10^9$ /L) to decrease the risk of bleeding AND has demonstrated a response to therapy as confirmed by increased platelet counts.

PART B PREREQUISITE

N/A

DOXIL

MEDICATION(S)

DOXIL, DOXORUBICIN HCL LIPOSOMAL

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

DPP4

MEDICATION(S)

ALOGLIPTIN BENZOATE, ALOGLIPTIN-METFORMIN HCL, ALOGLIPTIN-PIOGLITAZONE, KAZANO, KOMBIGLYZE XR, NESINA, ONGLYZA, OSENI, SAXAGLIPTIN HCL, SAXAGLIPTIN-METFORMIN 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

Individual has had a trial and inadequate response or intolerance to metformin (AACE/ACE 2020) OR Individual has a contraindication to metformin therapy [including but not limited to, renal insufficiency (eGFR less than 45 mL/min/1.73 m²)] AND Individual has had a trial and inadequate response or intolerance to ONE of the following: Januvia (sitagliptin), Tradjenta (linagliptin), Janumet (sitagliptin/metformin), Janumet XR (sitagliptin/metformin), Jentadueto (linagliptin/metformin), OR Jentadueto XR (linagliptin/metformin).

PART B PREREQUISITE

N/A

DUAVEE

MEDICATION(S)

DUAVEE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Age 18 through age 75

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

DUOBRII

MEDICATION(S)

DUOBRII

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/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 plaque psoriasis AND Documentation (verbal or written) has been provided for why the combination agent is clinically necessary and not for convenience.

PART B PREREQUISITE

N/A

DUOPA

MEDICATION(S)

DUOPA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

DUPIXENT

MEDICATION(S)

DUPIXENT

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For dx of mod-severe asthma as demon by (NHLBI 2007): (a) pretx FEV1 less than or equal to 80% predicted AND (b) FEV1 reversibility of at least 12% and 200ml after albuterol (salbutamol) admin. For dx of chronic rhinosinusitis with nasal polyposis (CRSwNP), dx is confirmed by (AAO-HNSF 2015): (a) Anterior rhinoscopy or (b) Nasal endoscopy or (c) CT scan. For initial use in atopic derm (AD), A) fx of BOTH (I and II): I. Daily tx of topical steroids of med to higher potency for at least 14 days has fx to achieve and maintain remission of low or mild dz activity state OR use not indicated due to severe hypersensitivity rx (HSR) or concomitant clinical situations, including but not limited to (AAD 2014): has lesions located in sensitive areas OR has steroid-induced atrophy OR Hx of long-term or uninterrupted topical steroid use. AND II. Daily tx of topical calcineurin inhibitors (TCI) for 6 weeks has fx to achieve and maintain remission of low or mild dz activity state OR TCI not indicated due to severe HSR or concomitant clinical situations, including but not limited to: hx of or active malignant or pre-malignant skin conditions OR has Netherton's Syndrome or other skin dz that can inc the risk of systemic absorption of TCI OR is considered to be immunocompromised, including those on systemic immunosuppressive medications on an ongoing basis. OR B) One of the following: Phototherapy (UVB or PUVA) has fx to achieve and maintain remission of low or mild dz activity state or is contraindicated OR Non-corticosteroid systemic immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil) has fx to achieve and maintain remission of low or mild dz activity state or is contraindicated. For cont use in AD, has resulted in significant improvement or stabilization in clinical signs and symptoms of dz (including but not limited to dec in affected body surface area, pruritus, or severity of inflammation, and/or improved QOL).

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

For initial tx of Asthma, (A) indiv has one of the following: (i) has a blood eosinophil count (in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic dz, and known or suspected parasitic infection) greater than or equal to 150 cells/microliter at initiation of therapy AND (ii) has had a 3 month trial and inadequate response or intolerance to combination controller therapy (medium-to-high dose inhaled steroids plus long acting beta2 –agonists, leukotriene modifiers, theophylline or oral steroids) (ERS/ATS 2013). OR (iii) has oral steroid dependent asthma AND (iv) has had a 3 month trial and inadequate response or intolerance to high dose inhaled steroid with daily oral glucocorticoids given in combination with a controller medication (either a long-acting beta2-agonist, or leukotriene receptor antagonist, or theophylline) (ERS/ATS 2013) AND (B) indiv has experienced two or more asthma exacerbations in the prior 12 months requiring use of a systemic steroid or temporary increase in the mbrs usual maintenance dosage of oral steroids. For cont tx of asthma: (a) mbr has exp one or more of the following: (i) Dec utilization of rescue medications OR (ii) Dec frequency of exacerbations (defined as worsening of asthma that requires an increase in inhaled steroid dose or tx with systemic steroids) OR (iii) Increase in predicted FEV1 from pretx baseline OR (iv) Reduction in reported asthma-related symptoms, such as, asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing. For dx CRSwNP, mbr has had a recent trial and inadequate response to maintenance intranasal steroid (AAO-HNSF 2015) AND is refractory to, or is ineligible or intolerant to the following: (a) Systemic steroids or (b) Sino-nasal surgery AND is using dupilumab as add on therapy to maintenance intranasal steroid. For continued use for CRSwNP, there is confirmed clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in nasal polyp score or nasal congestion score).

PART B PREREQUISITE

N/A

DURAGESIC PATCH

MEDICATION(S)

FENTANYL

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Individual is 2 years of age or older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

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

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

PART B PREREQUISITE

N/A

EGRIFTA

MEDICATION(S)

EGRIFTA SV

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial 6 months, Continuation 1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ELIDEL

MEDICATION(S)

ELIDEL, PIMECROLIMUS

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Individual is 2 years of age and older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

ELIGARD_GNRH

MEDICATION(S)

ELIGARD

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ELITEK

MEDICATION(S)

ELITEK

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

30 DAYS.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

ELYXYB

MEDICATION(S)

ELYXYB

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/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 trial of and inadequate response or intolerance to up to TWO generic non-steroidal anti-inflammatory drugs (NSAIDs) AND Documentation (written or verbal) has been provided which defines: (A) the inadequate response to the preferred oral NSAIDs AND (B) the medical reason Elyxyb (celecoxib oral solution) is clinically necessary.

PART B PREREQUISITE

N/A

EMFLAZA

MEDICATION(S)

EMFLAZA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

One of the following: (1) Documentation has been provided for excessive weight-gain with prednisone (increase of greater than 0.5 Z score from prior growth curve expectations [American Academy of Pediatrics/CDC Weight for Age Growth Chart, Z-score data files, CDC, Weight-for-age charts, 2 to 20 years, selected weight z-scores in kilograms, by sex and age]) AND Weight gain is likely to be a direct result of prednisone use. Or (2) Documentation has been provided regarding the presence of clinically significant neuropsychiatric side effects while on prednisone (such as but not limited to aggression) AND Neuropsychiatric side effects are likely to be the direct result of prednisone use.

AGE RESTRICTION

Individual is 5 years of age or older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

6 months

OTHER CRITERIA

For initial treatment of Duchenne Muscular Dystrophy (DMD) AND Individual has had a 6 month trial of oral prednisone (AAN 2016, DrugPoints B, IIa). Request for continuation of therapy when one of the following: (1) when approved due to excess weight gain with prednisone, individual has experienced a return to baseline growth curve expectations or remained on the same growth curve that was in effect when Emflaza was initiated (American Academy of Pediatrics/CDC Weight for Age Growth Chart, Z-

score data files, CDC, Weight-for-age charts, 2 to 20 years, selected weight z-scores in kilograms, by sex and age) Or (2) When approved due to neuropsychiatric side effects while on prednisone, individual has shown improvement in neuropsychiatric symptoms.

PART B PREREQUISITE

N/A

EMGALITY

MEDICATION(S)

EMGALITY, EMGALITY (300 MG DOSE)

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 3 months. Continuation: 1 year

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

EMPLICITI

MEDICATION(S)

EMPLICITI

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

EMSAM

MEDICATION(S)

EMSAM

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ENBREL

MEDICATION(S)

ENBREL, ENBREL MINI, ENBREL SURECLICK

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

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

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

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

PART B PREREQUISITE

N/A

ENHERTU

MEDICATION(S)

ENHERTU

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

ENSPRYNG

MEDICATION(S)

ENSPRYNG

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial therapy, Individual has neuromyelitis optica spectrum disorder that is seropositive as confirmed the presence of anti- aquaporin-4 (AQP4) antibodies AND has a history of at least one acute attack or relapse in the last 12 months prior to initiation of therapy (Yamamura 2019, Traboulsee 2020). For continued use, individual has experienced a clinical response (for example, a reduction in the frequency of relapse).

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ENTYVIO

MEDICATION(S)

ENTYVIO 300 MG RECON SOLN

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Individual is 6 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

For Initial use: UC or CD, individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as systemic corticosteroids or immunosuppressants) AND Individual has had a trial and an inadequate response or is intolerant to Humira (adalimumab) OR Stelara (ustekinumab). For the above indications, if the TNF agent (Humira (adalimumab)/Stelara (ustekinumab)) is not acceptable due to Individual's age. Entyvio may be allowed without trial of preferred TNF. For Continuation use: there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

PART B PREREQUISITE

N/A

EPCLUSA

MEDICATION(S)

EPCLUSA, SOFOSBUVIR-VELPATASVIR

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

EPIDIOLEX

MEDICATION(S)

EPIDIOLEX

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

EPIDUO AGENTS

MEDICATION(S)

ADAPALENE-BENZOYL PEROXIDE 0.1-2.5 % GEL, ADAPALENE-BENZOYL PEROXIDE 0.3-2.5 % GEL, EPIDUO, EPIDUO FORTE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/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 acne, Individual has had a prior trial and inadequate response to the following: (a) One preferred topical retinoid agent AND (b) One topical benzoyl peroxide agent.

PART B PREREQUISITE

N/A

EPOGEN AND PROCRIT

MEDICATION(S)

EPOGEN, PROCRIT, RETACRIT

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

ERAXIS

MEDICATION(S)

ERAXIS

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ERBITUX

MEDICATION(S)

ERBITUX

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

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

REQUIRED MEDICAL INFORMATION

Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis. For stage IV, kras wild type colon, rectal, colorectal, appendix, or anal adenocarcinoma when used as a single agent or as part of combination therapy. For squamous cell carcinoma of the Head and/or Neck cancer, Erbitux is used in combination with radiation therapy, for the treatment of locally or regionally advanced disease. Or as a single agent for the treatment of patients with recurrent or metastatic disease for whom prior platinum-based therapy has failed. Or in combination with platinum-based therapy with 5-FU (fluorouracil) as first-line treatment for individuals with recurrent locoregional disease or metastatic SCCHN. OR as a single agent or in combination therapy with or without radiation therapy for any of the following indications, unresectable locoregional recurrence or second primary in individuals who have received prior radiation therapy OR resectable locoregional recurrence in individuals who have not received prior radiation therapy OR distant metastases.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ERIVEDGE

MEDICATION(S)

ERIVEDGE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

ERLEADA

MEDICATION(S)

ERLEADA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ERWINASE

MEDICATION(S)

RYLAZE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ESBRIET

MEDICATION(S)

ESBRIET, PIRFENIDONE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

EVEKEO

MEDICATION(S)

AMPHETAMINE SULFATE, EVEKEO, EVEKEO ODT

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Individual is using for exogenous obesity/weight loss [Exclusion from Part D].

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

3 years of age or older for attention deficit hyperactivity disorder (ADHD). 6 years of age or older for narcolepsy.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

EVENITY

MEDICATION(S)

EVENITY

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 young adult reference population OR a Clinical diagnosis based on a history of a low trauma fracture (fragility fracture) at high risk for fracture.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Individual meets one of the following: (A) Individual has been refractory to a trial of a bisphosphonate therapy OR (B) Intolerance or contraindications to a bisphosphonate as defined by having at least one of the following: 1. Hypersensitivity to TWO bisphosphonates (one of which must be alendronate) 2. Inability to sit or stand upright for at least 30 minutes, 3. Pre-existing gastrointestinal disorders (Barrett's esophagus, hypersecretory disorders, delayed esophageal emptying, etc.). 4. Severe renal insufficiency as defined by creatinine clearance less than 35 mL/min for alendronate agents and zoledronic acid or creatinine clearance less than 30 mL/min for risedronate and ibandronate. (C) Individual is at very high risk for fracture as defined by one or more of the following (AACE/ACE 2020): Recent fracture (within the past 12 months), Fractures while on approved osteoporosis therapy,

Multiple fractures, Fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoids), Very low T-score (less than -3.0), High risk for falls or history of injurious falls, or Very high fracture probability by FRAX (fracture risk assessment tool) (e.g. major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or other validated fracture risk algorithm. Individual has utilized Evenity (romosozumab-aqqg) for a total duration of less than 12 months in their lifetime. Individual has been refractory to, is intolerant of, or has a contraindication to one of the following: Prolia (denosumab) OR Forteo/Bonsity (teriparatide) OR Tymlos (abaloparatide).

PART B PREREQUISITE

N/A

EVKEEZA

MEDICATION(S)

EVKEEZA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For Homozygous Familial Hypercholesterolemia (HoFH) confirmed (written or verbal) by: (1) Presence of two mutant alleles at the LDLR, apoB, PCSK9 or ARH adaptor protein (LDLRAP1) gene locus OR (2) Presence of the following: (a) 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). Genetic testing has confirmed (written or verbal) the individual is LDLR negative (NLA 2017).

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 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 contraindication for statin therapy including active liver disease, unexplained persistent elevation of serum hepatic, or pregnancy. Individual also has had a trial and inadequate

response or intolerance to Repatha (evolocumab). For continuation, Individual continues to receive concomitant lipid lower therapy including maximally tolerated statin therapy (unless contraindication or individual is statin intolerant), and/or PCSK9 inhibitor therapy (Repatha) AND there is confirmation (verbal or written attestation) of LDL reduction.

PART B PREREQUISITE

N/A

EVRYSDI

MEDICATION(S)

EVRYSDI

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis of spinal muscular atrophy (SMA) by confirmation (written or verbal attestation) of either: (A) Spinal Muscular Atrophy (SMA) diagnostic test results confirming 0 copies of SMN1 OR (B) Molecular genetic testing of 5q SMA for any of the following: (1) Homozygous gene deletion OR (2) Homozygous conversion mutation OR (3) Compound heterozygote.

AGE RESTRICTION

Individual is 2 months of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial and Continuation 6 months.

OTHER CRITERIA

Initial requests, individual has confirmation (written or verbal attestation) of SMA-associated signs and symptoms AND (1) has confirmation (written or verbal attestation) of genetic testing confirming 2 copies of SMN2 (Darras 2021) AND has confirmation of symptom onset before 3 months of age (Darras 2021). OR (2) Individual is 2 years of age or older AND is non-ambulant as defined by being unable to walk unassisted for greater than or equal to 10m (NCT02908685). AND Individual does not require use of invasive ventilation or tracheostomy as a result of advanced SMA disease. For continuation, when initial therapy was determined to meet the above criteria AND individual has confirmation (written or verbal attestation) of clinically significant improvement in spinal muscular

atrophy-associated signs and symptoms (i.e., progression, stabilization, or decreased decline in motor function) compared to the predicted natural history trajectory of disease AND does not require use of invasive ventilation or tracheostomy as a result of advanced SMA disease. For INITIAL use following treatment with Zolgensma (onasemnogene abeparvovec-xioi): individual meets initial criteria above AND individual has experienced a confirmed decline in clinical status (for example, loss of motor milestone) since receipt of gene therapy.

PART B PREREQUISITE

N/A

EXJADE

MEDICATION(S)

DEFERASIROX 125 MG TAB SOL, DEFERASIROX 250 MG TAB SOL, DEFERASIROX 500 MG TAB SOL, EXJADE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Individual is 2 years of age or older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

EXKIVITY

MEDICATION(S)

EXKIVITY

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

EYLEA

MEDICATION(S)

EYLEA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

FABIOR

MEDICATION(S)

ARAZLO, FABIOR, TAZAROTENE 0.1 % FOAM

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Individual is using for any of the following: Cosmetic purposes OR Photoaging OR Wrinkles OR Hyperpigmentation OR Sun damage OR Melasma.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

FABRAZYME

MEDICATION(S)

FABRAZYME

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

Individual is 8 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

For Initial use, 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. For continued use, individual has had a positive therapeutic response to treatment.

PART B PREREQUISITE

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

Individual is 12 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 6 months. Continuation: 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.

PART B PREREQUISITE

N/A

FASLODEX

MEDICATION(S)

FASLODEX, FULVESTRANT

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

FENTORA

MEDICATION(S)

FENTANYL CITRATE 100 MCG TAB, FENTANYL CITRATE 200 MCG TAB, FENTANYL CITRATE 400 MCG TAB, FENTANYL CITRATE 600 MCG TAB, FENTANYL CITRATE 800 MCG TAB, FENTORA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

FERRIPROX

MEDICATION(S)

DEFERIPRONE, FERRIPROX, FERRIPROX TWICE-A-DAY

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

FETZIMA

MEDICATION(S)

FETZIMA, FETZIMA TITRATION

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

FILSPARI

MEDICATION(S)

FILSPARI

PA INDICATION INDICATOR

N/A

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial request, diagnosis has been verified with kidney biopsy. Individual has had a trial of angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) therapy AND has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g AND has an eGFR greater than or equal to 30 mL/min/1.73 m².

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 6 months, Continuation: 1 year

OTHER CRITERIA

For continuation request, there is clinically significant reduction in proteinuria.

PART B PREREQUISITE

N/A

FINTEPLA

MEDICATION(S)

FINTEPLA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Individual is using for weight loss/reduction.

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

FIRAZYR

MEDICATION(S)

FIRAZYR, ICATIBANT ACETATE, SAJAZIR

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Prophylaxis for HAE attacks.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

FIRDAPSE

MEDICATION(S)

FIRDAPSE, RUZURGI

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis is confirmed (written or verbal) by one of the following: Presence of anti-P/Q type voltage-gated calcium channel (VGCC) antibodies or Characteristic electrodiagnostic findings using nerve conduction tests, repetitive nerve stimulation (RNS), exercise testing, or single fiber electromyography (SFEMG).

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 3 months. Continuation: 1 year

OTHER CRITERIA

For initial requests, individual has diagnosis of Lambert Eaton myasthenic syndrome. For Continued treatment, there is objective evidence that the individual achieved and sustained meaningful improvement in muscle strength.

PART B PREREQUISITE

N/A

FIRMAGON

MEDICATION(S)

FIRMAGON, FIRMAGON (240 MG DOSE)

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

FLECTOR PATCH

MEDICATION(S)

DICLOFENAC EPOLAMINE, FLECTOR, LICART

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

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 for the treatment of acute pain from one of the following: (a) Minor strain OR (b) Sprain OR (c) Contusion.

PART B PREREQUISITE

N/A

FORTEO

MEDICATION(S)

FORTEO, TERIPARATIDE (RECOMBINANT)

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

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

PART B PREREQUISITE

N/A

FOTIVDA

MEDICATION(S)

FOTIVDA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

GALAFOLD

MEDICATION(S)

GALAFOLD

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial use, Individual has a diagnosis of Fabry disease as confirmed (written or verbal) 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

For initial use, 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. For continued use, Individual has had a positive therapeutic response to treatment.

PART B PREREQUISITE

N/A

GAMASTAN

MEDICATION(S)

GAMASTAN

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Pre-Exposure of HAV, mbr will get IM inj prior to exposure AND mbr has no clinical manifestations of hepatitis A AND is unvaccinated (CDC 2018/2019) along with one of the following: unable to receive HAV vaccine (such as, contraindication to or unavailability of the vaccine) OR mbr is considered high-risk (such as but not limited to, travel to an endemic area, over 40 years of age, immunocompromised, or diagnosis of chronic liver disease) and will receive a simultaneous dose of HAV vaccine unless contraindicated. Post-Exposure of HAV, mbr will get IM inj within 2 weeks of exposure AND mbr has no clinical manifestations of hepatitis A AND is unvaccinated (CDC 2020) along with one of the following: unable to receive HAV vaccine (such as, contraindication to or unavailability of the vaccine) OR mbr is considered high-risk (such as but not limited to, immunocompromised, diagnosis of chronic liver disease, or vaccine contraindication). For post exposure prophylaxis of rubeola, must be given within 6 days of exposure and not concomitantly with a vaccine containing the measles virus AND eligible

exposed, non-immune individuals will receive a vaccine containing the measles virus greater than or equal to 6 months after receiving intramuscular immune globulin (CDC 2013) AND used in mbr considered at risk for severe disease and complications: infants or previously unvaccinated and ineligible to receive a vaccine containing the measles virus (such as, but not limited to, vaccine contraindication or an initial exposure greater than 72 hours) or no evidence of measles immunity in particular pregnant woman or severely immunocompromised individuals. For post-exposure prophylaxis of varicella infection in susceptible individuals (such as, immunocompromised) AND varicella-zoster immune globulin (human) (VZIG) and immune globulin intravenous (IGIV) are not available. For post-exposure prophylaxis administered within 72 hours of exposure to a confirmed case of rubella to modify to suppress symptoms (label, CDC 2001) AND mbr is in the early stages (first trimester) of pregnancy, and will not consider terminating the pregnancy.

PART B PREREQUISITE

N/A

GATTEX

MEDICATION(S)

GATTEX

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

GAUCHERS

MEDICATION(S)

VPRIV

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Continuation use, there is confirmation 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).

PART B PREREQUISITE

N/A

GAVRETO

MEDICATION(S)

GAVRETO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Individual is using as monotherapy.

PART B PREREQUISITE

N/A

GAZYVA

MEDICATION(S)

GAZYVA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

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

PART B PREREQUISITE

N/A

GILENYA

MEDICATION(S)

FINGOLIMOD HCL, GILENYA, TASCENSO ODT

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

GILOTRIF

MEDICATION(S)

GILOTRIF

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

GIVLAARI

MEDICATION(S)

GIVLAARI

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Individual has acute hepatic porphyria and confirmation (written or verbal) of one of the following subtypes (APF 2010-2019): Acute intermittent porphyria (AIP) OR Hereditary coproporphyria (HCP) OR Variegate porphyria (VP) OR ALA dehydratase-deficiency porphyria (ADP) AND documentation (written or verbal) of elevated urinary or plasma porphobiligen or delta-aminolevulinic acid within the past year (Balwani 2019) AND individual meets one of the following: (a) has active symptomatic disease with at least 2 documented (written or verbal) porphyria attacks within the last 6 months (Balwani 2019). OR (b) Individual is currently on prophylactic hemin treatment due to history of severe or frequent porphyria attacks.

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 6 months. Continuation: 1 Year.

OTHER CRITERIA

For Continuation Therapy: Individual has experienced a clinical response to therapy (for example, a reduction in the number of porphyria attacks) AND does not have severe or clinically significant transaminase elevations defined as alanine aminotransferase (ALT) greater than 5 times the upper limit of normal (Balwani 2019).

PART B PREREQUISITE

N/A

GLATIRAMER AGENTS

MEDICATION(S)

GLATIRAMER ACETATE, GLATOPA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/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 (including but not limited to confirmed clinical relapse, new or enlarged lesions on MRI or confirmed disability progression) or intolerance to MSB Copaxone AND documentation (written or verbal) has been provided for why the requested [Glatiramer acetate, Glatopa (glatiramer acetate)] agent is clinically necessary.

PART B PREREQUISITE

N/A

GLEEVEC

MEDICATION(S)

GLEEVEC, IMATINIB MESYLATE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

GLEOSTINE

MEDICATION(S)

GLEOSTINE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

GRANIX

MEDICATION(S)

GRANIX

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 0.1×10 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 $450/\mu L$) 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 $1500mm^3$), poor renal function (GFR less than $60mL/min$) , liver dysfunction (liver function tests at least 2x upper limit of normal or bilirubin gr than $2.0 mg/dL$) (Lyman 2014) (Aagaard 2018), recent surgery performed as part of cancer management within previous 30 days (not to include a procedure such as port placement, drain placement, IVC filter, etc) (Lyman 2014, Aagaard 2018). History of active infection within previous 60 days (Lyman 2014, Aagaard 2018). Current open wound and chemotherapy cannot be delayed (Lyman 2014, Aagaard 2018).

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

GRASTEK

MEDICATION(S)

GRASTEK

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For grass pollen induced allergic rhinitis, individual has a confirmed (verbal or written attestation) positive skin test OR positive in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens. Individual has had a trial of, and inadequate symptom control or intolerance to (1) nasal steroid and (1) non-sedating antihistamine AND individual has a confirmed (verbal or written attestation) prescription for an auto-injectable epinephrine product.

AGE RESTRICTION

Individual is between the ages of 5 years and 65 years old.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Treatment is initiated at least 12 weeks before the expected onset of grass pollen season and is continued throughout the season.

PART B PREREQUISITE

N/A

HAEGARDA

MEDICATION(S)

HAEGARDA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

Individual is 6 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

HARVONI

MEDICATION(S)

HARVONI, LEDIPASVIR-SOFOSBUVIR

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

HEPSERA

MEDICATION(S)

ADEFOVIR DIPIVOXIL, HEPSERA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

12 years of age and older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

HETLIOZ

MEDICATION(S)

HETLIOZ, HETLIOZ LQ, TASIMELTEON

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

HORIZANT

MEDICATION(S)

HORIZANT

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For diagnosis post herpetic neuralgia (PHN), individual has had a trial of immediate release gabapentin. For diagnosis restless leg syndrome (RLS) individual has has had a trial of or contraindication/intolerance to either pramipexole OR Ropinirole.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

HP ACTHAR

MEDICATION(S)

ACTHAR, CORTROPHIN

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

PART B PREREQUISITE

N/A

HRM AGE

MEDICATION(S)

AMOXAPINE, ANAFRANIL, 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, NORPRAMIN, PERPHENAZINE-AMITRIPTYLINE, PHENOBARBITAL 100 MG TAB, PHENOBARBITAL 15 MG TAB, PHENOBARBITAL 16.2 MG TAB, PHENOBARBITAL 20 MG/5ML ELIXIR, PHENOBARBITAL 30 MG TAB, PHENOBARBITAL 32.4 MG TAB, PHENOBARBITAL 60 MG TAB, PHENOBARBITAL 64.8 MG TAB, PHENOBARBITAL 97.2 MG TAB, PROTRIPTYLINE HCL

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

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

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

HRM AGE AU

MEDICATION(S)

ACTIVELLA, ADTHYZA, ALLZITAL, AMABELZ, ANGELIQ, ARMOUR THYROID, ASCOMP-CODEINE, BAC, BENZTROPINE MESYLATE, BIJUVA, BONJESTA, BUPAP, BUTALBITAL-ACETAMINOPHEN 50-300 MG CAP, BUTALBITAL-ACETAMINOPHEN 50-300 MG TAB, BUTALBITAL-ACETAMINOPHEN 50-325 MG TAB, BUTALBITAL-APAP-CAFF-COD, BUTALBITAL-APAP-CAFFEINE, BUTALBITAL-ASA-CAFF-CODEINE, BUTALBITAL-ASPIRIN-CAFFEINE, CARBINOXAMINE MALEATE, CHLORDIAZEPOXIDE-CLIDINIUM, CHLORZOXAZONE, CLEMASTINE FUMARATE 0.67 MG/5ML SYRUP, CLEMASTINE FUMARATE 2.68 MG TAB, CLIMARA, CLIMARA PRO, COMBIPATCH, CYCLOBENZAPRINE HCL 10 MG TAB, CYCLOBENZAPRINE HCL 5 MG TAB, CYCLOBENZAPRINE HCL 7.5 MG TAB, CYPROHEPTADINE HCL 2 MG/5ML SYRUP, DEMEROL, DICLEGIS, DIGOX 250 MCG TAB, DIGOXIN 0.25 MG/ML SOLUTION, DIGOXIN 250 MCG TAB, DIPHENHYDRAMINE HCL 12.5 MG/5ML ELIXIR, DIPYRIDAMOLE 25 MG TAB, DIPYRIDAMOLE 50 MG TAB, DIPYRIDAMOLE 75 MG TAB, DISOPYRAMIDE PHOSPHATE, DIVIGEL, DOTTI, DOXEPIN HCL 3 MG TAB, DOXEPIN HCL 6 MG TAB, DOXYLAMINE-PYRIDOXINE, EDLUAR, ELESTRIN, ERGOLOID MESYLATES 1 MG TAB, ESGIC, ESTRADIOL 0.025 MG/24HR PATCH TW, ESTRADIOL 0.025 MG/24HR PATCH WK, ESTRADIOL 0.0375 MG/24HR PATCH TW, ESTRADIOL 0.0375 MG/24HR PATCH WK, ESTRADIOL 0.05 MG/24HR PATCH TW, ESTRADIOL 0.05 MG/24HR PATCH WK, ESTRADIOL 0.06 MG/24HR PATCH WK, ESTRADIOL 0.075 MG/24HR PATCH TW, ESTRADIOL 0.075 MG/24HR PATCH WK, ESTRADIOL 0.1 MG/24HR PATCH TW, ESTRADIOL 0.1 MG/24HR PATCH WK, ESTRADIOL 0.25 MG/0.25GM GEL, ESTRADIOL 0.5 MG/0.5GM GEL, ESTRADIOL 0.75 MG/0.75GM GEL, ESTRADIOL 1 MG/GM GEL, ESTRADIOL 1.25 MG/1.25GM GEL, ESTRADIOL-NORETHINDRONE ACET, ESTROGEL, EVAMIST, FEXMID, FIORICET, FIORICET/CODEINE, FYAVOLV, GUANFACINE HCL, INDOCIN 25 MG/5ML SUSPENSION, INDOMETHACIN 25 MG CAP, INDOMETHACIN 50 MG CAP, INDOMETHACIN ER, JINTELI, KETOROLAC TROMETHAMINE 10 MG TAB, KETOROLAC TROMETHAMINE 15 MG/ML SOLUTION, KETOROLAC TROMETHAMINE 30 MG/ML SOLUTION, KETOROLAC TROMETHAMINE 60 MG/2ML SOLUTION, LANOXIN 0.25 MG/ML SOLUTION, LANOXIN 250 MCG TAB, LIBRAX, LORZONE, LYLLANA, MEGESTROL ACETATE 625 MG/5ML SUSPENSION, MENEST, MENOSTAR, 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, METAXALONE, MIMVEY, MINIVELLE, NIFEDIPINE 10 MG CAP, NIFEDIPINE 20 MG CAP, NORETHINDRONE-ETH ESTRADIOL, NORGESIC, NORGESIC FORTE, NORPACE, NORPACE CR, NP THYROID, ORPHENADRINE-ASPIRIN-CAFFEINE, ORPHENGESIC FORTE, PENTAZOCINE-NALOXONE HCL, PREFEST, 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, PREMPHASE, PREMPRO, PROMETHAZINE HCL 12.5 MG SUPPOS, PROMETHAZINE HCL 25 MG SUPPOS, PROMETHEGAN, RYCLORA, RYVENT, SILENOR, TENCON, TRIHEXYPHENIDYL HCL 0.4 MG/ML SOLUTION, VIVELLE-DOT, VTOL LQ, ZEBUTAL, ZOLPIDEM TARTRATE 1.75 MG SL TAB, ZOLPIDEM TARTRATE 3.5 MG SL TAB, ZOLPIMIST

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

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

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

HUMAN GROWTH HORMONE

MEDICATION(S)

NORDITROPIN FLEXPRO, OMNITROPE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

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

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

HUMIRA

MEDICATION(S)

HUMIRA, HUMIRA PEDIATRIC CROHNS START, HUMIRA PEN, HUMIRA PEN-CD/UC/HS STARTER, HUMIRA PEN-PEDIATRIC UC START, HUMIRA PEN-PS/UV/ADOL HS START, HUMIRA PEN-PSOR/UEIT STARTER

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

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

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

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

PART B PREREQUISITE

N/A

HUMULIN U500

MEDICATION(S)

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

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

IBRANCE

MEDICATION(S)

IBRANCE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ICLUSIG

MEDICATION(S)

ICLUSIG

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

IDHIFA

MEDICATION(S)

IDHIFA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ILARIS

MEDICATION(S)

ILARIS

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

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

For AOSD/SJIA, individual has had an inadequate response to, intolerant of, or has a medical contraindication to ONE corticosteroids or nonsteroidal anti-inflammatory drugs (NSAIDs) AND may be used alone or in combination with corticosteroids, methotrexate or NSAIDs. For FMF, individual has active type 1 FMF disease with genetic confirmation (written or verbal) of the diagnosis (MEFV gene exon 10 mutation) and confirmed recurrent, active disease (that is, at least one flare per month) and has failed to respond to, or is intolerant of colchicine therapy. For HIDS/MKD, individual has HIDS with genetic confirmation (written or verbal) of the diagnosis by deoxyribonucleic acid (DNA) analysis or enzymatic studies (that is, mutations in the MVK gene or markedly reduced mevalonate kinase activity) and confirmed prior history of greater than or equal to three febrile acute flares within a 6-month period

when not receiving prophylactic treatment. For TRAPS, genetic confirmation (written or verbal) of the diagnosis (TNFRSF1A gene mutation) and has chronic or recurrent disease activity defined as six flares in a 12-month period. For Continuation use, there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

PART B PREREQUISITE

N/A

ILUMYA

MEDICATION(S)

ILUMYA

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.

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) AND individual has had a trial of and an inadequate response or is intolerant to Humira (adalimumab) OR Enbrel (etanercept) OR Cosentyx (secukinumab) OR Skyrizi (risankizumab-rzaa) OR Stelara (ustekinumab) OR Otezla (apremilast). For any of the above indications, if the TNF agent [Humira(adalimumab) /Enbrel(etanercept)/ Cosentyx (secukinumab)/Skyrizi (risankizumab-rzaa)/Stelara (ustekinumab)] are not acceptable due to Individuals age. Ilumya may be allowed without trial of preferred TNF agents. For Continuation use:

there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

PART B PREREQUISITE

N/A

IMBRUVICA

MEDICATION(S)

IMBRUVICA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

IMFINZI

MEDICATION(S)

IMFINZI

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

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

REQUIRED MEDICAL INFORMATION

For locally advanced, unresectable non-small cell lung cancer, histologically or cytologically confirmed stage III and current Eastern Cooperative Oncology Group performance status 0-2.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

For locally advanced, unresectable non-small cell lung cancer (NSCLC), disease has not progressed after definitive chemoradiation or is using until disease has progressed or individual has reached a maximum of 12 months of treatment and is using as consolidation therapy. For extensive stage Small Cell Lung Cancer, Individual is using as first line therapy in combination with etoposide and either cisplatin or carboplatin for four (4) cycles (followed by maintenance Imfinzi monotherapy).

PART B PREREQUISITE

N/A

INCRELEX

MEDICATION(S)

INCRELEX

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

INGREZZA

MEDICATION(S)

INGREZZA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial use in Tardive dyskinesia confirmed by the following (DSM-5): A) Individual has had a stable (drug, dose) medication exposure (either typical or first generation antipsychotic agents [such as, chlorpromazine, haloperidol, fluphenazine], atypical or second-generation antipsychotic agents [such as, clozapine, risperidone, olanzapine, quetiapine, aripiprazole], or certain dopamine receptor-blocking used in treatment of nausea and gastroparesis [such as prochlorperazine, promethazine, metoclopramide] AND B) Presence of involuntary athetoid or choreiform movements.

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 3 months. Continuation: 1 year

OTHER CRITERIA

For continued use, Individual has experienced an improvement in symptoms deemed to be clinically significant by the provider based on stabilization or improvement in Abnormal Involuntary Movement Scale (AIMS) score.

PART B PREREQUISITE

N/A

INLYTA

MEDICATION(S)

INLYTA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 YEAR.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

INPEFA

MEDICATION(S)

INPEFA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For New York Heart Association (NYHA) class II, III or IV heart failure symptoms AND (A) has an ejection fraction of 40% or less AND will be taking Inpefa (sotagliflozin) in combination with the following (SOLOIST 2021): (a) Entresto (sacubitril/valsartan), angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) unless contraindicated or not tolerated AND (b) Beta-blocker (bisoprolol, carvedilol, metoprolol succinate) unless contraindicated or not tolerated OR (B) has an ejection fraction greater than 40%.

AGE RESTRICTION

18 years of age or older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

For type 2 diabetes AND chronic kidney disease, using Inpefa (sotagliflozin) in combination with an ACE inhibitor or ARB unless contraindicated or not tolerated (KDIGO 2022) AND meets one of the following (SCORED 2021) (A or B): (A) Presence of one of the following major CV risk factors: (i) hx of heart failure hospitalization within the previous two years, (ii) Ejection fraction of 40% or less, (iii) Left ventricular hypertrophy, (iv) Coronary artery calcium (CAC) score greater than or equal to 300 Agatston Units, (v) N-terminal pro-B-type natriuretic peptide greater than or equal to 400 pg/mL (47 pmol/L), (vi)

High-sensitivity troponin T greater than 15 pg/mL for men and greater than 10 pg/mL for women, (vii) High-sensitivity C-reactive protein greater than 3 mg/L (28.6 nmol/L), (viii) Urinary albumin-to-creatinine ratio greater than or equal to 300 mg/g OR (B) Age greater than or equal to 55 years AND presence of two or more of the following minor CV risk factors: (i) BMI greater than or equal to 35 kg/m², (ii) Dyslipidemia (LDL greater than 130 mg/dL OR HDL less than 40 mg/dL for men OR HDL less than 50 mg/dL for women) despite maximally tolerated statin therapy, (iii) Currently smoking tobacco, (iv) Coronary artery calcium (CAC) score greater than 100 and less than 300 Agatston Units, (v) Urinary albumin-to-creatinine ratio greater than or equal to 30 mg/g and less than 300 mg/g, (vi) Systolic bp greater than 140 mmHg and diastolic bp greater than 90 mmHg despite antihypertensive therapy, (vii) Family hx of premature coronary heart disease (myocardial infarction or coronary revascularization procedure) in a first-degree male relative less than 55 years or a first degree female relative less than 65 years.

PART B PREREQUISITE

N/A

INQOVI

MEDICATION(S)

INQOVI

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

INREBIC

MEDICATION(S)

INREBIC

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Individual is 18 years of age or older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

INTERFERONS FOR MS

MEDICATION(S)

AVONEX PEN, AVONEX PREFILLED, BETASERON

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

INTUNIV

MEDICATION(S)

GUANFACINE HCL ER, INTUNIV

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

Individual is 6 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

IRESSA

MEDICATION(S)

GEFITINIB, IRESSA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

ISTURISA

MEDICATION(S)

ISTURISA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ITRACONAZOLE

MEDICATION(S)

ITRACONAZOLE 100 MG CAP, SPORANOX 100 MG CAP, TOLSURA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

IVIG

MEDICATION(S)

GAMUNEX-C, OCTAGAM

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

OR for Kawasaki Dz tx initiated w/in 10dys of onset and tx for more than 5dys.

PART B PREREQUISITE

N/A

JADENU

MEDICATION(S)

DEFERASIROX 180 MG PACKET, DEFERASIROX 180 MG TAB, DEFERASIROX 360 MG PACKET, DEFERASIROX 360 MG TAB, DEFERASIROX 90 MG PACKET, DEFERASIROX 90 MG TAB, DEFERASIROX GRANULES, JADENU, JADENU SPRINKLE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

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

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

JAKAFI

MEDICATION(S)

JAKAFI

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

JAYPIRCA

MEDICATION(S)

JAYPIRCA

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 for mantle cell lymphoma.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

JEVTANA

MEDICATION(S)

JEVTANA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

For metastatic castration-resistant prostate cancer, individual has a Eastern Cooperative Oncology Group (ECOG) performance status is 0-2.

PART B PREREQUISITE

N/A

JOENJA

MEDICATION(S)

JOENJA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

For initial request, individual shows evidence of nodal and/or extranodal lymphoproliferation, and clinical findings and manifestations compatible with APDS/PASLI such as a history of repeated oto-sino-pulmonary infections and/or organ dysfunction (e.g., lung, liver). For continuation request, there is clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to, reduced lymphadenopathy and/or improved immune function).

PART B PREREQUISITE

N/A

JUXTAPID

MEDICATION(S)

JUXTAPID

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

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

PART B PREREQUISITE

N/A

JYNARQUE

MEDICATION(S)

JYNARQUE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

KADCYLA

MEDICATION(S)

KADCYLA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

KALBITOR

MEDICATION(S)

KALBITOR

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Prophylaxis for HAE attacks.

REQUIRED MEDICAL INFORMATION

HAE is confirmed (written or verbal attestation) by a C4 level below the lower limit of normal (as defined by laboratory testing) and either a C1 inhibitor antigenic level below the lower limit of normal (as defined by the lab performing test) or a C1 inhibitor functional level below the lower limit of normal.

AGE RESTRICTION

Individual is 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 (for example, airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, painful facial distortion) and using Kalbitor for acute HAE attacks.

PART B PREREQUISITE

N/A

KALYDECO

MEDICATION(S)

KALYDECO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

KESIMPTA

MEDICATION(S)

KESIMPTA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For diagnosis of relapsing multiple sclerosis (RMS) (including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease) AND Individual is able to ambulate without aid or rest for at least 100 meters AND If initiating therapy, individual has experienced at least two relapses within the previous two years or one relapse within the previous year or at least one T1 gadolinium-enhancing lesion on MRI within the previous year.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

KEVEYIS

MEDICATION(S)

DICHLORPHENAMIDE, KEVEYIS

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial 3 months, renewal 1 year

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

KEVZARA

MEDICATION(S)

KEVZARA

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 initial use: Rheumatoid Arthritis, individual has had an inadequate response to, methotrexate titrated to maximally tolerated dose (ACR 2021) OR If methotrexate is not tolerated or contraindicated, individual has had an inadequate response to, is intolerant of, or has a contraindication to other conventional therapy [sulfasalazine, leflunomide, or hydroxychloroquine] AND individual has had an inadequate response or is intolerant to Enbrel (etanercept) OR Humira (adalimumab). For any of the above indications, if the TNF agent [Enbrel (etanercept)/Humira (adalimumab)] are not acceptable due to Individuals age OR individual has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction, Kevzara may be allowed without trial of preferred TNF agents [Enbrel (etanercept)/Humira (adalimumab)]. For Continuation use, there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

PART B PREREQUISITE

N/A

KEYTRUDA

MEDICATION(S)

KEYTRUDA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

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

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

KINERET

MEDICATION(S)

KINERET

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 initial use: RA, Individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021) OR If methotrexate is not tolerated or contraindicated, individual has had an inadequate response to, is intolerant of, or has a contraindication to other conventional therapy [sulfasalazine, leflunomide, or hydroxychloroquine] AND Individual has had a trial and an inadequate response to or intolerance to Humira (adalimumab) OR Enbrel (etanercept). OR the TNF agent [Humira(adalimumab)/Enbrel(etanercept)] are not acceptable due to Individual's age. Kineret may be allowed without trial of preferred TNF agents [Humira(adalimumab)/Enbrel(etanercept)] For Continuation use, there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

PART B PREREQUISITE

N/A

KISQALI

MEDICATION(S)

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

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

KORLYM

MEDICATION(S)

KORLYM

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

KOSELUGO

MEDICATION(S)

KOSELUGO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

KRAZATI

MEDICATION(S)

KRAZATI

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

KRYSTEXXA

MEDICATION(S)

KRYSTEXXA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Individual has 1 or more of the following: 3 or more gout flares in the previous 18 months OR 1 or more tophus OR History of chronic gouty arthropathy, defined clinically or radiographically as joint damage due to gout. Individual has a confirmed baseline serum uric acid of 6 mg/dL or greater prior to initiating pegloticase (FitzGerald 2020).

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

For Initial use: Individual has chronic, treatment-refractory and has failed to respond to, is intolerant of, or has a medical contraindication to ONE of the following conventional therapies (FitzGerald 2020): A xanthine oxidase inhibitor (allopurinol or febuxostat) or combination therapy of 1 xanthine oxidase inhibitor given with a uricosuric agent (for example, probenecid). For Continuation use, there is confirmation (written or verbal) of clinically significant improvement in clinical signs and symptoms of disease (including but not limited to reduction in serum uric acid level, gout flare reduction, tophus resolution, reduction in joint pain) (Sundy 2011).

PART B PREREQUISITE

N/A

KUVAN

MEDICATION(S)

JAVYGTOR, KUVAN, SAPROPTERIN DIHYDROCHLORIDE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial 8 weeks, 1 year for continuation

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

KYPROLIS

MEDICATION(S)

KYPROLIS

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

LAZANDA

MEDICATION(S)

LAZANDA

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 Lazanda (fentanyl) for cancer related breakthrough pain.

PART B PREREQUISITE

N/A

LENVIMA

MEDICATION(S)

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

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

LEQVIO

MEDICATION(S)

LEQVIO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial requests, individual is at high risk for atherosclerotic cardiovascular disease (ASCVD) events as identified by one of the following: For (A) Heterozygous Familial Hypercholesterolemia (HeFH) confirmed by (Singh 2015, WHO 1999): 1. Presence of a mutation in LDLR, ApoB, PCSK9 or ARH adaptor protein (LDLRAP1) gene OR 2. World Health Organization (WHO)/Dutch Lipid Network Criteria with score of greater than 8 points. For (B) History of ASCVD, including one or more of the following (AHA/ACC 2018): 1. Acute coronary syndromes 2. Coronary Artery Disease (CAD) 3. History of myocardial infarction (MI) 4. Stable or unstable angina 5. Coronary or other arterial revascularization 6. Stroke 7. Transient ischemic attack (TIA) 8. Peripheral arterial disease (PAD).

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) on high intensity statin therapy or statin therapy at the maximum tolerated dose (high intensity statin is defined as atorvastatin 40 mg or higher or rosuvastatin 20 mg or higher) (AHA/ACC 2018), OR (B) individual is statin intolerant OR (C) has a contraindication for statin therapy including active liver disease, unexplained persistent elevation of

hepatic transaminases or pregnancy AND 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 therapy. For continuation, Individual continues to receive concomitant maximally tolerated statin therapy (unless contraindication or individual is statin intolerant and/or PCSK9 inhibitor therapy AND there is confirmation (verbal or written attestation) of LDL reduction.

PART B PREREQUISITE

N/A

LETAIRIS

MEDICATION(S)

AMBRISENTAN, LETAIRIS

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial use, Individual has diagnosis of Pulmonary Arterial Hypertension World Health Organization (WHO) Group 1. Individual has the diagnosis of PAH confirmed by a right heart catheterization showing all of the following: (a) Mean pulmonary artery pressure (mPAP) greater than or equal to 25 mm Hg at rest (b) Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg (c) Pulmonary vascular resistance (PVR) greater than 3 Wood units. AND Individual has WHO functional class II- IV symptoms.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

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 $0.1 \times 10^9/L$) 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

Adjuvant 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 $500/mm^3$ 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).

PART B PREREQUISITE

N/A

LEVOLEUCOVORIN

MEDICATION(S)

LEVOLEUCOVORIN CALCIUM, LEVOLEUCOVORIN CALCIUM PF

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

LIDOCAINE 3

MEDICATION(S)

DERMACINRX LIDOGEL, LIDOREX

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

LIDOCAINE 4

MEDICATION(S)

LIDOCAINE HCL 4 % SOLUTION

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

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.

PART B PREREQUISITE

N/A

LIDODERM PATCH

MEDICATION(S)

LIDOCAINE 5 % PATCH, LIDOCAN, LIDODERM, ZTLIDO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

LIVMARLI

MEDICATION(S)

LIVMARLI

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial requests, written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis AND evidence of cholestasis defined by one or more of the following (NCT02160782): total serum bile acid greater than 3x upper limit of normal for age, conjugated bilirubin greater than 1 mg/dL, fat- soluble vitamin deficiency otherwise unexplainable, gamma-glutamyl transferase greater than 3x ULN for age, OR intractable pruritus explainable only by liver disease.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial 6 months, Continuation 1 year.

OTHER CRITERIA

For initial requests, individual has a diagnosis of Alagille syndrome (ALGS) with moderate to severe pruritus due to ALGS AND has had a trial and inadequate response or intolerance to one systemic agent for ALGS, such as ursodeoxycholic acid, rifampicin, naltrexone, or sertraline (Ayoub 2020). For continuation requests, individual has had a positive therapeutic response to treatment [defined as a reduction in pruritus severity from baseline] AND DOES NOT have evidence of portal HTN AND does not have evidence of hepatic decomposition (for example, variceal hemorrhage, ascites, or hepatic

encephalopathy) AND individual does not have worsening or persistent fat-soluble vitamin (FSV) deficiency (includes vitamins A, D, E, and K) despite adequate supplementation.

PART B PREREQUISITE

N/A

LONSURF

MEDICATION(S)

LONSURF

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

LORBRENA

MEDICATION(S)

LORBRENA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

LOTRONEX

MEDICATION(S)

ALOSETRON HCL, LOTRONEX

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

LUCENTIS

MEDICATION(S)

LUCENTIS 0.3 MG/0.05ML SOLN PRSYR, LUCENTIS 0.5 MG/0.05ML 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

N/A

PART B PREREQUISITE

N/A

LUMAKRAS

MEDICATION(S)

LUMAKRAS

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

LUMIZYME

MEDICATION(S)

LUMIZYME

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

LUMRYZ

MEDICATION(S)

LUMRYZ

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 3 months. Continuation: 6 months

OTHER CRITERIA

For Initial tx in: idiopathic hypersomnia (IH) defined by the following (ICSD-3, Kahn 2015, Sateia 2014, AASM 2021): (A) Daily periods of irresistible need to sleep or daytime lapses into sleep for more than 3 months AND (B) Absence of cataplexy AND (C) Insufficient sleep syndrome ruled out (if deemed necessary, by lack of improvement of sleepiness after an adequate trial of increased nocturnal time in bed, preferably verified by at least 1 week of wrist actigraphy) AND (D) MSLT shows the following: (1) Fewer than 2 SOREMPs OR (2) No SOREMPs if the REM sleep latency period on the preceding overnight polysomnogram is 15 minutes or less AND (E) The presence of at least one of the following: (1) MSLT showing a mean sleep latency of 8 minutes or less OR (2) Total 24-hour sleep time of 660 minutes or longer (typically 12-14 hours) on 24-hour polysomnography monitoring (performed after the correction of chronic sleep deprivation) or by wrist actigraphy in association with a sleep log (averaged over at least 7 days with unrestricted sleep) AND (F) Hypersomnolence or MSLT findings are not better explained by another sleep disorder, medical or neurologic disorder, mental disorder, medication use, or substance abuse. For Continuation, Individual has met initial diagnostic criteria noted above AND use has resulted in a reduction in frequency of cataplexy attacks compared to baseline OR 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.

PART B PREREQUISITE

N/A

LUPKYNIS

MEDICATION(S)

LUPKYNIS

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial use, individual has Class III, IV, or V lupus nephritis showing active or chronic lesions, and confirmed by renal biopsy AND has a urinary protein to creatinine ratio of greater than or equal to 1.5 AND has a baseline eGFR of greater than 45 mL/min/1.73 m² AND is using in combination with background immunosuppressive therapy that includes mycophenolate mofetil (MMF) and corticosteroids.

AGE RESTRICTION

18 years of age or older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 6 months. Continuation: 1 Year.

OTHER CRITERIA

For continuation use, individual is using in combination with background immunosuppressive therapy that includes mycophenolate mofetil and corticosteroids AND Individual did not require rescue medications at any time (for example, rituximab), or repeated use of high dose steroids after 16 weeks following Lupkynis initiation (i.e., more than 10 mg of prednisone, or equivalent, for three (3) or more consecutive days or for more than seven (7) days in total in an 8 week period) AND there is confirmation of a therapeutic renal response (for example, improvement [or no worsening] of the urinary protein to creatinine ratio compared to baseline, or no decrease in eGFR of more than 20%

from baseline).

PART B PREREQUISITE

N/A

LUPRON DEPOT

MEDICATION(S)

FENSOLVI (6 MONTH), LEUPROLIDE ACETATE (3 MONTH), LUPRON DEPOT (1-MONTH), LUPRON DEPOT (3-MONTH), LUPRON DEPOT (4-MONTH), LUPRON DEPOT (6-MONTH), LUPRON DEPOT-PED (1-MONTH), LUPRON DEPOT-PED (3-MONTH)

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

LUPRON KIT IR

MEDICATION(S)

LEUPROLIDE ACETATE 1 MG/0.2ML KIT

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

LYNPARZA

MEDICATION(S)

LYNPARZA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 YEAR.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

LYRICA CR

MEDICATION(S)

LYRICA CR, PREGABALIN 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

Individual has had a prior trial of immediate-release form of Lyrica (pregabalin) AND Documentation (verbal or written) has been provided which defines the following: (a.) The inadequate response to Lyrica (pregabalin) AND (b.) The medical reason extended release Lyrica CR is clinically necessary, and the same medical reason and clinical reason benefits are not expected with Lyrica.

PART B PREREQUISITE

N/A

LYTGOBI

MEDICATION(S)

LYTGOBI (12 MG DAILY DOSE), LYTGOBI (16 MG DAILY DOSE), LYTGOBI (20 MG DAILY DOSE)

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

MAVENCLAD

MEDICATION(S)

MAVENCLAD (10 TABS), MAVENCLAD (4 TABS), MAVENCLAD (5 TABS), MAVENCLAD (6 TABS), MAVENCLAD (7 TABS), MAVENCLAD (8 TABS), MAVENCLAD (9 TABS)

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/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 relapsing multiple sclerosis (RMS), including relapsing-remitting disease and active secondary progressive disease AND has had a trial and inadequate response or intolerance to at least one alternative drug indicated for the treatment of multiple sclerosis.

PART B PREREQUISITE

N/A

MAVYRET

MEDICATION(S)

MAVYRET

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

MAYZENT

MEDICATION(S)

MAYZENT, MAYZENT STARTER PACK

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

MEGACE SUSPENSION HRM

MEDICATION(S)

MEGESTROL ACETATE 40 MG/ML SUSPENSION, MEGESTROL ACETATE 400 MG/10ML SUSPENSION, MEGESTROL ACETATE 800 MG/20ML SUSPENSION

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

MEGACE TABS HRM

MEDICATION(S)

MEGESTROL ACETATE 20 MG TAB, MEGESTROL ACETATE 40 MG TAB

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 YEAR.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

MEKINIST

MEDICATION(S)

MEKINIST

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

MEKTOVI

MEDICATION(S)

MEKTOVI

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

MEPRON

MEDICATION(S)

ATOVAQUONE, MEPRON

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Intolerance to trimethoprim-sulfamethoxazole (TMP-SMX)

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

METHYLPHENIDATE

MEDICATION(S)

APTENSIO XR, CONCERTA, COTEMPLA XR-ODT, JORNAY PM, METHYLIN, 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, METHYLPHENIDATE HCL ER (CD), METHYLPHENIDATE HCL ER (LA), METHYLPHENIDATE HCL ER (OSM), METHYLPHENIDATE HCL ER (XR), QUILLICHEW ER, QUILLIVANT XR, RELEXXII, RITALIN, RITALIN LA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

6 years of age and older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

MODAFINIL

MEDICATION(S)

MODAFINIL, PROVIGIL

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

MOZOBIL

MEDICATION(S)

MOZOBIL, PLERIXAFOR

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

3 months

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

MULPLETA

MEDICATION(S)

MULPLETA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Individual has a platelet count of less than 50 X 109/L

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

MYALEPT

MEDICATION(S)

MYALEPT

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

MYCAPSSA

MEDICATION(S)

MYCAPSSA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For continuation therapy, individual meets initial criteria AND IGF-1 levels remain less than 1.3 X the upper limit of normal (ULN) and a serum growth hormone level less than 2.5ng/mL (Melmed 2015).

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial 6mon. Continuation 1 year.

OTHER CRITERIA

Individual has a diagnosis of acromegaly AND has responded to and tolerated treatment with octreotide or lanreotide (defined as currently receiving a stable dose of either for at least the previous 3 months (Label, Melmed 2015).

PART B PREREQUISITE

N/A

NAGLAZYME

MEDICATION(S)

NAGLAZYME

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

For Continuation use, 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 reduction in urinary GAG excretion, reduction in hepatosplenomegaly, improvement in pulmonary function, improvement in walking distance and/or improvement in fine or gross motor function) compared to the predicted natural history trajectory of disease.

PART B PREREQUISITE

N/A

NAMENDA LINE

MEDICATION(S)

MEMANTINE HCL 10 MG TAB, MEMANTINE HCL 2 MG/ML SOLUTION, MEMANTINE HCL 28 X 5 MG & 21 X 10 MG TAB, MEMANTINE HCL 5 MG TAB, MEMANTINE HCL ER, NAMENDA, NAMENDA TITRATION PAK, NAMENDA XR

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

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

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

NATPARA

MEDICATION(S)

NATPARA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

NERLYNX

MEDICATION(S)

NERLYNX

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 YEAR.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

NEXAVAR

MEDICATION(S)

NEXAVAR, SORAFENIB TOSYLATE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

NINLARO

MEDICATION(S)

NINLARO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

NITYR

MEDICATION(S)

NITYR

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

NORTHERA

MEDICATION(S)

DROXIDOPA, 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 and inadequate response or intolerance to one prior symptomatic nOH pharmacologic therapy (which may include midodrine or fludrocortisone [AHFS]).

PART B PREREQUISITE

N/A

NOURIANZ

MEDICATION(S)

NOURIANZ

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

NOXAFIL

MEDICATION(S)

NOXAFIL 100 MG TAB DR, NOXAFIL 300 MG PACKET, NOXAFIL 40 MG/ML SUSPENSION, POSACONAZOLE 100 MG TAB DR, POSACONAZOLE 40 MG/ML SUSPENSION

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

NP CSF SA AGENTS

MEDICATION(S)

NEUPOGEN, NIVESTYM, RELEUKO

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 0.1×10 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 $450/\mu L$) 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 $1500mm^3$), 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 myelosuppressive doses (greater than 2 Grays [Gy] (such as Hematopoietic Syndrome of Acute Radiation Syndrome). After hematopoietic progenitor stem cell transplant (HPCT/HSCT) to promote myeloid reconstitution or when engraftment is delayed or has failed. To mobilize progenitor cells into peripheral blood for collection by leukapheresis, as an adjunct to peripheral blood/hematopoietic stem cell transplantation (PBSCT/PHSCT). Use as an alternate or adjunct to donor leukocyte infusions (DLI) in individuals with leukemic relapse after an allogeneic hematopoietic stem cell transplant.

PART B PREREQUISITE

N/A

NP HUMAN GROWTH HORMONE

MEDICATION(S)

GENOTROPIN, GENOTROPIN MINIQUICK, HUMATROPE, NUTROPIN AQ NUSPIN 10, NUTROPIN AQ NUSPIN 20, NUTROPIN AQ NUSPIN 5, SAIZEN, SEROSTIM, SKYTROFA, SOGROYA, ZOMACTON, ZORBTIVE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

NP INTERFERON FOR MS

MEDICATION(S)

EXTAVIA, PLEGRIDY, PLEGRIDY STARTER PACK, REBIF, REBIF REBIDOSE, REBIF REBIDOSE TITRATION PACK, REBIF TITRATION PACK

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Individual has 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 Betaseron (interferon beta-1b) OR MSB Tecfidera OR MSB Copaxone.

PART B PREREQUISITE

N/A

NP IVIG

MEDICATION(S)

ASCENIV, BIVIGAM, CUTAQUIG, CUVITRU, FLEBOGAMMA DIF, GAMMAGARD, GAMMAGARD S/D LESS IGA, GAMMAKED, GAMMAPLEX, HIZENTRA, HYQVIA, PANZYGA, PRIVIGEN, XEMBIFY

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Autoimmune (AI) MC blistering dx when mbr had inadeq response/intolerance/contraindication to other tx such as steroids/ISx. For AI neutropenia, active INFECTION 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 for at least 2 mons. 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 improvmt 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 not FDA/Off-label approved or due to clinical condition such as but not limited to needing IG specif agent w/specif prop: Severe IgA def less than 7mg/dl IgA or dif w/Ab against IgA req agnt w/very low IgA, Hyper-prolinemia, doc HS manifested by severe systemic/allergic or anaphylactic rxn to any ingred not also present NP agent OR doc rxn inc hemolysis/renal dys that mayb less w/NPF w/diff property. 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 AB tx and HGG w/total IgG less than 500mg/dL B)MM w/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 infect 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 w/hi panel reactive AB (PRA/cPRA) levels to human leukocyte antigens or in mbr w/hx of hi levels of donor-specific ab OR Transplant recipients(TR) at risk of CMV 3)TR 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 30,000mcL B)Fetal alloimmune TCP wAB 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,hi 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 CRP/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 assoc w/encephalitis. For CONT use of AE, is clinically sig improv in sx on phys exam and need is demon by clinical effect(i.e, pos res, stable on dose,or worsening of sx occurs from dose dec or inc in dose intervals, or prev dc resulted in relapse and Cancer screening cont.

PART B PREREQUISITE

N/A

NP LA OPIOID

MEDICATION(S)

BELBUCA, BUPRENORPHINE, BUTRANS, CONZIP, HYDROCODONE BITARTRATE ER, HYDROMORPHONE HCL ER, HYSINGLA ER, METHADONE HCL 10 MG TAB, METHADONE HCL 5 MG TAB, MORPHINE SULFATE ER, MORPHINE SULFATE ER BEADS, MS CONTIN, NUCYNTA ER, OXYMORPHONE HCL ER, TRAMADOL HCL (ER BIPHASIC), TRAMADOL HCL ER, TRAMADOL HCL ER (BIPHASIC), XTAMPZA ER

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

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

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

PART B PREREQUISITE

N/A

NP SGLT2

MEDICATION(S)

SEGLUROMET, STEGLATRO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/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 (AACE/ACE 2020) OR has a contraindication to metformin therapy [including but not limited to, renal insufficiency (eGFR is less than 45 mL/minute/1.73m²)]. AND has had a trial and inadequate response or intolerance to ONE preferred SGLT2 inhibitor: Jardiance (empagliflozin), Synjardy (empagliflozin/metformin), or Synjardy XR (empagliflozin/metformin extended-release), Farxiga (dapagliflozin), Xigduo XR (dapagliflozin/metformin), Invokamet (canagliflozin/metformin), Invokamet XR (canagliflozin/metformin), or Invokana (canagliflozin).

PART B PREREQUISITE

N/A

NP SGLT2 DPP4 COMBO

MEDICATION(S)

QTERN, STEGLUJAN

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/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 preferred DPP4 AND ONE preferred SGLT2 AND Individual has had an adequate response (achieved glucose control) with trial of the DPP-4 inhibitor and SGLT2 inhibitor at the same time AND Documentation (Verbal or Written) has been provided for why the combination agent is clinically necessary and not for convenience.

PART B PREREQUISITE

N/A

NP STATIN

MEDICATION(S)

ALTOPREV

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 of ONE generic statin at any dose and provider attests the individual has experienced failure, contraindication, or intolerance to a generic statin. Or Individual is currently on a agent that interacts with a generic statin.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

NPLATE

MEDICATION(S)

NPLATE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial therapy: For ITP, individual's has platelet count less than 30,000/mm³ or active bleeding AND individual had a prior trial and an insufficient response to corticosteroids, immunoglobulins (for example, IVIg or anti-D), or splenectomy. For ITP maintenance therapy, individual demonstrated response to therapy as evidenced by increased platelet counts, and the goal of ongoing treatment is to maintain an adequate platelet count (50,000-100,000/mm³) to decrease the risk of bleeding. For initial chemotherapy-induced thrombocytopenia therapy, individual has platelets less than 100 x 10⁹/L for at least 3 weeks following the last chemo administration OR Individual has platelets less than 100 x 10⁹/L and there are delays in chemo related to thrombocytopenia. For maintenance CIT therapy, Individual has demonstrated a response to therapy as evidenced by increased platelet counts AND Continuation of treatment is to maintain an adequate platelet count (100 - 150 X 10⁹/L) to allow for the resumption of chemotherapy regimen as appropriate.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

For ITP, MDS, and CIT: Initial 6 months, renewal 1 year. For all other diagnoses: 1 year

OTHER CRITERIA

Used For treatment of lower risk myelodysplastic syndrome (MDS) [Lower risk defined as IPSS-R

(Very Low, Low, Intermediate), IPSS (Low/Intermediate-1), WPSS (Very low, low, intermediate)]. AND individual has severe or refractory thrombocytopenia following disease progression or no response to hypomethylating agents or immunosuppressive therapy. For chemotherapy-induced thrombocytopenia, Individual was using a cytotoxic chemotherapy agent that is known to cause thrombocytopenia AND the goal of therapy is to maintain the dosing schedule and/or intensity of the chemotherapy regimen when such benefit outweighs the potential risks.

PART B PREREQUISITE

N/A

NUBEQA

MEDICATION(S)

NUBEQA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

NUCALA

MEDICATION(S)

NUCALA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

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

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 6 months. Continuation: 1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

NUEDEXTA

MEDICATION(S)

NUEDEXTA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Individual is using for the treatment of amyotrophic lateral sclerosis (ALS) (Orphan indication) OR Individual has a diagnosis of pseudobulbar affect (PBA) AND has a concomitant diagnosis with an unrelated neurologic disease or injury [amyotrophic lateral sclerosis (AAN 2020, Pioro et al. 2010), multiple sclerosis (AAN 2019, Pioro et al, 2010), stroke (2016 AHA/ASA)].

PART B PREREQUISITE

N/A

NULOJIX

MEDICATION(S)

NULOJIX

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

NUPLAZID

MEDICATION(S)

NUPLAZID

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial:3 months, Maintenance: 1 Year

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

NURTEC

MEDICATION(S)

NURTEC

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

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

PART B PREREQUISITE

N/A

NUVIGIL

MEDICATION(S)

ARMODAFINIL, NUVIGIL

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

OALIVA

MEDICATION(S)

OALIVA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 6 months. Continuation: 1 Year.

OTHER CRITERIA

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

compensated cirrhosis with portal hypertension.

PART B PREREQUISITE

N/A

OCREVUS

MEDICATION(S)

OCREVUS

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/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 primary progressive, multiple sclerosis (PPMS) and individual able to ambulate more than 5 meters (not considered wheelchair bound). For diagnosis of relapsing multiple sclerosis (RMS) including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease and individual able to ambulate without aid or rest for at least 1000 meters AND If initiating therapy, individual has experienced a least 2 relapses within the previous 2 years or one relapse within the previous year.

PART B PREREQUISITE

N/A

OCTREOTIDE LINE

MEDICATION(S)

OCTREOTIDE ACETATE, SANDOSTATIN, SANDOSTATIN LAR DEPOT

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ODACTRA

MEDICATION(S)

ODACTRA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For house dust mite-induced allergic rhinitis, individual has a documented positive skin test OR positive in vitro testing for pollen-specific IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites. Individual has had a trial of, and inadequate symptom control or intolerance to (1) nasal steroid and (1) non-sedating antihistamine AND individual has a confirmed (verbal or written attestation) prescription for an auto-injectable epinephrine product.

AGE RESTRICTION

Individual is between the ages of 12 years and 65 years old.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ODOMZO

MEDICATION(S)

ODOMZO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

OFEV

MEDICATION(S)

OFEV

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

OJJAARA

MEDICATION(S)

OJJAARA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Individual has hemoglobin less than 10 g/dL (NCT04173494, NCT01969838).

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

OLUMIANT

MEDICATION(S)

OLUMIANT

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Individual using for alopecia areata/hair growth.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

For RA, Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

For the treatment of COVID: 30 days. For all other indications: 1 year

OTHER CRITERIA

For initial use: moderate to severe RA, individual has had an inadequate response to MTX titrated to maximally tolerated dose (ACR 2021) OR if MTX is not tolerated or contraindicated, individual had an inadequate response to, is intolerant of or has contraindication to other conventional therapy (sulfasalazine, leflunomide or hydroxychloroquine) AND individual had a trial and inadequate response/intolerance to Enbrel(etanercept) OR Humira(adalimumab) OR TNF agents [Humira(adalimumab)/Enbrel(etanercept)] are not acceptable due to concomitant clinical conditions, such as Individual's age. Olumiant may be allowed without trial of preferred TNF agents. For Continuation use, there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease. For COVID use, individual is a hospitalized adult requiring oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

PART B PREREQUISITE

N/A

ONFI

MEDICATION(S)

CLOBAZAM, ONFI, SYMPAZAN

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ONGENTYS

MEDICATION(S)

ONGENTYS

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ONUREG

MEDICATION(S)

ONUREG

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

OPDIVO

MEDICATION(S)

OPDIVO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

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

REQUIRED MEDICAL INFORMATION

Current ECOG performance status 0-2. For NSCLC, SCCHN, Urothelial carcinoma, confirmation (verbal or written) of disease progression. 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: used as a single agent or in combination with Yervoy, as first-line therapy for untreated melanoma OR used as a single agent or in combination with Yervoy, as second-line or subsequent therapy for disease progression while receiving or since completing most recent therapy. For resected advanced melanoma for up to 12 months of adjuvant therapy when individual has resected state IIIB, IIIC or stage IV disease. For recurrent/metastatic NSCLC when: agent is used in combination with ipilimumab and two (2) cycles of platinum-double chemotherapy AND does not have presence of actionable molecular markers. For intermediate or poor risk renal cell carcinoma, agent used as single agent OR used in combination with ipilimumab for four cycles followed

by nivolumab, as subsequent therapy if no checkpoint blockade (PD-1, PD-L1 or CTLA-4) antibody treatment has been previously administered. For malignant pleural or peritoneal mesothelioma, used as a single agent, or in combination with ipilimumab for subsequent therapy. For merkel cell carcinoma (MCC), used as a single agent and Presence of metastatic or recurrent locoregional MCC determined to be not amenable to definitive surgery or radiation therapy.

PART B PREREQUISITE

N/A

OPSUMIT

MEDICATION(S)

OPSUMIT

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial requests, Individual has diagnosis of Pulmonary Arterial Hypertension World Health Organization (WHO) Group 1. Individual has the diagnosis of PAH confirmed by a right heart catheterization showing all of the following: (a) Mean pulmonary artery pressure (mPAP) greater than or equal to 25 mm Hg at rest (b) Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg (c) Pulmonary vascular resistance (PVR) greater than 3 Wood units. AND Individual has WHO functional class II- IV symptoms.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

OPZELURA

MEDICATION(S)

OPZELURA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial use for nonsegmental vitiligo, mbr has total body area impacted by vitiligo (facial and non-facial) does not exceed 10% of body surface area (BSA) (NCT04057573) AND meets one of the following (A or B) (Eleftheriadou,2022): (A) Failure of topical pharmacological therapy as indicated by 1 and 2 of the following: (1) Daily tx of topical corticosteroids (TC) of medium to higher potency for at least twelve (12) weeks has failed to achieve and maintain remission of low or mild disease activity state OR (a) TC are not indicated due to severe hypersensitivity reactions or concomitant clinical situations, including but not limited to: (1) mbr has lesions located in sensitive areas (including, but not limited to, face, anogenital area or skin folds) OR (2) mbr has steroid-induced atrophy OR (3) Hx of long-term or uninterrupted topical steroid use AND (2) Daily tx of topical calcineurin inhibitors (TCI) for twelve (12) weeks has failed to achieve and maintain remission of low or mild disease activity state OR (a) TCI are not indicated due to severe hypersensitivity reactions or concomitant clinical situations, including but not limited to: (1) Hx of or active malignant or pre-malignant skin conditions OR (2) mbr has Netherton's Syndrome or other skin diseases that can increase the risk of systemic absorption of TCI OR (3) mbr is considered to be immunocompromised, including those on systemic immunosuppressive medications on an ongoing basis OR (2) Phototherapy (UVB or PUVA) has failed to achieve and maintain remission of low or mild disease activity state or is contraindicated. For continued use of Vitiligo, tx has resulted in significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to evidence of repigmentation, decrease in disease progression, decrease in affected body surface area, and/or improved quality of life).

AGE RESTRICTION

Individual is 12 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

For Initial request of atopic Dermatitis, (1) mbr has had a trial of and inadequate response or intolerance to one topical corticosteroid OR (a) Topical corticosteroid use is not acceptable due to the following concomitant clinical conditions: (i) Individual has atopic dermatitis recalcitrant to topical corticosteroids or (ii) Individual has atopic dermatitis lesions in sensitive areas (such as face, anogenital area or skin folds) or (iii) Individual has steroid-induced atrophy or (iv) Individual has history of long-term or uninterrupted topical steroid use. AND (2) Daily treatment of topical calcineurin inhibitors for six (6) weeks has failed to achieve and maintain remission of low or mild disease activity state OR (a) Topical calcineurin inhibitors (TCI) are not indicated due to severe hypersensitivity reactions or concomitant clinical situations, including but not limited to (Elidel 2017, Protopic 2019): (i) History of or active malignant or pre-malignant skin conditions or (ii) Individual has Netherton's Syndrome or other skin diseases that can increase the risk of systemic absorption of TCI or (iii) Individual is considered to be immunocompromised, including those on systemic immunosuppressive medications on an ongoing basis. For continuation use of AD, tx has resulted in significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to decrease in affected body surface area, pruritus, or severity of inflammation, and/or improved quality of life).

PART B PREREQUISITE

N/A

ORALAIR

MEDICATION(S)

ORALAIR

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For grass pollen induced allergic rhinitis, individual has a confirmed (verbal or written attestation) positive skin test OR positive in vitro testing for pollen-specific IgE antibodies for at least one of the following grass pollens: Sweet vernal, orchard, perennial rye, Timothy, or Kentucky blue grass pollen. Individual has had a trial of, and inadequate symptom control or intolerance to one (1) nasal steroid and (1) non-sedating antihistamine AND individual has a confirmed (verbal or written attestation) prescription for an auto-injectable epinephrine product.

AGE RESTRICTION

Individual is between the ages of 10 years and 65 years old.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Treatment is initiated at least 16 weeks before the expected onset of grass pollen season and is continued throughout the season.

PART B PREREQUISITE

N/A

ORENCIA

MEDICATION(S)

ORENCIA, ORENCIA CLICKJECT

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

For RA and PsA, Patient is 18 years of age or older. For JIA and acute graft versus host disease prophylaxis, Patient is 2 years of age or older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

For initial use: RA, Individual has had an inadequate response to MTX titrated to maximally tolerated dose (ACR 2021) OR if MTX is not tolerated or contraindicated, individual had an inadequate response to, is intolerant of or has contraindication to other conventional therapy (sulfasalazine, leflunomide or hydroxychloroquine) AND has had a trial and inadequate response or intolerance to Humira (adalimumab) OR Enbrel (etanercept). For PsA, individual has had an inadequate response to ONE conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, or leflunomide)] (ACR 2019) AND has had a trial and inadequate response or intolerance to Humira (adalimumab) OR Enbrel (etanercept) OR Cosentyx (secukinumab) OR Stelara (ustekinumab) OR Otezla (apremilast). For JIA, Individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional Therapy [non-biologic DMARD such as methotrexate)](ACR 2019) AND has had a

trial and inadequate response or intolerance to Humira (adalimumab) OR Enbrel (etanercept). For any of the above indications, if the TNF agent [Enbrel(etanercept)/Humira(adalimumab)/Cosentyx (secukinumab)/Stelara (ustekinumab)/ Otezla (apremilast)] are not acceptable due to Individual's age OR mbr has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction, Orencia may be allowed without trial of preferred TNF agents. For Continuation use, there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

PART B PREREQUISITE

N/A

ORENITRAM

MEDICATION(S)

ORENITRAM, ORENITRAM MONTH 1, ORENITRAM MONTH 2, ORENITRAM MONTH 3

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial requests, Individual has diagnosis of Pulmonary Arterial Hypertension World Health Organization (WHO) Group 1. Individual has the diagnosis of PAH confirmed by a right heart catheterization showing all of the following: (a) Mean pulmonary artery pressure (mPAP) greater than or equal to 25 mm Hg at rest (b) Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg (c) Pulmonary vascular resistance (PVR) greater than 3 Wood units. AND Individual has WHO functional class II- IV symptoms.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

ORFADIN

MEDICATION(S)

NITISINONE, ORFADIN

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ORGOVYX

MEDICATION(S)

ORGOVYX

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial and Continuation 6 months.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

ORILISSA

MEDICATION(S)

ORILISSA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial 6 months, Renewal is 6 months. Continuation beyond 24 months (2 years) should not be approved.

OTHER CRITERIA

For initial requests, Individual is using for moderate or severe endometriosis-associated pain AND has had a trial and inadequate response or intolerance to the following agents or has a contraindication (ACOG 2010): (a) Nonsteroidal antiinflammatory drugs (NSAIDs) AND (b) Hormonal contraceptives OR (c) Progestins (oral or depot) AND one of the following: (a) is naive to Orilissa (elagolix) OR (b) is using low dose (150 mg once daily), has mild (Child-Pugh class A) or no hepatic impairment, and has utilized Orilissa (elagolix) for a combined total duration of less than 24 months in their lifetime OR (c) is using high dose (200 mg twice daily) or has moderate hepatic impairment (Child-Pugh class B), and has utilized Orilissa (elagolix) for a combined total duration of less than 6 months in their lifetime. For continuation requests, Individual is using low dose (150 mg once daily) and has mild (Child-Pugh Class A) or no hepatic impairment AND has experienced a clinically significant improvement in

endometriosis-associated pain.

PART B PREREQUISITE

N/A

ORKAMBI

MEDICATION(S)

ORKAMBI

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

Individual is 1 years of age or older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ORLADEYO

MEDICATION(S)

ORLADEYO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

12 years of age or older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial 6 months. Continuation 1 year.

OTHER CRITERIA

For initial use, 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. For continued use, there is confirmation of a positive clinical response defined as a clinically significant reduction in the number and/or frequency of HAE attacks occurred.

PART B PREREQUISITE

N/A

ORSERDU

MEDICATION(S)

ORSERDU

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Individual is using as a single agent.

PART B PREREQUISITE

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

N/A

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, or 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) OR individual had an inadequate response to, is intolerant of , or has a contraindication ton ONE of the following topical therapies for psoriasis (Gold 2022): Medium to high potency topical steroid Tazarotene, Vitamin D analogs (calcitriol, calcipotriene, or calcipotriene/betamethasone combination agents), Topical calcineurin inhibitors (tacrolimus or pimecrolimus), Anthralin. 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].

PART B PREREQUISITE

N/A

OXANDRIN

MEDICATION(S)

OXANDROLONE 10 MG TAB, OXANDROLONE 2.5 MG TAB

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

OXLUMO

MEDICATION(S)

OXLUMO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Individual has primary hyperoxaluria type 1 (PH1) and has been confirmed by (Cochat 2012, Milliner 2005): (a) Genetic testing demonstrating mutation in the alanine:glyoxylate aminotransferase (AGXT) gene OR (b) Liver biopsy demonstrating significantly decreased or absent alanine:glyoxylate aminotransferase (AGT) enzyme activity.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 6 months, Continuation: 1 year.

OTHER CRITERIA

For initial requests, Individual is using in combination with high fluid intake (at least 3 liters/1.73 m² per day) (Cochat 2012, Hoppe 2009) AND is using in combination with pyridoxine OR individual has had a trial and inadequate response to pyridoxine (Cochat 2012, Hoppe 2009). For Continuation, there is confirmation of clinically significant reduction in urinary oxalate excretion AND is using in combination with high fluid intake and pyridoxine (unless individual is a pyridoxine non-responder) (Cochat 2012, Hoppe 2009).

PART B PREREQUISITE

N/A

OXYCONTIN

MEDICATION(S)

OXYCODONE HCL ER, OXYCONTIN

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Individual is 11 years of age or older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

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

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

PART B PREREQUISITE

N/A

OZURDEX IMPLANT

MEDICATION(S)

OZURDEX

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

PALFORZIA

MEDICATION(S)

PALFORZIA (12 MG DAILY DOSE), PALFORZIA (120 MG DAILY DOSE), PALFORZIA (160 MG DAILY DOSE), PALFORZIA (20 MG DAILY DOSE), PALFORZIA (200 MG DAILY DOSE), PALFORZIA (240 MG DAILY DOSE), PALFORZIA (3 MG DAILY DOSE), PALFORZIA (300 MG MAINTENANCE), PALFORZIA (300 MG TITRATION), PALFORZIA (40 MG DAILY DOSE), PALFORZIA (6 MG DAILY DOSE), PALFORZIA (80 MG DAILY DOSE), PALFORZIA INITIAL ESCALATION

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Individual has a confirmed (written or verbal) prescription for an auto-injectable epinephrine agent. For initial requests, a clinical history of allergy to peanuts or peanut-containing food AND if Individual has had a positive clinician-supervised oral food challenge and peanut allergy is confirmed by a positive skin prick test to peanuts greater than or equal to 3mm compared to control OR serum IgE to peanuts greater than or equal to 0.35 kUA/L. In the absence of a positive clinician-supervised food challenge, the peanut allergy is confirmed by a positive skin prick test to peanuts greater than or equal to 8mm compared to control (unless skin testing is contraindicated) OR have a serum IgE to peanuts greater than or equal to 14 kUA/L.

AGE RESTRICTION

Individual is between 4 to 17 years of age at initiation of therapy

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Individual is using in conjunction to peanut allergen avoidance to reduce the risk of anaphylaxis due to accidental exposure. For continuation requests, there is confirmation (written or verbal) of positive clinical response to Palforzia as evidenced by the ability to tolerate and comply with maintenance therapy.

PART B PREREQUISITE

N/A

PALYNZIQ

MEDICATION(S)

PALYNZIQ

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Individual has a confirmed prescription for an auto-injectable epinephrine agent.

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

For initial requests, individual has a diagnosis of phenylketonuria (PKU) and has uncontrolled blood phenylalanine (PHE) concentrations (greater than 600 micromol/L) on existing management, including but not limited to the following: (a) Dietary therapy with restriction of dietary PHE (b) Kuvan (sapropterin dihydrochloride) agents. For continued use, there is confirmation of positive response to therapy as evidenced by a reduction and maintenance of blood PHE levels below 600 micromol/L OR individual showing signs of continuing improvement but has not completed titration to maximum tolerated dose.

PART B PREREQUISITE

N/A

PART D VS PART B

MEDICATION(S)

ABELCET, ACETYLCYSTEINE 10 % SOLUTION, ACETYLCYSTEINE 20 % SOLUTION, ACYCLOVIR SODIUM, ADRIAMYCIN, ALBUTEROL SULFATE (2.5 MG/3ML) 0.083% NEBU SOLN, ALBUTEROL SULFATE (5 MG/ML) 0.5% NEBU SOLN, ALBUTEROL SULFATE 0.63 MG/3ML NEBU SOLN, ALBUTEROL SULFATE 1.25 MG/3ML NEBU SOLN, ALBUTEROL SULFATE 2.5 MG/0.5ML NEBU SOLN, AMBISOME, AMINOSYN II 15 % SOLUTION, AMINOSYN-PF 7 % SOLUTION, AMIODARONE HCL 150 MG/3ML SOLUTION, AMIODARONE HCL 450 MG/9ML SOLUTION, AMIODARONE HCL 900 MG/18ML SOLUTION, AMPHOTERICIN B 50 MG RECON SOLN, AMPHOTERICIN B LIPOSOME, ANZEMET, APREPITANT, ARFORMOTEROL TARTRATE, ARIKAYCE, ASTAGRAF XL, AZASAN, AZATHIOPRINE 100 MG TAB, AZATHIOPRINE 50 MG TAB, AZATHIOPRINE 75 MG TAB, BACLOFEN 10 MG/20ML SOLUTION, BACLOFEN 20000 MCG/20ML SOLUTION, BACLOFEN 40 MG/20ML SOLUTION, BACLOFEN 50 MCG/ML SOLN PRSYR, BENDAMUSTINE HCL, BENDEKA, BETHKIS, BLEOMYCIN SULFATE, BROVANA, BUDESONIDE 0.25 MG/2ML SUSPENSION, BUDESONIDE 0.5 MG/2ML SUSPENSION, BUDESONIDE 1 MG/2ML SUSPENSION, CALCITONIN (SALMON) 200 UNIT/ML SOLUTION, CALCITRIOL 0.25 MCG CAP, CALCITRIOL 0.5 MCG CAP, CALCITRIOL 1 MCG/ML SOLUTION, CALCITRIOL INJ 1 MCG/ML, CANCIDAS, CARBOPLATIN, CARNITOR, CARNITOR SF, CASPOFUNGIN ACETATE, CELLCEPT, CIDOFOVIR 75 MG/ML SOLUTION, CINACALCET HCL, CISPLATIN 100 MG/100ML SOLUTION, CISPLATIN 200 MG/200ML SOLUTION, CISPLATIN 50 MG/50ML SOLUTION, 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 1 GM RECON SOLN, CYCLOPHOSPHAMIDE 2 GM RECON SOLN, CYCLOPHOSPHAMIDE 25 MG CAP, CYCLOPHOSPHAMIDE 25 MG TAB, CYCLOPHOSPHAMIDE 50 MG CAP, CYCLOPHOSPHAMIDE 50 MG TAB, CYCLOPHOSPHAMIDE 500 MG RECON SOLN, CYCLOSPORINE 100 MG CAP, CYCLOSPORINE 25 MG CAP, CYCLOSPORINE 50 MG/ML SOLUTION, CYCLOSPORINE MODIFIED, DEFEROXAMINE MESYLATE 2 GM RECON SOLN, DOCETAXEL 160 MG/8ML CONC, DOCETAXEL 20 MG/ML CONC, DOCETAXEL 80 MG/4ML CONC, DOCETAXEL 80 MG/8ML SOLUTION, DOXERCALCIFEROL, DOXORUBICIN HCL, DRONABINOL, EMEND 125 MG/5ML RECON SUSP, EMEND 80 MG CAP, EMEND TRI-PACK, ENGERIX-B, ENVARSUS XR, ETOPOSIDE 1 GM/50ML SOLUTION, ETOPOSIDE 100 MG/5ML SOLUTION, ETOPOSIDE 500 MG/25ML SOLUTION, EVEROLIMUS 0.25 MG TAB, EVEROLIMUS 0.5 MG TAB, EVEROLIMUS 0.75

MG TAB, EVEROLIMUS 1 MG TAB, FLUOROURACIL 1 GM/20ML SOLUTION, FLUOROURACIL 2.5 GM/50ML SOLUTION, FLUOROURACIL 5 GM/100ML SOLUTION, FLUOROURACIL 500 MG/10ML SOLUTION, FORMOTEROL FUMARATE 20 MCG/2ML NEBU SOLN, GABLOFEN, GANCICLOVIR SODIUM, GEMCITABINE HCL 1 GM RECON SOLN, GEMCITABINE HCL 1 GM/10ML SOLUTION, GEMCITABINE HCL 2 GM RECON SOLN, GEMCITABINE HCL 2 GM/20ML SOLUTION, GEMCITABINE HCL 200 MG RECON SOLN, GEMCITABINE HCL 200 MG/2ML SOLUTION, GENGRAF, GRANISETRON HCL 1 MG TAB, HECTOROL, HEPARIN (PORCINE) IN NACL 12500-0.45 UT/250ML-% SOLUTION, HEPARIN (PORCINE) IN NACL 25000-0.45 UT/500ML-% SOLUTION, HEPARIN SODIUM (PORCINE) 1000 UNIT/ML SOLUTION, HEPARIN SODIUM (PORCINE) 10000 UNIT/ML SOLUTION, HEPARIN SODIUM (PORCINE) 20000 UNIT/ML SOLUTION, HEPARIN SODIUM (PORCINE) 5000 UNIT/ML SOLUTION, HEPLISAV-B, HERCEPTIN, HERCEPTIN HYLECTA, IBANDRONATE SODIUM 3 MG/3ML SOLUTION, IMURAN, INTRALIPID, INTRON A, IPRATROPIUM BROMIDE 0.02 % SOLUTION, IPRATROPIUM-ALBUTEROL, IRINOTECAN HCL 500 MG/25ML SOLUTION, JYNNEOS, KABIVEN, KANJINTI, KITABIS PAK, LEUCOVORIN CALCIUM 100 MG RECON SOLN, LEUCOVORIN CALCIUM 200 MG RECON SOLN, LEUCOVORIN CALCIUM 350 MG RECON SOLN, LEUCOVORIN CALCIUM 50 MG RECON SOLN, LEUCOVORIN CALCIUM 500 MG RECON SOLN, LEVALBUTEROL HCL 0.31 MG/3ML NEBU SOLN, LEVALBUTEROL HCL 0.63 MG/3ML NEBU SOLN, LEVALBUTEROL HCL 1.25 MG/0.5ML NEBU SOLN, LEVALBUTEROL HCL 1.25 MG/3ML NEBU SOLN, LEVOCARNITINE 1 GM/10ML SOLUTION, LEVOCARNITINE 200 MG/ML SOLUTION, LEVOCARNITINE 330 MG TAB, LEVOCARNITINE SF, LIORESAL, MARINOL, MELPHALAN, MIACALCIN, MITOMYCIN 20 MG RECON SOLN, MITOMYCIN 40 MG RECON SOLN, MITOMYCIN 5 MG RECON SOLN, MUTAMYCIN, MYCOPHENOLATE MOFETIL 200 MG/ML RECON SUSP, MYCOPHENOLATE MOFETIL 250 MG CAP, MYCOPHENOLATE MOFETIL 500 MG TAB, MYCOPHENOLATE SODIUM, MYFORTIC, NEBUPENT, NEORAL, NITROGLYCERIN 5 MG/ML SOLUTION, NUTRILIPID, OGIVRI, OMEGAVEN, ONDANSETRON, ONDANSETRON HCL 24 MG TAB, ONDANSETRON HCL 4 MG TAB, ONDANSETRON HCL 4 MG/5ML SOLUTION, ONDANSETRON HCL 8 MG TAB, ONIVYDE, OXALIPLATIN, PACLITAXEL, PAMIDRONATE DISODIUM 6 MG/ML SOLUTION, PARAPLATIN 1000 MG/100ML SOLUTION, PARICALCITOL, PENTAMIDINE ISETHIONATE 300 MG RECON SOLN FOR NEBULIZATION, PERFOROMIST, PERIKABIVEN, PLENAMINE, POTELIGEO, PREHEVBRIO, PREMASOL, PROGRAF, PROSOL, PULMICORT, PULMOZYME, RAPAMUNE, RECOMBIVAX HB, RIABNI, RITUXAN, RITUXAN HYCELA, ROCALTROL, RUXIENCE, SANDIMMUNE, SENSIPAR, SIROLIMUS 0.5 MG TAB, SIROLIMUS 1 MG TAB, SIROLIMUS 1 MG/ML SOLUTION, SIROLIMUS 2 MG TAB, SMOFLIPID, SYNDROS, TACROLIMUS 0.5 MG CAP, TACROLIMUS 1 MG CAP, TACROLIMUS 5 MG CAP, TICE BCG, TOBI, TOBRAMYCIN 300 MG/4ML NEBU SOLN, TOBRAMYCIN 300 MG/5ML NEBU SOLN, TOPOSAR 500 MG/25ML SOLUTION, TRAVASOL, TRAZIMERA 150 MG RECON SOLN, TREANDA, TROPHAMINE, TRUXIMA, VARUBI (180 MG DOSE), VINBLASTINE SULFATE, VINCRISTINE

SULFATE, VINORELBINE TARTRATE, XOPENEX, XOPENEX CONCENTRATE, YUPELRI, ZEMPLAR, ZOLADEX, ZORTRESS

DETAILS

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

PEGFILGRASTIM AGENTS

MEDICATION(S)

FULPHILA, FYLNETRA, NEULASTA, NEULASTA ONPRO, NYVEPRIA, UDENYCA, ZIEXTENZO

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 $0.1 \times 10^9/L$) 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 $450/\mu L$) 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 $1500/mm^3$), poor renal function (GFR less than $60mL/min$) , liver dysfunction (liver function tests at least 2x upper limit of normal or bilirubin gr than $2.0 mg/dL$) (Lyman 2014) (Aagaard 2018), recent surgery performed as part of cancer management within previous 30 days (not to include a procedure such as port placement, drain placement, IVC filter, etc) (Lyman 2014, Aagaard 2018). History of active infection within previous 60 days (Lyman 2014, Aagaard 2018). Current open wound and chemotherapy cannot be delayed (Lyman 2014, Aagaard 2018).

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

PEMAZYRE

MEDICATION(S)

PEMAZYRE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

PERJETA

MEDICATION(S)

PERJETA

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 confirmed by one of the following, immunohistochemistry (IHC) 3+ or In Situ hybridization (ISH) positive.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

following: docetaxel with or without carboplatin or paclitaxel AND pertuzumab is used for a maximum of 18 cycles (12 month course) OR individual is requesting Perjeta in combination with trastuzumab (or trastuzumab biosimilars) for 12 months after completing 6 cycles (18 weeks) of TCHP (docetaxel, carboplatin, trastuzumab (or trastuzumab biosimilars), pertuzumab) for early stage, locally advanced, or inflammatory breast cancer.

PART B PREREQUISITE

N/A

PHESGO

MEDICATION(S)

PHESGO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

PIQRAY

MEDICATION(S)

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

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

POMALYST

MEDICATION(S)

POMALYST

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

PONVORY

MEDICATION(S)

PONVORY, PONVORY STARTER PACK

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

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

PART B PREREQUISITE

N/A

PROLIA

MEDICATION(S)

PROLIA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

For Osteoporosis 18 years of age or older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

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

PART B PREREQUISITE

N/A

PROMACTA

MEDICATION(S)

PROMACTA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 6 months. Continuation: 1 Year.

OTHER CRITERIA

For initial therapy: 1) Diagnosis of chronic immune (idiopathic) thrombocytopenia (ITP) AND individual has platelet count of less than $30 \times 10^9/L$ or active bleeding (ASH, 2011. Hicks et al., 2014) AND has had a prior trial and insufficient response to one of the following: a) corticosteroids OR b) immunoglobulins [for example, intravenous, anti-D] or c) splenectomy OR 2) Diagnosis of severe aplastic anemia AND individual has a platelet count of less than or equal to $30 \times 10^9/L$ (Olmes et al., 2012. Desmond et al., 2014) AND individual has had a prior trial and insufficient response to an immunosuppressive therapy [such as, anti-thymocyte globulin (ATG)] OR 3) individual is using as first-line treatment in combination with standard immunosuppressive therapy 4) Treatment of thrombocytopenia in individual with hepatitis C AND individual has thrombocytopenia that prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy. For continuation therapy, for ITP, severe aplastic anemia or thrombocytopenia in individuals with Hep C,

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

PART B PREREQUISITE

N/A

PROTOPIC

MEDICATION(S)

PROTOPIC, TACROLIMUS 0.03 % OINTMENT, TACROLIMUS 0.1 % OINTMENT

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

PURIXAN

MEDICATION(S)

PURIXAN

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

PYRUKYND

MEDICATION(S)

PYRUKYND, PYRUKYND TAPER PACK

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial therapy, individual has a diagnosis of hemolytic anemia due to pyruvate kinase deficiency AND is confirmed by ONE of the following: (a) Low levels of red blood cells PK enzymatic activity OR (b) at least 2 mutations of the pyruvate kinase liver and red blood cell (RBC) gene known or expected to impair PK activity, one of which is a missense mutation AND ONE of the following: (a) Hemoglobin is 10 g/dL or below OR (b) has had six or more RBC mutations for hemolytic anemia due to PKD in the last 52 weeks prior to initiation of Pyrukynd. For continuation therapy, individual has experienced an increase of hemoglobin of at least 1.5 g/dL from baseline or has decreased RBC transfusion episodes from baseline.

AGE RESTRICTION

18 years of age or older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

QINLOCK

MEDICATION(S)

QINLOCK

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

QUININE

MEDICATION(S)

QUALAQUIN, QUININE SULFATE 324 MG CAP

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

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

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

QULIPTA

MEDICATION(S)

QULIPTA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For Initial use, individual has a diagnosis of one of the following: (1) 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 OR (2) 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) AND is using agent for migraine prophylaxis AND If individual is also currently using botulinum toxin for prophylaxis and is going to be using Qulipta and botulinum toxin together (i.e., not switching from one agent to another), the following must apply: (A) Individual has had a reduction in the overall number of migraine days or reduction in number of severe migraine days per month with botulinum toxin use AND (B) Individual continues to experience a significant number of migraine headache days or severe migraine days per month requiring additional therapy for migraine prevention AND had a trial of and inadequate response to a 2 month trial at target or usual effective dose or intolerance to up to two agents for migraine prophylaxis (at least in any 2 of the following classes) or has a contraindication to all the following medications: The following antidepressants: amitriptyline, venlafaxine, nortriptyline, duloxetine OR One of the following beta blockers: Metoprolol, propranolol, timolol (oral), nadolol, atenolol, nebivolol OR The following calcium channel blocker: verapamil OR One of the following antiepileptic agents: valproate sodium, divalproex sodium, topiramate, gabapentin OR Botox (for chronic migraine).

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial 3 Months, Continuation 1 year.

OTHER CRITERIA

For Continuation, individual has a reduction in the overall number of migraine days or reduction in number of severe migraine days per month AND has obtained clinical benefit deemed significant by individual or prescriber including any of the following (AHS 2019): (a) 50% reduction in frequency of days with headache or migraine OR (b) Significant decrease in attack duration OR (c) Significant decrease in attack severity OR (d) Improved response to acute treatment OR (e) Reduction in migraine-related disability and improvements in functioning in important areas of life OR (f) Improvements in health-related quality of life and reduction in psychological stress due to migraine AND If individual is using concurrently with botulinum toxin for migraine prophylaxis, the following must apply: (a) Individual has had further reduction in the overall number of migraine days or reduction in number of severe migraine days per month compared to monotherapy with botulinum toxin.

PART B PREREQUISITE

N/A

RAGWITEK

MEDICATION(S)

RAGWITEK

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For short ragweed pollen induced allergic rhinitis, individual has a documented positive skin test OR positive in vitro testing for pollen-specific IgE antibodies for short ragweed pollen. Individual has had a trial of, and inadequate symptom control or intolerance to (1) nasal steroid and (1) non-sedating antihistamine AND individual has a confirmed (verbal or written attestation) prescription for an auto-injectable epinephrine product.

AGE RESTRICTION

Individual is between the ages of 5 years and 65 years old.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Treatment is initiated at least 12 weeks before the expected onset of ragweed pollen season and is continued throughout the season.

PART B PREREQUISITE

N/A

RANEXA

MEDICATION(S)

ASPRUZYO SPRINKLE, RANEXA, RANOLAZINE ER

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

RAVICTI

MEDICATION(S)

RAVICTI

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

REBLOZYL

MEDICATION(S)

REBLOZYL

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Baseline hemoglobin level is less than or equal to 11.0.

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial 6 months, Continuation 1 Year.

OTHER CRITERIA

For initial requests: For dx beta thalassemia/hg E beta thalassemia, Individual required regular red blood cell transfusions at initiation, defined as both of the following (NCT02604433): individual received six to twenty RBC units in the last 24 weeks and had no transfusion-free period greater than 35 days in the last 24 weeks AND individual has a baseline hemoglobin level less than or equal to 11 g/dL. For MDS or MDS/MPN RS T, Individual has required regular red blood cell transfusions of two (2) or more RBC units over eight (8) weeks in the last 16 weeks AND has a baseline hemoglobin (Hgb) level less than or equal to 11 g/dL. AND has one of the following (A or B) (A) has a diagnosis very low to intermediate risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) greater than or equal to 15% (or ring sideroblasts 5% to 14% with an SF3B1 mutation) (Label, NCCN 2A) AND meets one of the following criteria: (1) Serum erythropoietin (EPO) level of greater than 500 mU/mL OR (2) Serum EPO level of less than or equal to 500 mU/mL following no response to combination treatment with

erythropoiesis-stimulating agent (ESA) and granulocyte-colony stimulating factor (G-CSF). OR (B) Individual has a diagnosis of myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) with all the following: (1) Ring sideroblasts greater than or equal to 15% (WHO 2017) AND (2) Thrombocytosis (defined as platelets greater than or equal to $450 \times 10^9/L$) (WHO 2017) AND (3) Insufficient response to ESAs. For continuation requests, individual demonstrates continued need for treatment and has confirmation of response to treatment as evidenced by a decrease in transfusion burden from baseline.

PART B PREREQUISITE

N/A

REBYOTA

MEDICATION(S)

REBYOTA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For CDI, Individual has had at least three episodes of Clostridioides difficile infection (initial episode and two recurrences) treated with antibiotic therapy (including Difacid, metronidazole or oral vancomycin) AND the current episode of Clostridioides difficile infection has been verified with a positive stool test for Clostridioides difficile toxin AND is administered within 24 to 72 hours of completing antibiotic treatment for the current Clostridioides difficile infection episode.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

One Time.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

RECLAST

MEDICATION(S)

RECLAST, ZOLEDRONIC ACID 5 MG/100ML SOLUTION

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

RECORLEV

MEDICATION(S)

RECORLEV

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 and older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Individual has had a trial of ketoconazole and experienced inadequate response (Nieman 2015) AND one of the following: (a) Disease persists or recurs following pituitary surgery OR (b) pituitary surgery is not indicated or an option.

PART B PREREQUISITE

N/A

REGRANEX

MEDICATION(S)

REGRANEX

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

3 months

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

RELISTOR

MEDICATION(S)

RELISTOR

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

REMICADE

MEDICATION(S)

AVSOLA, INFLECTRA, INFLIXIMAB, REMICADE, RENFLEXIS

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

For Crohn's Disease or Ulcerative colitis, 6 yr of age or older. For JIA, 2 yr of age or older. For all other indications 18 yr of age.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

For initial use: RA, MTX titrated to maximally tolerated dose (ACR 2021) OR if MTX is not tolerated or contraindicated, individual had an inadequate response to, is intolerant of or has contraindication to other conventional therapy (sulfasalazine, leflunomide or hydroxychloroquine. For moderate to severe Crohn's Disease, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy (such as 5-ASA products, sulfasalazine, systemic corticosteroids, or immunosuppressive drugs). For moderate to severe Ulcerative Colitis, individual an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy (such

as 5-ASA products, sulfasalazine, systemic corticosteroids, or immunosuppressive drugs). For Ankylosing Spondylitis, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy [such as NSAIDs, or nonbiologic DMARDs (such as sulfasalazine)] (ACR 2019)]. For Psoriatic Arthritis, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy [nonbiological DMARDs (such as methotrexate, sulfasalazine, or leflunomide)]. For chronic plaque psoriasis, individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or ONE other systemic therapy (such as methotrexate, acetretin, or cyclosporine). For Refractory Wegener's Granulomatosis, individual is using in combination with ONE corticosteroid. For PJIA, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE Conventional Therapy [nonbiologic DMARD (such as methotrexate)]. For chronic, recurrent, treatment-refractory or vision-threatening, non-infectious uveitis, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy (such as corticosteroids or immunosuppressive drugs [for example, azathioprine, cyclosporine, or methotrexate]). For Sarcoidosis (Baughman 2006), mbr has had an inadequate response to, is intolerant of, or has a contraindication to systemic corticosteroids AND has had an inadequate response to, is intolerant of, or has a contraindication to nonbiologic DMARDs (such as methotrexate or azathioprine). For Continuation use there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

PART B PREREQUISITE

N/A

REMODULIN

MEDICATION(S)

REMODULIN, TREPROSTINIL

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

associated with congenital heart defects, and all Group 1 subtypes) AND Individual has confirmed inability to tolerate treatment by subcutaneous infusion of Remodulin (treprostinil). For continuation, there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in walk distance, dyspnea and/or functional class).

PART B PREREQUISITE

N/A

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 than 190 mg/dL) OR (B) Heterozygous Familial Hypercholesterolemia (HeFH) with diagnosis confirmed by: 1. Presence of a mutation in LDLR, apolipoprotein B (ApoB), PCSK9 or ARH adaptor protein (LDLRAP1) gene locus OR 2. World Health Organization (WHO)/Dutch Lipid Network Criteria with score of greater 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) 4. Stable or unstable angina 5. Coronary or other arterial revascularization 6. Stroke 7. Transient ischemic attack (TIA) 8. Peripheral arterial disease (PAD) OR (D) Primary hyperlipidemia alone or in combination with other lipid lowering agents. OR (E) using prophylactically for Established CVD.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 6 months. Continuation: 1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

RETEVMO

MEDICATION(S)

RETEVMO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

REVATIO

MEDICATION(S)

REVATIO 10 MG/ML RECON SUSP, REVATIO 20 MG TAB, SILDENAFIL CITRATE 10 MG/ML RECON SUSP, SILDENAFIL CITRATE 20 MG TAB

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Individuals requesting for the treatment of erectile dysfunction.

REQUIRED MEDICAL INFORMATION

For initial requests, individual has diagnosis of Pulmonary Arterial Hypertension in adults World Health Organization (WHO) Group I AND Individual has the diagnosis of PAH confirmed by a right heart catheterization showing all of the following: (a) Mean pulmonary artery pressure (mPAP) greater than or equal to 25 mm Hg at rest (b) Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg (c) Pulmonary vascular resistance (PVR) greater than 3 Wood units AND Individual has WHO functional class II- IV symptoms.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

REVATIO IV

MEDICATION(S)

REVATIO 10 MG/12.5ML SOLUTION, SILDENAFIL CITRATE 10 MG/12.5ML SOLUTION

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

Initial requests, individual has diagnosis of Pulmonary Arterial Hypertension World Health Organization (WHO) Group 1. Individual has the diagnosis of PAH confirmed by a right heart catheterization showing all of the following: (a) Mean pulmonary artery pressure (mPAP) greater than or equal to 25 mm Hg at rest (b) Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg (c) Pulmonary vascular resistance (PVR) greater than 3 Wood units. AND Individual has WHO functional class II- IV symptoms.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

For initial sildenafil INJ requests, individual is temporarily unable to take oral dose forms and requires continued therapy. For continuation requests, there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in walk distance, dyspnea and/or functional class) AND individual is unable to take oral dose forms and requires continued injection therapy.

PART B PREREQUISITE

N/A

REVLIMID

MEDICATION(S)

LENALIDOMIDE, REVLIMID

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 YEAR.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

REYVOW

MEDICATION(S)

REYVOW

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

REZLIDHIA

MEDICATION(S)

REZLIDHIA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial use, individual has AML, and written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis. Individual has an ECOG performance status of 0-2.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 6 months, Continuation: 1 year

OTHER CRITERIA

For Continued use, there is confirmation of clinically significant improvement (e.g. no disease progression) or stabilization of disease.

PART B PREREQUISITE

N/A

REZUROCK

MEDICATION(S)

REZUROCK

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 12 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

For cGVHD after failure of at least two prior lines of systemic therapy.

PART B PREREQUISITE

N/A

RINVOQ

MEDICATION(S)

RINVOQ

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

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

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

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

PART B PREREQUISITE

N/A

ROLVEDON

MEDICATION(S)

ROLVEDON

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 $0.1 \times 10^9/L$) 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 $450/\mu L$) 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 $1500/mm^3$), poor renal function (GFR less than $60 mL/min$) , 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. Indv using for autologous hematopoietic stem cell (HSC) mobilization as part of the development of an FDA-approved ex vivo gene therapy (e.g. Zynteglo (betibeglogene autotemcel)).

PART B PREREQUISITE

N/A

ROZLYTREK

MEDICATION(S)

ROZLYTREK

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

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

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Individual is using as monotherapy.

PART B PREREQUISITE

N/A

RUBRACA

MEDICATION(S)

RUBRACA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

RUCONEST

MEDICATION(S)

RUCONEST

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 ONE of the following (a or b): a) C1 inhibitor (C1-INH) antigenic level below the lower limit of normal OR b) C1-INH functional level below the lower limit of normal AND Individual has a history of moderate or severe attacks (for example, airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, painful facial distortion).

AGE RESTRICTION

13 years and older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

RYBREVANT

MEDICATION(S)

RYBREVANT

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Using Rybrevant as a single agent.

PART B PREREQUISITE

N/A

RYDAPT

MEDICATION(S)

RYDAPT

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

SABRIL

MEDICATION(S)

SABRIL, VIGABATRIN, VIGADRONE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

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

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 YEAR.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

SAMSCA

MEDICATION(S)

SAMSCA, TOLVAPTAN

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

30 Days

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

SANCUSO

MEDICATION(S)

SANCUSO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/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 of and inadequate response or intolerance to EITHER generic ondansetron or oral granisetron OR individual is unable to take oral medications due to the following: (A)The presence of head and neck cancer OR (B)Mucositis due to recent radiation to the head and neck area.

PART B PREREQUISITE

N/A

SARCLISA

MEDICATION(S)

SARCLISA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

SCEMBLIX

MEDICATION(S)

SCEMBLIX

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

SIGNIFOR IR

MEDICATION(S)

SIGNIFOR

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

SIGNIFOR LAR

MEDICATION(S)

SIGNIFOR LAR

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

SIKLOS

MEDICATION(S)

SIKLOS

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/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 sickle cell anemia with recurrent moderate to severe painful crises AND is unable to swallow the oral tablet dosage form and requires a dispersible tablet due to a clinical condition such as but not limited to the following: (a) Dysphagia or (b) Individuals age.

PART B PREREQUISITE

N/A

SILIQ

MEDICATION(S)

SILIQ

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.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

For initial use: a dx of 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) AND individual has had a trial of and an inadequate response or is intolerant to: Humira(adalimumab) or Enbrel (etanercept) OR Cosentyx (secukinumab) OR Skyrizi (risankizumab-rzaa) OR Stelara (ustekinumab) OR Otezla (apremilast) OR if the TNF agent [Enbrel(etanercept)/Humira(adalimumab)/Cosentyx (secukinumab)/Skyrizi (risankizumab-rzaa)/Stelara (ustekinumab)/Otezla (apremilast)] are not acceptable due to Individual's age, Siliq may be allowed without trial of preferred TNF agents. For Continuation use, there is confirmation (written or verbal) of

clinically significant improvement or stabilization in clinical signs and symptoms of disease.

PART B PREREQUISITE

N/A

SIMPONI

MEDICATION(S)

SIMPONI

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 initial use: RA, individual had an inadequate response to MTX titrated to maximally tolerated dose (ACR 2021) OR if MTX is not tolerated or contraindicated, individual has had an inadequate response to, is intolerant of or has a contraindication to other conventional therapy (sulfasalazine, leflunomide or hydroxychloroquine) AND individual has had a trial of and inadequate response or intolerance to: Humira (adalimumab) OR Enbrel (etanercept). 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)] AND individual has had a trial of and an inadequate response or intolerance to Humira (adalimumab) OR Enbrel(etanercept) OR Cosentyx (secukinumab) OR Stelara (ustekinumab) OR Otezla (apremilast). For Ankylosing Spondylitis, had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy (e.g. NSAIDs or nonbiologic DMARDs) AND individual has had a trial of and an inadequate response or

intolerance to: Humira (adalimumab) OR Enbrel(etanercept) OR Cosentyx (secukinumab). For UC, individual has had an inadequate response, is intolerant of, or has a contraindication to ONE conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants) AND individual has had a trial of and an inadequate response or is intolerant to Humira (adalimumab) OR Stelara (ustekinumab). For any of the above indications, if the TNF agent [Enbrel(etanercept)/Humira(adalimumab)/Cosentyx (secukinumab)/Stelara (ustekinumab)] are not acceptable due to Individual's age. Simponi may be allowed without trial of preferred TNF agents [Enbrel(etanercept)/Humira(adalimumab)/Cosentyx (secukinumab)/Stelara (ustekinumab)/Otezla (apremilast)]. For Continuation use, there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

PART B PREREQUISITE

N/A

SIMPONI ARIA

MEDICATION(S)

SIMPONI ARIA

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 initial use: RA, individual had an inadequate response to MTX titrated to maximally tolerated dose (ACR 2021) OR if MTX is not tolerated or contraindicated, individual has had an inadequate response to, is intolerant of or has a contraindication to other conventional therapy (sulfasalazine, leflunomide or hydroxychloroquine) AND individual has had a trial of and an inadequate response or intolerance to: Humira (adalimumab) OR Enbrel (etanercept). For PsA, individual has had an inadequate response to, is intolerant of or has a contraindication to ONE conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, or leflunomide)] AND has had a trial of and an inadequate response or intolerance to: Humira (adalimumab) OR Enbrel (etanercept) OR Cosentyx (secukinumab) OR Stelara (ustekinumab) OR Otezla (apremilast). For Ankylosing Spondylitis, individual has had an inadequate response to, is intolerant of or has a contraindication to conventional therapy [NSAIDs or nonbiologic DMARDs (such as sulfasalazine)] AND individual has had a trial of and an inadequate response or

intolerance to Humira (adalimumab) OR Enbrel(etanercept) OR Cosentyx (secukinumab). For PJIA, individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic DMARDs (such as methotrexate)] (ACR 2019). For any of the above indications, if the TNF agent [Enbrel(etanercept)/Humira(adalimumab)/Cosentyx (secukinumab)/Stelara (ustekinumab)/ Otezla (apremilast)] are not acceptable due to Individual's age. Simponi Aria may be allowed without trial of preferred TNF. For Continuation use, there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

PART B PREREQUISITE

N/A

SIRTURO

MEDICATION(S)

SIRTURO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 YEAR.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

SIVEXTRO

MEDICATION(S)

SIVEXTRO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Individual has been diagnosed with acute bacterial skin and skin structure infection (ABSSSI) defined as one of the following (FDA, 2013): Cellulitis/erysipelas OR Wound infection OR Major cutaneous abscess. AND Individual has at least 1 regional or 1 systemic sign of infection as defined by: Lymphadenopathy OR temperature greater than or equal to 38 degrees Celsius OR White blood cell count greater than or equal to 10,000 per microliter OR White blood cell count less than 4000 per microliter OR Greater than 10% of immature neutrophils AND is caused by methicillin-resistant Staphylococcus aureus (MRSA).

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

30 days

OTHER CRITERIA

Individual has had a trial and inadequate response or intolerance to of 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: Trimethoprim/sulfamethoxazole (TMP/SMX), doxycycline, vancomycin, daptomycin, telavancin, clindamycin) (IDSA 2014) OR Individual started treatment with intravenous antibiotic(s) in

the hospital and requires continued outpatient therapy for an organism susceptible to Sivextro (tedizolid).

PART B PREREQUISITE

N/A

SKYCLARYS

MEDICATION(S)

SKYCLARYS

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

N/A

PART B PREREQUISITE

N/A

SKYRIZI

MEDICATION(S)

SKYRIZI, SKYRIZI PEN

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year.

OTHER CRITERIA

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

symptoms of disease.

PART B PREREQUISITE

N/A

SOLARAZE

MEDICATION(S)

DICLOFENAC SODIUM 3 % GEL

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Dx of Actinic Keratosis

AGE RESTRICTION

18 years of age or older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

SOLIRIS

MEDICATION(S)

SOLIRIS

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial tx of Paroxysmal nocturnal hemoglobinuria (PNH) as doc by flow cytometry, including the presence of (Parker 2005): (1)PNH type III red cell clone or a measurable granulocyte or monocyte clone OR (2)Glycosylphosphatidylinositol-anchored proteins (GPI-AP)-deficient polymorphonuclear cells (PMNs) AND mbr has been immunized with a meningococcal (MEN) vaccine at least 2 wk prior to admin of the first dose of eculizumab (unless risks of delaying outweigh the risk of MEN infection) AND NO evidence of active MEN infection AND mbr has (a)LDH is greater than 1.5 times the ULN AND (b)One or more PNH-related sign or symptom (such as but not limited to anemia or hx of a major ADV vascular event from thromboembolism). For initial tx of atypical hemolytic uremic syndrome (aHUS) if the following is met: (A)Dx of aHUS is supported by the absence of Shiga toxin-producing E. coli infection AND (B)Thrombotic thrombocytopenic purpura (TTP) has been ruled out (i.e, normal ADAMTS 13 activity and no evidence of ADAMTS 13 inhibitor), or if TTP cannot be ruled out by lab and clinical eval, a trial of plasma exchange did not result in clinical improvement AND (C)Mbr has been immunized with a MEN vaccine at least 2 wk prior to admin of first dose of eculizumab (unless risks of delaying outweigh risk of MEN infection) AND (D) There is NO evidence of active MEN infection. Initial tx, neuromyelitis optica spectrum disorder (NMOSD) is seropositive as confirmed (written or verbal) by the presence of anti- aquaporin-4 (AQP4) antibodies AND has a hx of at least 2 acute attack or relapses in last 12 months prior to initiation of therapy OR has hx of at least 3 acute attacks or relapses in the last 24 months AND at least 1 relapse in the 12 mon prior to initiation of therapy AND immunized with a MEN vaccine at least 2 wks prior to admin of the first dose of eculizumab, unless risks of delaying eculizumab outweigh risk of MEN infection AND has no evidence of active MEN infection.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

For PNH Initial 6 mon. For aHUS Initial 3 mon. For MG Initial 7 mon. Continuation 1 year for all dx.

OTHER CRITERIA

For Cont for the tx of NMOSD may be approved when mbr has experienced a clinical response. For initial tx of myasthenia gravis (MG) if the following criteria are met: (A)mbr has MG Foundation of America Clinical Classification Class II to IV disease AND (B)has a documented (written or verbal) positive serologic test for binding anti-acetylcholine receptor antibodies (AChR-ab) AND (C) had inadequate response to, is intolerant of, or has a medical CI to two or more immunosuppressive drug agents (such as, azathioprine, cyclosporine, or MTX) as monotherapy or in comb therapy for greater than or equal to 12 mon OR (D)had inadequate response to, is intolerant of, or has a CI to one or more immunosuppressive drug agents as monotherapy or in comb therapy and requires chronic plasma exchange or plasmapheresis or intravenous IG therapy AND (E)has been immunized with a MEN vaccine at least 2 wks prior to admin of the first dose of eculizumab unless the clinical record documents the risks of delaying eculizumab outweigh the risk of MEN infection AND (F)no evidence of an active MEN infection AND (G)has MG ADL score of at least 6 or higher. For Cont following initial tx of aHUS may be approved if: clinical improvement after the initial trial (i.e., increased platelet count or lab evidence of reduced hemolysis) until an mbr becomes a candidate for physician directed cessation as evidenced by the following (Merrill 2017): (a)Complete clinical remission has been achieved (that is, resolution of thrombocytopenia and mechanical hemolysis, and normalization or new baseline plateau of renal function) and improvement of precipitating illness is clinically apparent AND (b)Duration of clinical remission has been stable for 2 mon. Resumption of eculizumab in aHUS may be approved (Fakhouri 2017): (A)mbr exp a relapse after d/c of therapy as defined by: (1)Reduction in platelet count to less than 150,000/mm³ or greater than 25% from baseline OR (2)Mechanical hemolysis (having 2 or more features of hg less than 10 g/dL, lactate dehydrogenase greater than 2 times ULN, undetectable haptoglobin, or presence of schistocytes on smear) OR (3)Acute kidney injury with serum creatinine increase gr than 15% from baseline. For Cont for the tx of gMG, mbr has experienced a clinical response as evidenced by both: (1)Reduction in signs or symptoms that impact daily function AND (2)At least a 3 point reduction in MG-ADL total score from baseline.

PART B PREREQUISITE

N/A

SOMATULINE DEPOT

MEDICATION(S)

LANREOTIDE ACETATE, 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

PART B PREREQUISITE

N/A

SOMAVERT

MEDICATION(S)

SOMAVERT

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

SOTYKTU

MEDICATION(S)

SOTYKTU

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial therapy, individual has extensive or disabling plaque psoriasis that involves greater than 3% body surface area (BSA) OR Plaque Ps involving less than or equal to 3% BSA involving sensitive areas or areas with significant impact on daily function (such as palms, soles of feet, head/neck, or genitalia) AND has had inadequate response to, is intolerant of or has a contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine or MTX) AND has had a trial and inadequate response or intolerance to Enbrel (etanercept) OR Humira (adalimumab) OR Cosentyx (secukinumab) OR Stelara (ustekinumab) OR Skyrizi (risankizumab-rzaa) OR Otezla (apremilast) OR The PF agent [Humira (adalimumab)/Enbrel (etanercept)/ Cosentyx (secukinumab)/Stelara (ustekinumab)/Skyrizi (risankizumabrzaa)/Otezla (apremilast)] are not acceptable due to individual's age.

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

For continuation therapy, there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

PART B PREREQUISITE

N/A

SOVALDI

MEDICATION(S)

SOVALDI

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

Criteria will be applied consistent with current AASLD/IDSA guidance. For GT 1, Individual has had a prior trial and inadequate response to Harvoni(sofosbuvir/ledipasvir) OR individual is currently on and completing a course of therapy with the requested regimen OR Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Harvoni (ledipasvir/sofosbuvir) which is not also in Sovaldi OR Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Harvoni(sofosbuvir/ledipasvir) OR Individual has a unique

disease characteristic to which the preferred regimen(s) is not recommended (examples include specific genotype subtype, resistance-associated substitution [RAS], or polymorphism). For GT 4, individual has had a prior trial and inadequate response to Harvoni(sofosbuvir/ledipasvir) or Epclusa(sofosbuvir/velpatasvir) OR individual is currently on and completing a course of therapy with the requested regimen OR Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Harvoni(sofosbuvir/ledipasvir) or Epclusa (sofosbuvir/velpatasvir) which is not also in Sovaldi OR Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Harvoni (sofosbuvir/ledipasvir) or Epclusa(sofosbuvir/velpatasvir) OR Individual has a unique disease characteristic to which the preferred regimen(s) is not recommended (examples include specific genotype subtype, resistance-associated substitution [RAS], or polymorphism).

PART B PREREQUISITE

N/A

SPRAVATO

MEDICATION(S)

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

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

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

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

PART B PREREQUISITE

N/A

SPRYCEL

MEDICATION(S)

SPRYCEL

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

STELARA

MEDICATION(S)

STELARA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

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

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

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

PART B PREREQUISITE

N/A

STIVARGA

MEDICATION(S)

STIVARGA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

STRENSIQ

MEDICATION(S)

STRENSIQ

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Total serum alkaline phosphatase level is below the lower limit of normal for the individual's age and gender at diagnosis (Whyte 2012) and plasma pyridoxal 5'-phosphate levels are greater than the upper limit of normal at the time of diagnosis (Whyte 2012).

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 3 months. Continuation: 1 year

OTHER CRITERIA

For initial treatment of perinatal/infantile onset hypophosphatasia (HPP) and had onset of symptoms prior to 6 months of age OR has a diagnosis of juvenile-onset HPP and had onset of disease at less than or equal to 18 years of age. and has one or more of the following: (a) Radiographic evidence of poor bone mineralization including flared and frayed metaphyses, severe/ generalized osteopenia, or widened growth plates (Whyte 2012) or (b) Genetic test results that confirm infantile HPP or (c) one of the following: (1) History or presence of nontraumatic postnatal fracture healing or (2) History of elevated serum calcium or (3) Functional craniosynostosis with decreased head circumference growth or (4) Nephrocalcinosis or (5) Rachitic chest deformity or (6) Respiratory compromise or (7) Vitamin B6-responsive seizures or (8) Failure to thrive. For Continuation of Therapy: The individual has

demonstrated clinical improvement in symptoms (for example, respiratory status, radiographic findings, growth) following asfotase alfa therapy.

PART B PREREQUISITE

N/A

STROMECTOL

MEDICATION(S)

IVERMECTIN 3 MG TAB, STROMECTOL

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

For the treatment or prophylaxis of COVID-19.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

SUBSYS

MEDICATION(S)

SUBSYS

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 Subsys (fentanyl) for cancer related breakthrough pain.

PART B PREREQUISITE

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

PART B PREREQUISITE

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.

PART B PREREQUISITE

N/A

SYMLIN

MEDICATION(S)

SYMLINPEN 120, SYMLINPEN 60

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

SYNAGIS

MEDICATION(S)

SYNAGIS

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Individual is using when the following are met: A) Maximum of Five (5) doses of palivizumab for infants during the first RSV season within the first year of life (infants in their first year of life who were administered RSV prophylaxis in April - September for coverage during a delayed RSV season may be evaluated under first RSV season criteria in the upcoming year): Born before 29 weeks 0 days gestation (up to and including 28 weeks, 6 days) and younger than 12 months of age at the start of the RSV season OR Chronic lung disease (CLD) of prematurity defined as birth at less than 32 weeks, 0 days gestation and a requirement for greater than 21% oxygen for at least 28 days after birth OR Hemodynamically significant congenital heart disease (CHD) (including infants with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures and infants with moderate to severe pulmonary hypertension OR infants with anatomic pulmonary abnormalities (i.e., tracheal ring) or a neuromuscular condition that impairs the ability to clear secretions from the upper airway because of ineffective cough OR Cystic fibrosis with clinical evidence of chronic lung disease or nutritional compromise (weight for length less than tenth percentile). B) Maximum of five (5) doses of palivizumab for children younger than 24 months of age with any of the following: Profoundly immunocompromised, including severe combined immunodeficiency, advanced acquired immunodeficiency syndrome undergoing organ or hematopoietic stem cell transplant, or an absolute lymphocyte count of less than 100 cell/mm³ OR undergoing cardiac transplantation of less than 100 cell/mm³ OR undergoing cardiac transplantation.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

5 Months.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

SYNAREL NASAL SOLUTION

MEDICATION(S)

SYNAREL

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Endometriosis: 6 months, all other indications: 1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

SYNRIBO

MEDICATION(S)

SYNRIBO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

TABRECTA

MEDICATION(S)

TABRECTA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Individual is using Tabrecta (capmatinib) as monotherapy.

PART B PREREQUISITE

N/A

TAFAMIDIS AGENTS

MEDICATION(S)

VYNDAMAX, VYNDAQEL

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/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, Individual has a diagnosis of wild type or hereditary transthyretin amyloid cardiomyopathy confirmed (written or verbal) by (Dorbala 2021): Endomyocardial or extracardiac biopsy OR radionuclide scintigraphy (99mTc-PYP/DPD/HMDP) AND is using for the treatment of New York Heart Association class I, II or III heart failure symptoms (Maurer, 2018). For Continuation, there is confirmation (verbal or written attestation is acceptable) of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to reduction in hospitalizations, improvement, or stabilization in 6-minute walk test, improvement in symptom burden or frequency).

PART B PREREQUISITE

N/A

TAFINLAR

MEDICATION(S)

TAFINLAR

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

TAGRIS

MEDICATION(S)

TAGRIS

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

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

2 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.

PART B PREREQUISITE

N/A

TALTZ

MEDICATION(S)

TALTZ

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: 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

For PS, individual is age 6 and older. For all others, Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

For Initial use: For a dx of moderate to severe psoriatic arthritis, the individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional drug therapy [nonbiologic DMARDS (such as methotrexate, sulfasalazine, or leflunomide)] (ACR 2019) AND individual has tried and failed: Humira(adalimumab) OR Enbrel(etanercept) OR Cosentyx (secukinumab) OR Stelara (ustekinumab) OR Otezla (apremilast). For a dx of moderate to severe plaque psoriasis, had an inadequate response, is intolerant of, or has a medical contraindication to phototherapy or any ONE systemic therapy (for example acitretin, methotrexate, cyclosporine) AND individual has tried and failed: Humira(adalimumab)OR Enbrel(etanercept) OR Cosentyx (secukinumab) OR Stelara

(ustekinumab) OR Skyrizi (risankizumab-rzaa) OR Otezla (apremilast). For a dx of Active Ankylosing Spondylitis (AS) Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)] AND has had a trial and inadequate response or intolerance to Enbrel (etanercept) OR Humira (adalimumab) OR Cosentyx (secukinumab). For NR-axSpA, Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)] AND has had a trial and inadequate response or intolerance to Cosentyx (secukinumab). For either of the above indications, if the TNF agent [Humira(adalimumab)/Enbrel(etanercept)/Cosentyx (secukinumab)/Stelara (ustekinumab)/Skyrizi (risankizumab-rzaa)/Otezla (apremilast)] are not acceptable due to Individual's age OR The individual has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction, Taltz (ixekizumab) may be allowed without trial of preferred TNF agents. For Continuation requests, there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

PART B PREREQUISITE

N/A

TALZENNA

MEDICATION(S)

TALZENNA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Individual has the applicable mutations based on use/diagnosis.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

TARCEVA

MEDICATION(S)

ERLOTINIB HCL, TARCEVA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 YEAR.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

TARGRETIN

MEDICATION(S)

BEXAROTENE, TARGRETIN

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

TASIGNA

MEDICATION(S)

TASIGNA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

TASMAR

MEDICATION(S)

TASMAR, TOLCAPONE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

TAVALISSE

MEDICATION(S)

TAVALISSE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For Initial therapy, Individual has a platelet count of less than 50 X 10⁹/L. For continuation therapy, individual has demonstrated increased platelet counts AND maintained an adequate platelet count (50 to 100 x10⁹/L) to decrease the risk of bleeding.

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 6 months. Continuation: 1 Year.

OTHER CRITERIA

For initial ITP therapy, Individual has had a prior trial and insufficient response to one of the following:
(1) Corticosteroids or (2) Immunoglobulins (for example, IVIG, anti-D) or (3) Splenectomy

PART B PREREQUISITE

N/A

TAVNEOS

MEDICATION(S)

TAVNEOS

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 one of the following: (a) Severe, active granulomatosis with polyangiitis (GPA) or (b) Severe, active microscopic polyangiitis (MPA) AND is using in combination with cyclophosphamide or rituximab AND is using with or without glucocorticoids.

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

Avacopan is prescribed by or in consultation with a rheumatologist or nephrologist.

COVERAGE DURATION

1 year per lifetime.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

TAZORAC

MEDICATION(S)

TAZAROTENE 0.05 % GEL, TAZAROTENE 0.1 % CREAM, TAZAROTENE 0.1 % GEL, TAZORAC

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

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

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

TAZVERIK

MEDICATION(S)

TAZVERIK

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

TECENTRIQ

MEDICATION(S)

TECENTRIQ

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

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

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

TECFIDERA

MEDICATION(S)

TECFIDERA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

TECVAYLI

MEDICATION(S)

TECVAYLI

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

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 $100 \times 10^9/L$ 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 $100 \times 10^9/L$ AND most recent urinary protein to creatinine ratio (UPCR) was within the past month and was less than 1000 mg/g.

PART B PREREQUISITE

N/A

TEPMETKO

MEDICATION(S)

TEPMETKO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

TESTOSTERONE INJ

MEDICATION(S)

AVEED, DEPO-TESTOSTERONE, TESTOSTERONE CYPIONATE 100 MG/ML SOLUTION, TESTOSTERONE CYPIONATE 200 MG/ML SOLUTION, TESTOSTERONE ENANTHATE 200 MG/ML SOLUTION, XYOSTED

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 Injections for replacement therapy, (a) Individual met all diagnostic criteria for initial therapy and (b) Individual has had serum testosterone level measured in the previous 180 days and (c) Individual has obtained clinical benefits as noted by symptom improvement. For treatment of delayed puberty when ALL the criteria below are met: Individual is using to stimulate puberty and has documented (verbal or written) few to no signs of puberty. For tx of breast cancer when the following are met: Female 1-5 years post-menopause and Individual is using secondarily for advanced inoperable metastatic (skeletal) breast cancer OR Premenopausal female who has benefited from oophorectomy and is considered to have a hormone responsive tumor. For tx of HIV-infected male adults with low testosterone and HIV-associated weight loss and wasting. For transgender individuals who meet ALL the following criteria: Individual has a diagnosis of gender dysphoria/incongruence or gender identity disorder and goal of treatment is female-to-male gender reassignment.

PART B PREREQUISITE

N/A

TEZSPIRE

MEDICATION(S)

TEZSPIRE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial requests, individual has a diagnosis of severe asthma AND Evidence of asthma is demonstrated by the following (NAEPP 2008): (A) A pretreatment forced expiratory volume in 1 second (FEV1) less than 80% predicted AND (B) FEV1 reversibility of at least 12% and 200 milliliters after albuterol administration AND 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, long-acting muscarinic antagonists or oral corticosteroids) (GINA 2021) AND has experienced two or more asthma exacerbations in the prior 12 months requiring use of a systemic corticosteroid or temporary increase in the individual's usual maintenance dosage of oral corticosteroids (ERS/ATS 2013).

AGE RESTRICTION

Individual is 12 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 6 months. Continuation: 1 Year.

OTHER CRITERIA

For Continuation, treatment has resulted in clinical improvement as confirmed (written or verbal attestation) 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, including asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance or wheezing.

PART B PREREQUISITE

N/A

THALOMID

MEDICATION(S)

THALOMID

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

THIOLA

MEDICATION(S)

THIOLA, THIOLA EC, TIOPRONIN 100 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 9 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 YEAR.

OTHER CRITERIA

Individual has a diagnosis of severe homozygous cystinuria. If initiating therapy, individual has urinary cysteine concentration greater than 250 mg/L.

PART B PREREQUISITE

N/A

TIBSOVO

MEDICATION(S)

TIBSOVO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

TOPICAL ACNE ANTIBIOTIC

MEDICATION(S)

CLINDAMYCIN-TRETINOIN, VELTIN, ZIANA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/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 Acne, Individual has had a prior trial and inadequate response to the following: (1) One preferred generic topical tretinoin agent AND (2) One preferred generic erythromycin/benzoyl peroxide combination agent OR (3) One preferred generic clindamycin/benzoyl peroxide combination agent.

PART B PREREQUISITE

N/A

TOPICAL ANDROGENS

MEDICATION(S)

ANDRODERM, ANDROGEL 20.25 MG/1.25GM (1.62%) GEL, ANDROGEL 40.5 MG/2.5GM (1.62%) GEL, ANDROGEL PUMP, FORTESTA, TESTIM, TESTOSTERONE 1.62 % GEL, TESTOSTERONE 10 MG/ACT (2%) GEL, TESTOSTERONE 12.5 MG/ACT (1%) GEL, TESTOSTERONE 20.25 MG/1.25GM (1.62%) GEL, TESTOSTERONE 20.25 MG/ACT (1.62%) GEL, TESTOSTERONE 25 MG/2.5GM (1%) GEL, TESTOSTERONE 30 MG/ACT SOLUTION, TESTOSTERONE 40.5 MG/2.5GM (1.62%) GEL, TESTOSTERONE 50 MG/5GM (1%) GEL, VOGELXO, VOGELXO PUMP

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

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

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

AND Goal of treatment is female-to-male gender reassignment. For continuation use, Individual meets all criteria for initial therapy AND has had serum testosterone level measured in the previous 180 days AND Individual has obtained clinical benefits as noted by symptom improvement.

PART B PREREQUISITE

N/A

TOPICAL DOXEPIN AGENTS

MEDICATION(S)

DOXEPIN HCL 5 % CREAM, PRUDOXIN, ZONALON

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/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 moderate pruritis associated with atopic dermatitis (AAD 2014), (1) Individual has had a trial of and inadequate response or intolerance to one topical corticosteroid OR Topical corticosteroid use is not acceptable due to the following concomitant clinical conditions: (a) Individual has atopic dermatitis recalcitrant to topical corticosteroids OR (b) has atopic dermatitis lesions in sensitive areas (such as face, anogenital area or skin folds) OR (c) has steroid-induced atrophy OR (d) has history of long-term or uninterrupted topical steroid use. AND (2) Individual has had a trial of and inadequate response or intolerance to one of the following: (a) A topical calcineurin inhibitor OR (b) Eucrisa (crisaborole). For dx moderate pruritis associated with lichen simplex chronicus, Individual has had a trial of and inadequate response or intolerance to one topical corticosteroid.

PART B PREREQUISITE

N/A

TOPICAL ONYCHOMYCOSIS

MEDICATION(S)

JUBLIA, KERYDIN, TAVABOROLE

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.

PART B PREREQUISITE

N/A

TOPICAL TRETINOIN AGENTS

MEDICATION(S)

ALTRENO, ATRALIN, AVITA, RETIN-A, RETIN-A MICRO, RETIN-A MICRO PUMP, TRETINOIN 0.01 % GEL, TRETINOIN 0.025 % CREAM, TRETINOIN 0.025 % GEL, TRETINOIN 0.05 % CREAM, TRETINOIN 0.05 % GEL, TRETINOIN 0.1 % CREAM, TRETINOIN MICROSPHERE, TRETINOIN MICROSPHERE PUMP

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

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

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

TRACLEER

MEDICATION(S)

BOSENTAN, TRACLEER

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

TRANSMUCOSAL FENTANYL CITRATE

MEDICATION(S)

FENTANYL CITRATE 1200 MCG LOZ HANDLE, FENTANYL CITRATE 1600 MCG LOZ HANDLE, FENTANYL CITRATE 200 MCG LOZ HANDLE, FENTANYL CITRATE 400 MCG LOZ HANDLE, FENTANYL CITRATE 600 MCG LOZ HANDLE, FENTANYL CITRATE 800 MCG LOZ HANDLE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Individual is 16 years of age or older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

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

PART B PREREQUISITE

N/A

TREMFYA

MEDICATION(S)

TREMFYA

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.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

For initial use: a dx of chronic plaque psoriasis, individual has failed to respond to, is intolerant of, or has a contraindication to phototherapy or any ONE systemic therapy (for example acitretin, methotrexate, cyclosporine) AND individual has had a trial of and had an inadequate response or is intolerant to either: Humira (adalimumab) or Enbrel (etanercept) OR Cosentyx (secukinumab) OR Skyrizi (risankizumab-rzaa) OR Stelara (ustekinumab) OR Otezla (apremilast). 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)] or a tumor necrosis factor (TNF) antagonist AND has had a trial and an inadequate response or is intolerant

to Humira (adalimumab) OR Enbrel (etanercept) OR Cosentyx (secukinumab) OR Stelara (ustekinumab) OR Otezla (apremilast). For any of the above indications, if the TNF agent [Enbrel(etanercept)/Humira(adalimumab)/Cosentyx (secukinumab)/Skyrizi (risankizumab-rzaa)/Stelara (ustekinumab)/Otezla (apremilast)] are not acceptable due to individuals age OR individual has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction, Tremfya may be allowed without trial of preferred TNF agents. For Continuation use, there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

PART B PREREQUISITE

N/A

TRIKAFTA

MEDICATION(S)

TRIKAFTA

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

For dx of CF, individual has a confirmed mutation-positive result in the cystic fibrosis transmembrane conductance regulator (CFTR) gene with confirmation of mutations where applicable based on use/diagnosis.

PART B PREREQUISITE

N/A

TRIPTODUR

MEDICATION(S)

TRIPTODUR

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Precocious puberty, defined as beginning of secondary sexual characteristics before age 8 in girls and before age 9 in boys.

AGE RESTRICTION

For CPP, individual is 14 years of age or younger (clinical judgement, Kaplowitz, et al. 2016). For Gender Dysphoria, individual is greater than or equal to 10 years of age and less than 18 years of age.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

TRODELVY

MEDICATION(S)

TRODELVY

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Individual has confirmation of disease progression (written or verbal) after two prior therapies.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

TROGARZO

MEDICATION(S)

TROGARZO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

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

PART B PREREQUISITE

N/A

TRUSELTIQ

MEDICATION(S)

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

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

TUKYSA

MEDICATION(S)

TUKYSA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

TURALIO

MEDICATION(S)

TURALIO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

TYKERB

MEDICATION(S)

LAPATINIB DITOSYLATE, TYKERB

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

TYMLOS

MEDICATION(S)

TYMLOS

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial therapy, Individual is a postmenopausal female or a male using to increase bone density 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

1 Year.

OTHER CRITERIA

For continuation therapy, there is confirmation of clinically significant response to therapy (including but not limited to confirmation of no new fractures or reduction of fractures, or no worsening vertebral fractures, or no clinically significant adverse reaction) AND if individual has been on therapy greater than or equal to 24 months of treatment, a repeat BMD demonstrates a stable or increase in BMD.

PART B PREREQUISITE

N/A

TYSABRI

MEDICATION(S)

TYSABRI

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/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 as monotherapy for relapsing forms of multiple sclerosis (RMS) (including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease)). For diagnosis of Crohns disease, Individual has an inadequate response to, or is unable to tolerate conventional CD therapies and TNF inhibitors. For all uses, mbr is enrolled in and meets all conditions of the CD or MS Touch Prescribing Program.

PART B PREREQUISITE

N/A

TYVASO

MEDICATION(S)

TYVASO, TYVASO DPI MAINTENANCE KIT, TYVASO DPI TITRATION KIT, TYVASO REFILL, TYVASO STARTER

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Initial requests for inhalation therapy with Tyvaso for PAH, patient must meet all of the following: meets diagnostic criteria for PAH AND demonstrates an unfavorable acute response to vasodilators AND Individual has New York Heart Association (NYHA) functional class III, or IV symptoms: AND World health Organization (WHO) Group I PAH (idiopathic PAH, PAH associated with connective tissue disorders, PAH associated with congenital heart defects, and all Group 1 subtypes). For PH-ILD, individual meets diagnostic criteria for PH-ILD AND Chest high resolution computed tomography (HRCT) demonstrating diffuse parenchymal lung disease. For continuation, there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in walk distance, dyspnea and/or functional class).

PART B PREREQUISITE

N/A

UBRELVY

MEDICATION(S)

UBRELVY

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

UCERIS

MEDICATION(S)

BUDESONIDE ER, UCERIS 9 MG TAB ER 24H

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

UPTRAVI

MEDICATION(S)

UPTRAVI 1000 MCG TAB, UPTRAVI 1200 MCG TAB, UPTRAVI 1400 MCG TAB, UPTRAVI 1600 MCG TAB, UPTRAVI 200 & 800 MCG TAB THPK, UPTRAVI 200 MCG TAB, UPTRAVI 400 MCG TAB, UPTRAVI 600 MCG TAB, UPTRAVI 800 MCG TAB

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

VALCHLOR

MEDICATION(S)

VALCHLOR

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

VANCOCIN

MEDICATION(S)

VANCOCIN, VANCOMYCIN HCL 125 MG CAP, VANCOMYCIN HCL 25 MG/ML RECON SOLN, VANCOMYCIN HCL 250 MG CAP, VANCOMYCIN HCL 250 MG/5ML RECON SOLN, VANCOMYCIN HCL 50 MG/ML 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

3 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

VANFLYTA

MEDICATION(S)

VANFLYTA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Individual has the applicable mutations based on use/diagnosis.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

VECTIBIX

MEDICATION(S)

VECTIBIX

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

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

REQUIRED MEDICAL INFORMATION

For Stage IV colon, rectal, colorectal, appendiceal or anal adenocarcinoma AND unresectable, advanced or metastatic colorectal cancer 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 Stage IV colon, rectal, colorectal, appendiceal, or anal adenocarcinoma, Used as a single agent or as part of combination therapy for stage IV colon, rectal, colorectal, appendiceal, or anal adenocarcinoma. For unresectable, advanced, or metastatic colorectal cancer, used as a single line of therapy AND in combination with encorafenib AND has demonstrated disease progression after one or more prior lines of systemic therapy AND not used in combination with anti-VEGF agents (bevacizumab, ziv-aflibercept or ramucirumab) AND has not received prior therapy with cetuximab.

PART B PREREQUISITE

N/A

VELCADE

MEDICATION(S)

BORTEZOMIB 1 MG RECON SOLN, BORTEZOMIB 2.5 MG RECON SOLN, BORTEZOMIB 3.5 MG RECON SOLN, VELCADE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

VEMLIDY

MEDICATION(S)

VEMLIDY

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 12 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

VENCLEXTA

MEDICATION(S)

VENCLEXTA, VENCLEXTA STARTING PACK

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

VENTAVIS

MEDICATION(S)

VENTAVIS

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

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

PART B PREREQUISITE

N/A

VERQUVO

MEDICATION(S)

VERQUVO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial use, individual has experienced one of the following: (A) Heart failure hospitalization within 6 months OR (B) Use of intravenous outpatient diuretics within 3 months AND Individual will be taking Verquvo (vericiguat) in combination with the following (2017 ACC/AHA/HFSA): (A) Entresto (sacubitril/valsartan), angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) unless contraindicated or not tolerated AND (B) Beta-blocker (bisoprolol, carvedilol, metoprolol succinate) unless contraindicated or not tolerated.

AGE RESTRICTION

18 years of age or older

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 improvement in heart failure symptoms, reduction in heart failure related physical limitations, reduction in hospitalizations) AND continues to receive concomitant Entresto (sacubitril/valsartan), angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) unless contraindicated or not tolerated AND continues to receive concomitant beta-blocker (bisoprolol, carvedilol, metoprolol succinate) therapy

unless contraindicated or not tolerated.

PART B PREREQUISITE

N/A

VERZENIO

MEDICATION(S)

VERZENIO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

VFEND

MEDICATION(S)

VFEND, VFEND IV, VORICONAZOLE 200 MG RECON SOLN, VORICONAZOLE 200 MG TAB, VORICONAZOLE 40 MG/ML RECON SUSP, VORICONAZOLE 50 MG TAB

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

VIBATIV

MEDICATION(S)

VIBATIV

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

30 days

OTHER CRITERIA

Individual has started therapy in an inpatient setting and requires continued outpatient therapy for an organism susceptible to telavancin. For hospital-acquired or ventilator-associated bacterial pneumonia (HABP or VABP), Individual has had a trial and an inadequate response or intolerance to or has a contraindication to at least one alternative antibiotic (such as but not limited to, intravenous vancomycin) (ATS/IDSA 2016). For complicated skin and skin structure infections (cSSSI), Individual has had an inadequate response or intolerance to or has a contraindication to at least one alternative antibiotic (such as but not limited to, intravenous vancomycin) (IDSA 2014, 2011).

PART B PREREQUISITE

N/A

VIBERZI

MEDICATION(S)

VIBERZI

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

VIDAZA

MEDICATION(S)

AZACITIDINE, VIDAZA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

VIJOICE

MEDICATION(S)

VIJOICE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial requests: Individual has a Karnofsky (in those greater than 16 years old)/Lansky (in those less than and equal to 16) performance status index of greater than or equal to 50 AND Has at least one PROS-related measurable lesion defined as a lesion with longest diameter greater than or equal to 2 cm. For continuation requests: there is a reduction in size of PROS lesions OR improvement in signs or symptoms of PROS (eg, growth of lesions, seizures, thrombotic events, pain, cognitive impairment).

AGE RESTRICTION

2 years of age or older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 6 months, Continuation: 1 year

OTHER CRITERIA

Individual has a diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS) disorder defined as any of the following: Fibroadipose hyperplasia, CLOVES syndrome, Megalencephaly-capillary malformation syndrome (MCAP syndrome), Hemihyperplasia-multiple liomatosis syndrome (HHML syndrome), Hemimegalencephaly OR Facial infiltrating lipomatosis.

PART B PREREQUISITE

N/A

VIMIZIM

MEDICATION(S)

VIMIZIM

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Confirmed (written or verbal attestation) diagnosis of Morquio A syndrome (Hendriksz 2015, Wood 2013) by documented (written or verbal) reduced fibroblast or leukocyte N-acetylgalactosamine-6-sulfatase (GALNS) enzyme activity combined with normal enzyme activity level or another sulfatase or by genetic testing and confirmed (written or verbal) clinical signs and symptoms of Morquio A syndrome (for example, knee deformity, corneal opacity or pectus carinatum) (Hendriksz 2015, Wood 2013).

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

For Continuation, there is confirmation (written or verbal attestation) of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to reduction in urinary GAG excretion, reduction in hepatosplenomegaly, improvement in pulmonary function, improvement in walking distance and/or improvement in fine or gross motor function) compared to the predicted natural history trajectory of disease.

PART B PREREQUISITE

N/A

VITRAKVI

MEDICATION(S)

VITRAKVI

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

VIZIMPRO

MEDICATION(S)

VIZIMPRO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

VONJO

MEDICATION(S)

VONJO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Individual is 18 years of age or older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

VOSEVI

MEDICATION(S)

VOSEVI

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

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

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

PART B PREREQUISITE

N/A

VOTRIENT

MEDICATION(S)

VOTRIENT

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

VOWST

MEDICATION(S)

VOWST

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Individual has had at least three episodes of Clostridioides difficile infection (initial episode and two recurrences) treated with antibiotic therapy (including Difcid, metronidazole or oral vancomycin) (IDSA/SHEA 2021) AND Current episode of Clostridioides difficile infection has been verified (written or verbal) with a positive stool test for Clostridioides difficile toxin AND treatment will be initiated within 2 to 4 days of completing antibiotic treatment for the current Clostridioides difficile infection episode.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 month

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

VOXZOGO

MEDICATION(S)

VOXZOGO

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 5 to 17 years of age.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 6 months. Continuation: 1 year.

OTHER CRITERIA

Initial therapy, individual has epiphyses that have not yet closed. For continuation, there is confirmation of clinically significant improvement in growth velocity AND individual has epiphyses that have not yet closed.

PART B PREREQUISITE

N/A

VTAMA

MEDICATION(S)

VTAMA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/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 plaque psoriasis, individual has had a trial of and inadequate response or intolerance to TWO of the following topical therapies for psoriasis (AAD 2020): (A) Medium to high potency topical corticosteroids OR (B) Tazarotene OR (C) Vitamin D analogs (calcitriol, calcipotriene, or calcipotriene/betamethasone combination agents) OR (D) Topical calcineurin inhibitors (tacrolimus or pimecrolimus) OR (E) Salicylic acid OR (F) Anthralin OR (G) Coal tar preparations.

PART B PREREQUISITE

N/A

VUMERITY

MEDICATION(S)

VUMERITY

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

VYVANSE

MEDICATION(S)

LISDEXAMFETAMINE DIMESYLATE 10 MG CAP, LISDEXAMFETAMINE DIMESYLATE 20 MG CAP, LISDEXAMFETAMINE DIMESYLATE 30 MG CAP, LISDEXAMFETAMINE DIMESYLATE 40 MG CAP, LISDEXAMFETAMINE DIMESYLATE 50 MG CAP, LISDEXAMFETAMINE DIMESYLATE 60 MG CAP, LISDEXAMFETAMINE DIMESYLATE 70 MG CAP, VYVANSE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Individual is using for weight loss.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Individual has diagnosis of moderate to severe binge-eating disorder OR has a diagnosis of attention deficit hyperactivity disorder (ADHD) AND Individual has had a trial of and insufficient response or intolerance to one of the following: (1) Methylphenidate extended-release or (2) Extended-release amphetamine/dextroamphetamine salt combination OR Individual has been diagnosed with coexisting ADHD and substance use disorder.

PART B PREREQUISITE

N/A

WAKIX

MEDICATION(S)

WAKIX

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

WELIREG

MEDICATION(S)

WELIREG

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Using Welireg (belzutifan) as monotherapy.

PART B PREREQUISITE

N/A

XALKORI

MEDICATION(S)

XALKORI

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

XELJANZ

MEDICATION(S)

XELJANZ, XELJANZ XR

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 Initial use: RA, Individual had an inadequate response to MTX titrated to maximally tolerated dose (ACR 2021) OR if MTX is not tolerated or contraindicated, individual had an inadequate response to, is intolerant of or has contraindication to other conventional therapy (sulfasalazine, leflunomide or hydroxychloroquine) and individual has had a trial of and an inadequate response or is intolerant to: Humira (adalimumab) OR Enbrel (etanercept) OR Rinvoq (upadacitinib). For PsA, Individual had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy [nonbiologic DMARDS (such as methotrexate, sulfasalazine, or leflunomide)] and individual has had a trial of and an inadequate response or is intolerant to: Humira (adalimumab) OR Enbrel (etanercept) OR Stelara (ustekinumab) OR Cosentyx (secukinumab) OR Otezla (apremilast) OR Rinvoq (upadacitinib). For UC, Individual had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy (such as 5-Aminosalicylic acid products, systemic

corticosteroids, or immunosuppressant) AND had a trial of and an inadequate response or is intolerant to Humira (adalimumab), Stelara (ustekinumab) OR Rinvoq(upadacitinib). For PJIA, Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic DMARDS (such as methotrexate)] AND had a trial and inadequate response or intolerance to ONE tumor necrosis factor (TNF) antagonist agent. For Ankylosing Spondylitis (AS), Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [such as NSAIDs or nonbiologic DMARDS (such as sulfasalazine)] AND has had a trial of and an inadequate response to, or is intolerant to Enbrel (etanercept) OR Humira(adalimumab) OR Cosentyx (secukinumab). For Continuation use, there is confirmation (written or verbal) of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

PART B PREREQUISITE

N/A

XENAZINE

MEDICATION(S)

TETRABENAZINE, XENAZINE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

XENPOZYME

MEDICATION(S)

XENPOZYME

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial therapy, individual has a diagnosis of acid sphingomyelinase deficiency (ASMD) AND has a clinical presentation consistent with ASMD type B OR ASMD type A/B AND Diagnosis has been confirmed (written or verbal attestation) by (McGovern 2017): (a) Pathogenic sphingomyelin phosphodiesterase-1 (SMPD1) gene mutation OR (b) Deficiency in acid sphingomyelinase (ASM) activity as measured in fibroblasts, leukocytes or dried blood spot AND is using for the treatment of non-central nervous system disease manifestations. For continuation requests, there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in splenomegaly, hepatomegaly, pulmonary function or platelet count).

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 6 months, Continuation: 1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

XERMELO

MEDICATION(S)

XERMELO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 3 months. Continuation: 1 year

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

XGEVA

MEDICATION(S)

XGEVA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

XIAFLEX

MEDICATION(S)

XIAFLEX

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For Peyronie disease, stable disease as define by symptoms (including, but not limited to, penile curvature and pain) for at least 6 months (American Urological Assoc)and Penile curvature greater than or equal to 30 and less than or equal to 90 degrees (American Urological Assoc) and Intact erectile function with or without use of medications and Palpable penile plaque. For Dupuytren's contracture, there is documented impairment to the individual's functional activities which measures either: 20 degrees or more at the metacarpophalangeal (MP) joint or 20 degrees or more at the proximal interphalangeal (PIP) joint AND The total number of injections does not exceed 3 injections per cord at approximately 4-week intervals.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

XIFAXAN - HE

MEDICATION(S)

XIFAXAN 550 MG TAB

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

XIFAXAN 200MG

MEDICATION(S)

AEMCOLO, XIFAXAN 200 MG TAB

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

30 Days

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

XOLAIR

MEDICATION(S)

XOLAIR

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 6 months. Continuation: 1 Year.

OTHER CRITERIA

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

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

PART B PREREQUISITE

N/A

XOSPATA

MEDICATION(S)

XOSPATA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

18 years of age and older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

XPOVIO

MEDICATION(S)

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

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

XTANDI

MEDICATION(S)

XTANDI

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

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

PART B PREREQUISITE

N/A

XYREM

MEDICATION(S)

SODIUM OXYBATE, XYREM, XYWAV

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. Mbr has idiopathic hypersomnia confirmed by (1) daily periods of strong need to sleep or daytime lapses into sleep for more than 3 mon. (2) absence of cataplexy (3) Insuff sleep syndrome ruled out (if nec, by lack of improvement of sleepiness after adequate trial of increased nocturnal time in bed, preferably confirmed by at least 1 wk. of wrist actigraphy) (4) MSLT shows fewer than 2 SOREMPs OR No SOREMPs if the REM sleep latency period on the preceding overnights polysomnogram is 15min or less (5) The presence of at least one: MSLT shows mean sleep latency of 8 min or less OR total 24hr sleep time of 660 min or longer (typically 12-14 hrs) on 24-hr polysomnography monitoring (performed after the correction of chronic sleep deprivation) or by wrist actigraphy in assoc with a sleep log (avg over at least 7 days with unrestricted sleep) AND (6) hypersomolence or MSLT findings are not better explained by another sleep disorder, medical or neurologic disorder, mental disorder, med use or substance abuse. 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.

PART B PREREQUISITE

N/A

YERVOY

MEDICATION(S)

YERVOY

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

For small cell lung cancer, unresectable or metastatic melanoma (cutaneous or uveal), colorectal cancer, renal cell carcinoma, small bowel adenocarcinoma or first line treatment of stage IV/recurrent NSCLC, individual has an Eastern Cooperative Oncology Group (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

For the tx of unresectable or metastatic melanoma (cutaneous and uveal): Used in combo with nivolumab as: (a) First-line therapy or (b) Second-line or subsequent therapy for disease progression if nivolumab was not prev used or Ipilimumab is used as a single agent for one of the following: (a) First line therapy as a single course of 4 tx or (b) Second-line or subsequent lines of therapy as a single course of 4 treatments or (c) Retreatment, consisting of a 4-dose limit, for an individual who had no significant systemic toxicity during prior ipilimumab therapy, and whose disease progressed after being

stable for greater than 3 mon following completion of a prior course of ipilimumab, and for whom no intervening therapy has been admin. OR used for the adjuvant treatment of cutaneous melanoma in mbr with pathologic involvement of regional lymph nodes of more than 1 millimeter who have undergone complete resection, including lymphadenectomy. For colorectal cancer AND meets one of the following criteria: (a) Primary tx used in combination with nivolumab for unresectable metachronous metastases (deficient mismatch repair/high microsatellite instability [dMMR/MSIH] only) and previous adjuvant FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 mon or (b) Ipilimumab is used in combo with nivolumab as subsequent therapy for unresectable advanced or metastatic colorectal cancer with dMMR or high microsatellite instability (MSIH) mutations that has progressed following tx with fluoropyrimidine and oxaliplatin or irinotecan. For RCC, when: (a) used in combination with nivolumab, for four cycles followed by single agent nivolumab as first-line therapy for previously untreated RCC or (b) used in subsequent therapy with nivolumab for four cycles followed by single agent nivolumab if no checkpoint blockade (PD-1, PD-L1, or CTLA-4) antibody tx has been previously administered and (c) Histologic confirmation of RCC with clear-cell component. For stage IV/recurrent NSCLC when: used in combo with nivolumab and 2 cycles of platinum-doublet chemotherapy AND does not have presence of actionable molecular markers. For small bowel adenocarcinoma AND has advanced or metastatic disease (deficient mismatch repair/microsatellite instability [dMMR/MSI-H] only) AND using as initial or subsequent therapy as monotherapy or in combo with nivolumab.

PART B PREREQUISITE

N/A

YONSA

MEDICATION(S)

YONSA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

ZARXIO

MEDICATION(S)

ZARXIO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Febrile neutropenic Individuals who are at high risk for infection-associated complications by any of the following: Expected prolonged (greater than 10 day) and profound (less than 0.1×10 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 $450/\mu L$) 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 $1500mm^3$), 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 myelosuppressive doses (greater than 2 Grays [Gy] (such as Hematopoietic Syndrome of Acute Radiation Syndrome). After hematopoietic progenitor stem cell transplant (HPCT/HSCT) to promote myeloid reconstitution or when engraftment is delayed or has failed. To mobilize progenitor cells into peripheral blood for collection by leukapheresis, as an adjunct to peripheral blood/hematopoietic stem cell transplantation (PBSCT/PHSCT). Use as an alternate or adjunct to donor leukocyte infusions (DLI) in individuals with leukemic relapse after an allogeneic hematopoietic stem cell transplant.

PART B PREREQUISITE

N/A

ZAVESCA

MEDICATION(S)

MIGLUSTAT, YARGESA, ZAVESCA

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).

PART B PREREQUISITE

N/A

ZEJULA

MEDICATION(S)

ZEJULA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 YEAR.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ZELBORAF

MEDICATION(S)

ZELBORAF

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ZEPATIER

MEDICATION(S)

ZEPATIER

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

Individual is 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

Criteria will be applied consistent with current AASLD/IDSA guidance. For GT 1, Individual has had a prior trial and inadequate response to Harvoni (sofosbuvir/ledipasvir) OR individual is currently on and completing a course of therapy with the requested regimen OR Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Harvoni (ledipasvir/sofosbuvir) which is not also in Zepatier OR Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Harvoni (sofosbuvir/ledipasvir) OR Individual has concomitant

severe or end-stage CKD or requires dialysis OR Individual has a unique disease characteristic to which the preferred regimen(s) is not recommended (examples include specific genotype subtype, resistance-associated substitution (RAS), or polymorphism). For GT 4, individual has had a prior trial and inadequate response to Harvoni (sofosbuvir/ledipasvir) or Epclusa(sofosbuvir/velpatasvir) OR individual is currently on and completing a course of therapy with the requested regimen OR Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Harvoni(sofosbuvir/ledipasvir) or Epclusa(sofosbuvir/velpatasvir) which is not also in Zepatier OR Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Harvoni(sofosbuvir/ledipasvir) or Epclusa(sofosbuvir/velpatasvir) OR Individual has concomitant severe or end-stage CKD or requires dialysis OR Individual has a unique disease characteristic to which the preferred regimen(s) is not recommended (examples include specific genotype subtype, resistance-associated substitution (RAS), or polymorphism).

PART B PREREQUISITE

N/A

ZEPOSIA

MEDICATION(S)

ZEPOSIA, ZEPOSIA 7-DAY STARTER PACK, ZEPOSIA STARTER KIT 0.23MG & 0.46MG
0.92MG(21) CAP THPK

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/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 moderately to severely active Ulcerative Colitis (UC) AND has had an inadequate response to, is intolerant of or has a contraindication to conventional therapy (including 5-aminosalicylic acid products, systemic corticosteroids or immunosuppressants) OR Individual has a diagnosis of relapsing multiple sclerosis (RMS) (including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease

PART B PREREQUISITE

N/A

ZEPZELCA

MEDICATION(S)

ZEPZELCA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

Individual is using as a single agent for subsequent therapy.

PART B PREREQUISITE

N/A

ZINPLAVA

MEDICATION(S)

ZINPLAVA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/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 confirmed Clostridioides difficile infection when the following are met: (a) Passage of three or more loose stools within 24 hours or less AND (b) Positive stool test for toxigenic Clostridioides difficile from a stool sample collected not more than 7 days prior to scheduled infusion AND (c) currently receiving antibacterial therapy for Clostridioides difficile infection AND (d) Individual is at high risk of Clostridioides difficile infection recurrence meeting any one of the following: (1) Individual 65 years of age or older, or (2) history of Clostridioides difficile infection in the past 6 months or (3) Immunocompromised state or (4) Severe Clostridioides difficile infection at presentation or (4 5) Clostridioides difficile ribotype 027.

PART B PREREQUISITE

N/A

ZOKINVY

MEDICATION(S)

ZOKINVY

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Has a confirmed diagnosis (written or verbal attestation is acceptable) of one of the following:

(a)Hutchinson-Gilford progeria syndrome (HGPS) or (b)Processing deficient progeroid laminopathy with either: (i)Heterozygous LMNA mutation with progerin-like protein accumulation or (ii) Homozygous or compound heterozygous ZMPSTE24 mutations.

AGE RESTRICTION

12 months of age or older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 Year.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ZOLINZA

MEDICATION(S)

ZOLINZA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ZOMETA

MEDICATION(S)

ZOLEDRONIC ACID 4 MG/100ML SOLUTION, ZOLEDRONIC ACID 4 MG/5ML CONC

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

ZORYVE

MEDICATION(S)

ZORYVE

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/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 plaque psoriasis, individual has had a trial of and inadequate response or intolerance to TWO of the following topical therapies for psoriasis (AAD 2020): (A) Medium to high potency topical corticosteroids OR (B) Tazarotene OR (C) Vitamin D analogs (calcitriol, calcipotriene, or calcipotriene/betamethasone combination agents) OR (D) Topical calcineurin inhibitors (tacrolimus or pimecrolimus) OR (E) Salicylic acid OR (F) Anthralin OR (G) Coal tar preparations.

PART B PREREQUISITE

N/A

ZYDELIG

MEDICATION(S)

ZYDELIG

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 6 months. Continuation: 1 Year.

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

ZYFLO

MEDICATION(S)

ZYFLO

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/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 therapy, for prophylaxis and chronic treatment of persistent asthma, Individual is using in combination with an orally inhaled corticosteroid (GINA 2019) AND Individual has had a previous trial and inadequate response or a confirmed (written or verbal) intolerance to montelukast and zafirlukast. For continuation therapy, treatment with zileuton has resulted in clinical improvement as confirmed by one or more of the following: a) Decreased utilization of rescue medications b) Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids c) Increase in percent predicted FEV1 from pretreatment baseline OR d) Reduction in reported asthma-related symptoms, including but not limited to wheezing, shortness of breath, coughing, fatigue, sleep disturbance or asthmatic symptoms upon awakening.

PART B PREREQUISITE

N/A

ZYKADIA

MEDICATION(S)

ZYKADIA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ZYTIGA

MEDICATION(S)

ABIRATERONE ACETATE, ZYTIGA

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 year

OTHER CRITERIA

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

PART B PREREQUISITE

N/A

ZYVOX

MEDICATION(S)

LINEZOLID 100 MG/5ML RECON SUSP, LINEZOLID 600 MG TAB, ZYVOX 100 MG/5ML RECON SUSP, ZYVOX 600 MG TAB

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

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

PART B PREREQUISITE

N/A