ACTHAR GEL PA

MEDICATION(S)
ACTHAR, ACTHAR SELFJECT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. ONE of the following: A. Patient has a diagnosis of infantile spasm OR B. Patient has a diagnosis of nephrotic syndrome AND ONE of the following: i. Patient has failed a conventional agent (i.e., prednisone, tacrolimus) for the requested indication OR ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a conventional agent OR C. Patient has a diagnosis of multiple sclerosis AND ALL of the following: i. Patient is experiencing an acute exacerbation AND ii. If indicated, there is evidence of a claim that the patient is currently being treated with a disease modifying drug (DMD) within the past 90 days [e.g., Avonex, dimethyl fumarate, glatiramer] to control disease progression OR has an intolerance, FDA labeled contraindication, or hypersensitivity to a DMD AND iii. ONE of the following: 1. Patient has failed corticosteroid therapy (e.g., methylprednisolone) within the last 30 days OR 2. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to corticosteroid therapy OR Criteria continues: see Other Criteria

AGE RESTRICTION
For diagnosis of infantile spasm, patient is less than 2 years of age.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 months for infantile spasm, 1 month for all other indications

OTHER CRITERIA

D. Patient has a diagnosis of rheumatic disorder (e.g., ankylosing spondylitis, juvenile idiopathic arthritis, juvenile rheumatoid arthritis, psoriatic arthritis, rheumatoid arthritis) AND ALL of the following: i. The requested agent will be used as adjunct therapy for short-term administration (to tide the patient over an acute episode or exacerbation) AND ii. There is evidence of a claim that the patient is currently being treated with a conventional agent within the past 90 days [e.g., DMARD (methotrexate, leflunomide), biologics (Hadlima)] to control disease progression AND iii. ONE of the following: 1. Patient has failed corticosteroid therapy (e.g., methylprednisolone) within the last 30 days OR 2. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to corticosteroid therapy OR E. Patient has a diagnosis of systemic lupus erythematosus (SLE) disease AND the patient will continue standard SLE therapy [corticosteroids (e.g., methylprednisolone, prednisone), hydroxychloroquine, immunosuppressives (e.g., azathioprine, methotrexate, oral cyclophosphamide)] in combination with the requested agent OR F. Patient has another FDA approved indication AND ONE of the following: i. Patient has failed corticosteroid therapy (e.g., methylprednisolone) within the last 30 days OR ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to corticosteroid therapy OR G. Patient has another indication that is supported in CMS approved compendia for the requested agent AND ONE of the following: i. Patient has failed corticosteroid therapy (e.g., methylprednisolone) within the last 30 days OR ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to corticosteroid therapy AND 2. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

PART B PREREQUISITE

N/A

ACTIMMUNE PA

MEDICATION(S)
ACTIMMUNE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND 2. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ACYCLOVIR TOPICAL PA

MEDICATION(S)
ACYCLOVIR 5% OINTMENT, ZOVIRAX 5% OINTMENT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

AIMOVIG PA

MEDICATION(S)
AIMOVIG AUTOINJECTOR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of migraine AND 2. The requested agent is being used for migraine prophylaxis AND 3. Patient has 4 or more migraine headache days per month AND 4. Patient will NOT be using the requested agent in combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of migraine AND 3. The requested agent is being used for migraine prophylaxis AND 4. Patient has had clinical benefit with the requested agent AND 5. Patient will NOT be using the requested agent in combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

ALCOHOL SWABS PA

MEDICATION(S)
ISOPROPYL ALCOHOL 0.7 ML/ML MEDICATED PAD

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
This program will be implemented as a dynamic PA. Criteria for approval require BOTH of the following: 1. The requested medical supply product will be used in the delivery of insulin to the body AND 2. Patient's medication history includes use of insulin within the past 180 days

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ALOSETRON PA

MEDICATION(S)
ALOSETRON HCL, LOTRONEX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require ALL of the following: 1. Patient has a diagnosis of irritable bowel syndrome with severe diarrhea (IBS-D) AND 2. Patient's sex is female AND 3. Patient exhibits at least ONE of the following: a. Frequent and severe abdominal pain/discomfort OR b. Frequent bowel urgency or fecal incontinence OR c. Disability or restriction of daily activities due to IBS AND 4. Prescriber has ruled out anatomic or biochemical abnormalities of the gastrointestinal tract

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ALPHA-1-PROTEINASE INHIBITOR PA - PROLASTIN-C

MEDICATION(S)
PROLASTIN C

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of alpha-1 antitrypsin deficiency (AATD) with clinically evident emphysema AND 2. Patient has a pre-treatment serum alpha-1 antitrypsin (AAT) level less than 11 micromol/L (80 mg/dL by immunodiffusion or 57 mg/dL using nephelometry) AND 3. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of alpha-1 antitrypsin deficiency (AATD) with clinically evident emphysema AND 3. Patient has had clinical benefit with the requested agent AND 4. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

ANABOLIC STEROID PA - DANAZOL

MEDICATION(S)
DANAZOL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. Patient has ONE of the following diagnoses: A. Patient has an FDA labeled indication for the requested agent OR B. Patient has an indication that is supported in CMS approved compendia for the requested agent AND 2. ONE of the following: A. Patient will NOT be using the requested agent in combination with another androgen or anabolic steroid OR B. Prescriber has provided information in support of therapy with more than one agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ANDROGEN INJECTABLE PA - TESTOSTERONE CYPIONATE

MEDICATION(S)

DEPO-TESTOSTERONE, TESTOSTERONE CYP 1,000 MG/10ML, TESTOSTERONE CYP 1,000 MG/5 ML, TESTOSTERONE CYP 100 MG/ML, TESTOSTERONE CYP 2,000 MG/10ML, TESTOSTERONE CYP 200 MG/ML, TESTOSTERONE CYP 500 MG/2.5 ML, TESTOSTERONE CYP 500 MG/5 ML, TESTOSTERONE CYP 6,000 MG/30ML

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION

Criteria for approval require ALL of the following: 1. Patient has ONE of the following diagnoses: A. Patient's sex is male with AIDS/HIV-associated wasting syndrome AND BOTH of the following: i. ONE of the following: a. Unexplained involuntary weight loss (greater than 10% baseline body weight within 12 months, or 7.5% within 6 months) OR b. Body mass index less than 20 kg/m2 OR c. At least 5% total body cell mass (BCM) loss within 6 months OR d. BCM less than 35% of total body weight and BMI less than 27 kg/m2 AND ii. All other causes of weight loss have been ruled out OR B. Patient's sex is female with metastatic/inoperable breast cancer OR C. Patient's sex is male with primary or secondary (hypogonadotropic) hypogonadism OR D. Patient's sex is male and is an adolescent with delayed puberty AND 2. If the patient's sex is a male, ONE of the following: A. Patient is NOT currently receiving testosterone replacement therapy AND has ONE of the following pretreatment levels: i. Total serum testosterone level that is below the testing laboratory's lower limit of the normal range or is less than 300 ng/dL OR ii. Free serum testosterone level that is below the testing laboratory's lower limit of the normal range OR B. Patient is currently receiving testosterone replacement therapy AND has ONE of the following current levels: i. Total serum testosterone level that is within the testing laboratory's normal range OR below the testing laboratory's lower limit of the normal range OR is less than 300 ng/dL OR ii. Free serum testosterone level is within the testing laboratory's normal range OR below the testing laboratory's normal range AND 3. ONE of the following: A. Patient will NOT be using the requested agent in combination with another androgen or anabolic steroid OR B. Prescriber has provided information in support of therapy with more than one agent

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be 6 months for delayed puberty, 12 months for all other indications

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ANDROGEN INJECTABLE PA - TESTOSTERONE ENANTHATE

MEDICATION(S)
TESTOSTERONE ENANTHATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require ALL of the following: 1. Patient has ONE of the following diagnoses: A. Patient's sex is male with AIDS/HIV-associated wasting syndrome AND BOTH of the following: i. ONE of the following: a. Unexplained involuntary weight loss (greater than 10% baseline body weight within 12 months, or 7.5% within 6 months) OR b. Body mass index less than 20 kg/m2 OR c. At least 5% total body cell mass (BCM) loss within 6 months OR d. BCM less than 35% of total body weight and BMI less than 27 kg/m2 AND ii. All other causes of weight loss have been ruled out OR B. Patient's sex is female with metastatic/inoperable breast cancer OR C. Patient's sex is male with primary or secondary (hypogonadotropic) hypogonadism OR D. Patient's sex is male and is an adolescent with delayed puberty AND 2. If the patient's sex is a male, ONE of the following: A. Patient is NOT currently receiving testosterone replacement therapy AND has ONE of the following pretreatment levels: i. Total serum testosterone level that is below the testing laboratory's lower limit of the normal range or is less than 300 ng/dL OR ii. Free serum testosterone level that is below the testing laboratory's lower limit of the normal range OR B. Patient is currently receiving testosterone replacement therapy AND has ONE of the following current levels: i. Total serum testosterone level that is within the testing laboratory's normal range OR below the testing laboratory's lower limit of the normal range OR is less than 300 ng/dL OR ii. Free serum testosterone level is within the testing laboratory's normal range OR below the testing laboratory's normal range AND 3. ONE of the following: A. Patient will NOT be using the requested agent in combination with another androgen or anabolic steroid OR B. Prescriber has provided information in support of therapy with more than one agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be 6 months for delayed puberty, 12 months for all other indications

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ANDROGEN ORAL PA

MEDICATION(S)
METHYLTESTOSTERONE 10 MG CAP

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require ALL of the following: 1. Patient has ONE of the following diagnoses: A. Patient's sex is male with cryptorchidism OR B. Patient's sex is male with hypogonadism OR C. Patient's sex is male and is an adolescent with delayed puberty OR D. Patient's sex is female with metastatic/inoperable breast cancer AND 2. If the patient's sex is male, ONE of the following: A. Patient is NOT currently receiving testosterone replacement therapy AND has ONE of the following pretreatment levels: i. Total serum testosterone level that is below the testing laboratory's lower limit of the normal range or is less than 300 ng/dL OR ii. Free serum testosterone level that is below the testing laboratory's lower limit of the normal range OR B. Patient is currently receiving testosterone replacement therapy AND has ONE of the following current levels: i. Total serum testosterone level that is within the testing laboratory's normal range OR below the testing laboratory's lower limit of the normal range OR is less than 300 ng/dL OR ii. Free serum testosterone level is within the testing laboratory's normal range OR below the testing laboratory's normal range AND 3. ONE of the following: A. Patient will NOT be using the requested agent in combination with another androgen or anabolic steroid OR B. Prescriber has provided information in support of therapy with more than one agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be 6 months for delayed puberty, 12 months for all other indications

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ANDROGEN TOPICAL PA

MEDICATION(S)

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

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION

Criteria for approval require ALL of the following: 1. Patient has ONE of the following diagnoses: A. Patient has AIDS/HIV-associated wasting syndrome AND BOTH of the following: i. ONE of the following: a. Unexplained involuntary weight loss (greater than 10% baseline body weight within 12 months, or 7.5% within 6 months) OR b. Body mass index less than 20 kg/m2 OR c. At least 5% total body cell mass (BCM) loss within 6 months OR d. In men: BCM less than 35% of total body weight and BMI less than 27 kg/m2 OR e. In women: BCM less than 23% of total body weight and BMI less than 27 kg/m2 AND ii. All other causes of weight loss have been ruled out OR B. Patient's sex is male with primary or secondary (hypogonadotropic) hypogonadism AND 2. If the patient's sex is male, ONE of the following: A. Patient is NOT currently receiving testosterone replacement therapy AND has ONE of the following pretreatment levels: i. Total serum testosterone level that is below the testing laboratory's lower limit of the normal range or is less than 300 ng/dL OR ii. Free serum testosterone level that is below the testing laboratory's lower limit of the normal range OR B. Patient is currently receiving testosterone replacement therapy AND has ONE of the following current levels: i. Total serum testosterone level that is within the testing laboratory's normal range OR below the testing laboratory's lower limit of the normal range OR is less than 300 ng/dL OR ii. Free serum testosterone level is within the testing laboratory's normal range OR below the testing laboratory's normal range AND 3. ONE of the following: A. Patient will NOT be using the requested agent in combination with another androgen or anabolic steroid OR B. Prescriber has submitted information in support of therapy with more than one agent

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ANTIPSYCHOTICS PA

MEDICATION(S)

ABILIFY, ARIPIPRAZOLE, ARIPIPRAZOLE ODT, ASENAPINE MALEATE, CHLORPROMAZINE 10 MG TABLET, CHLORPROMAZINE 100 MG TABLET, CHLORPROMAZINE 100 MG/ML CONC, CHLORPROMAZINE 200 MG TABLET, CHLORPROMAZINE 25 MG TABLET, CHLORPROMAZINE 30 MG/ML CONC, CHLORPROMAZINE 50 MG TABLET, CLOZAPINE, CLOZAPINE ODT, CLOZARIL, FANAPT, FLUPHENAZINE DECANOATE, FLUPHENAZINE HCL, GEODON, HALDOL DECANOATE 100, HALDOL DECANOATE 50, HALOPERIDOL, HALOPERIDOL DECANOATE, HALOPERIDOL DECANOATE 100, HALOPERIDOL LACTATE, INVEGA ER 3 MG TABLET, INVEGA ER 6 MG TABLET, INVEGA ER 9 MG TABLET, LATUDA, LOXAPINE, LURASIDONE HCL, LYBALVI, MOLINDONE HCL, OLANZAPINE, OLANZAPINE ODT, PALIPERIDONE ER, PERPHENAZINE, PIMOZIDE, QUETIAPINE FUMARATE, QUETIAPINE FUMARATE ER, REXULTI 0.25 MG TABLET, REXULTI 0.5 MG TABLET, REXULTI 1 MG TABLET, REXULTI 2 MG TABLET, REXULTI 3 MG TABLET, REXULTI 4 MG TABLET, RISPERDAL 0.5 MG TABLET, RISPERDAL 1 MG TABLET, RISPERDAL 1 MG/ML SOLUTION, RISPERDAL 2 MG TABLET, RISPERDAL 3 MG TABLET, RISPERDAL 4 MG TABLET, RISPERIDONE 1 MG/ML SOLUTION, RISPERIDONE ODT, SAPHRIS, SECUADO, SEROQUEL, SEROQUEL XR 150 MG TABLET, SEROQUEL XR 200 MG TABLET, SEROQUEL XR 300 MG TABLET, SEROQUEL XR 400 MG TABLET, SEROQUEL XR 50 MG TABLET, THIORIDAZINE HCL, THIOTHIXENE, TRIFLUOPERAZINE HCL, VERSACLOZ, ZIPRASIDONE MESYLATE, ZYPREXA, ZYPREXA RELPREVV, ZYPREXA ZYDIS

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

PA does NOT apply to patients less than 65 years of age. Criteria for approval require BOTH of the following: 1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND 2. ONE of the following: a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR b. Prescriber states the patient is currently being treated with the requested agent OR c. ONE of the

following: i. Patient has a diagnosis other than dementia-related psychosis or dementia related behavioral symptoms OR ii. Patient has dementia-related psychosis or dementia related behavioral symptoms AND BOTH of the following: 1. Dementia-related psychosis is determined to be severe or the associated behavior puts the patient or others in danger AND 2. Prescriber has documented that s/he has discussed the risk of increased mortality with the patient and/or the patient's surrogate decision maker Approval authorizations will apply to the requested medication only.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

APOMORPHINE INJ PA

MEDICATION(S)
APOKYN, APOMORPHINE HCL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require ALL of the following: 1. The requested agent will be used to treat acute, intermittent hypomobility, off episodes (end of dose wearing off and unpredictable on/off episodes) associated with advanced Parkinson's disease AND 2. The requested agent will be used in combination with agents used for therapy in Parkinson's disease (e.g., levodopa, dopamine agonist, monoamine oxidase B inhibitor) AND 3. Patient will NOT be using the requested agent in combination with a 5-HT3 antagonist (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ARCALYST PA

MEDICATION(S)
ARCALYST

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. ONE of the following: A. Patient has been diagnosed with Cryopyrin-Associated Periodic Syndromes (CAPS) including Familial Cold Auto-inflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS) OR B. BOTH of the following: i. Patient has a diagnosis of deficiency of interleukin-1 receptor antagonist AND ii. The requested agent is being used for maintenance of remission OR C. BOTH of the following: i. Patient has a diagnosis of recurrent pericarditis AND ii. The requested agent is being used to reduce the risk of recurrence AND 2. Patient will NOT be using the requested agent in combination with another biologic agent

AGE RESTRICTION
For diagnosis of CAPS including FCAS or MWS, patient is 12 years of age or over For diagnosis of recurrent pericarditis and reduction in risk of recurrence, patient is 12 years of age or over

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ARIKAYCE PA

MEDICATION(S)
ARIKAYCE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of Mycobacterium avium complex (MAC) lung disease AND 2. Patient has not achieved negative sputum cultures despite at least 6 consecutive months of treatment with standard combination antibiotic therapy for MAC lung disease [e.g., standard combination may include a macrolide (clarithromycin, azithromycin), a rifamycin (rifampin, rifabutin), and ethambutol] AND 3. Patient will continue treatment with a combination antibiotic therapy for MAC lung disease with the requested agent [e.g., combination may include a macrolide (clarithromycin, azithromycin), a rifamycin (rifampin, rifabutin), and ethambutol] Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of Mycobacterium avium complex (MAC) lung disease AND 3. Patient has had clinical benefit with the requested agent AND 4. Patient will continue treatment with a combination antibiotic therapy for MAC lung disease with the requested agent [e.g., combination may include a macrolide (clarithromycin, azithromycin), a rifamycin (rifampin, rifabutin), and ethambutol]

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., infectious disease, immunologist, pulmonologist, thoracic specialist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ARMODAFINIL PA

MEDICATION(S)
ARMODAFINIL, NUVIGIL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND 2. Patient will NOT be using the requested agent in combination with another target agent (i.e., modafinil)

AGE RESTRICTION
Patient is 17 years of age or over

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ATOPIC DERMATITIS PA - PIMECROLIMUS

MEDICATION(S)
ELIDEL, PIMECROLIMUS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require ONE of the following: 1. Patient has a diagnosis of atopic dermatitis or vulvar lichen sclerosus AND ONE of the following: A. Patient has tried and had an inadequate response to a topical corticosteroid or topical corticosteroid combination preparation (e.g., hydrocortisone, triamcinolone) OR B. Patient has an intolerance or hypersensitivity to a topical corticosteroid or topical corticosteroid combination preparation OR C. Patient has an FDA labeled contraindication to a topical corticosteroid or topical corticosteroid combination preparation OR 2. Patient has a diagnosis of facial seborrheic dermatitis associated with HIV infection AND BOTH of the following: A. Patient is currently on an antiretroviral treatment regimen AND B. ONE of the following: i. Patient has tried and had an inadequate response to a topical corticosteroid or topical antifungal treatment (e.g., hydrocortisone, triamcinolone, ketoconazole) OR ii. Patient has an intolerance or hypersensitivity to a topical corticosteroid or topical antifungal treatment OR iii. Patient has an FDA labeled contraindication to a topical corticosteroid or topical antifungal treatment OR 3. Patient has an indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ATOPIC DERMATITIS PA - TACROLIMUS

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require ONE of the following: 1. Patient has a diagnosis of atopic dermatitis AND ONE of the following: A. Patient has tried and had an inadequate response to a topical corticosteroid or topical corticosteroid combination preparation (e.g., hydrocortisone, triamcinolone) OR B. Patient has an intolerance or hypersensitivity to a topical corticosteroid or topical corticosteroid combination preparation OR C. Patient has an FDA labeled contraindication to a topical corticosteroid or topical corticosteroid combination preparation OR 2. Patient has an indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ATOVAQUONE PA

MEDICATION(S)
ATOVAQUONE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. ONE of the following: A. BOTH of the following: i. ONE of the following: 1. Patient has a diagnosis of mild-to-moderate Pneumocystis jirovecii pneumonia OR 2. Patient is using the requested agent for prevention of Pneumocystis jirovecii pneumonia AND ii. ONE of the following: 1. Patient has an intolerance or hypersensitivity to trimethoprim/sulfamethoxazole (TMP/SMX) OR 2. Patient has an FDA labeled contraindication to trimethoprim/sulfamethoxazole (TMP/SMX) OR B. Patient has an indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

AUSTEDO PA

MEDICATION(S)
AUSTEDO, AUSTEDO XR, AUSTEDO XR TITRATION KT(WK1-4)

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require ALL of the following: 1. ONE of the following: A. Patient has a diagnosis of chorea associated with Huntington's disease AND BOTH of the following: i. ONE of the following: 1. Patient does NOT have a current diagnosis of depression OR 2. Patient has a current diagnosis of depression and is being treated for depression AND ii. ONE of the following: 1. Patient does NOT have a diagnosis of passive suicidal ideation and/or behavior OR 2. Patient has a diagnosis of passive suicidal ideation and/or behavior and must NOT be actively suicidal OR B. Patient has a diagnosis of tardive dyskinesia AND ONE of the following: i. Prescriber has reduced the dose of or discontinued any medications known to cause tardive dyskinesia (i.e., dopamine receptor blocking agents) OR ii. Prescriber has provided clinical rationale indicating that a reduced dose or discontinuation of any medications known to cause tardive dyskinesia is not appropriate AND 2. Patient will NOT be using the requested agent in combination with a monoamine oxidase inhibitor (MAOI) AND 3. Patient will NOT be using the requested agent in combination with reserpine

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

BELSOMRA PA

MEDICATION(S)
BELSOMRA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has an FDA labeled indication for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

BENIGN PROSTATIC HYPERPLASIA PA - TADALAFIL

MEDICATION(S)
TADALAFIL 2.5 MG TABLET, TADALAFIL 5 MG TABLET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Requested agent will be used to treat erectile dysfunction AND FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. Patient has a diagnosis of benign prostatic hyperplasia (BPH) AND 2. Patient has tried and had an insufficient response, intolerance or hypersensitivity, or FDA labeled contraindication to TWO alpha blocker agents (e.g., terazosin, doxazosin, tamsulosin)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

BENLYSTA SC PA

MEDICATION(S)
BENLYSTA 200 MG/ML AUTOINJECT, BENLYSTA 200 MG/ML SYRINGE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. ONE of the following: a. Patient has a diagnosis of active systemic lupus erythematosus (SLE) disease AND the following: i. Patient will continue standard SLE therapy [corticosteroids (e.g., methylprednisolone, prednisone), hydroxychloroquine, immunosuppressives (e.g., azathioprine, methotrexate, oral cyclophosphamide)] in combination with the requested agent OR b. Patient has a diagnosis of active lupus nephritis (LN) AND the following: i. Patient will continue standard LN therapy [corticosteroids (e.g., methylprednisolone, prednisone), immunosuppressives (e.g., azathioprine, mycophenolate)] in combination with the requested agent AND 2. Patient will NOT be using the requested agent in combination with another biologic agent AND 3. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. ONE of the following: a. Patient has diagnosis of active systemic lupus erythematosus (SLE) disease AND the following: i. Patient will continue standard SLE therapy [corticosteroids (e.g., methylprednisolone, prednisone), hydroxychloroquine, immunosuppressives (e.g., azathioprine, methotrexate, oral cyclophosphamide)] in combination with the requested agent OR b. Patient has a diagnosis of active lupus nephritis (LN) AND the following: i. Patient will continue standard LN therapy [corticosteroids (e.g., methylprednisolone, prednisone), immunosuppressives (e.g., azathioprine, mycophenolate)] in combination with the requested agent AND 3. Patient has had clinical benefit with the requested agent AND 4. Patient will NOT be using the requested agent in combination with another biologic agent AND 5. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
Patient is 5 years of age or over

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

BENZODIAZEPINES PA - CHLORDIAZEPOXIDE

MEDICATION(S)
CHLORDIAZEPOXIDE HCL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
PA does NOT apply to patients less than 65 years of age. Criteria for approval require the following: 1. ONE of the following: A. BOTH of the following: i. ONE of the following: a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR b. Prescriber states the patient is currently being treated with the requested agent AND ii. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent OR B. BOTH of the following: i. Patient has ONE of the following diagnoses: a. Anxiety disorder AND ONE of the following: 1) Patient has tried and had an inadequate response to a formulary selective serotonin reuptake inhibitor (SSRI) or serotonin norepinephrine reuptake inhibitor (SNRI) OR 2) Patient has an intolerance or hypersensitivity to a formulary SSRI or SNRI OR 3) Patient has an FDA labeled contraindication to a formulary SSRI or SNRI OR b. Alcohol withdrawal OR c. Patient has an indication that is supported in CMS approved compendia for the requested agent AND ii. Patient does NOT have any FDA labeled contraindications to the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

BENZODIAZEPINES PA - CLOBAZAM

MEDICATION(S)
CLOBAZAM, ONFI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
PA does NOT apply to patients less than 65 years of age. Criteria for approval require the following: 1. ONE of the following: A. BOTH of the following: i. ONE of the following: a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR b. Prescriber states the patient is currently being treated with the requested agent AND ii. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent OR B. BOTH of the following: i. Patient has ONE of the following diagnoses: a. Seizure disorder OR b. Patient has an indication that is supported in CMS approved compendia for the requested agent AND ii. Patient does NOT have any FDA labeled contraindications to the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

BENZODIAZEPINES PA - CLORAZEPATE

MEDICATION(S)
CLORAZEPATE DIPOTASSIUM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
PA does NOT apply to patients less than 65 years of age. Criteria for approval require the following: 1. ONE of the following: A. BOTH of the following: i. ONE of the following: a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR b. Prescriber states the patient is currently being treated with the requested agent AND ii. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent OR B. BOTH of the following: i. Patient has ONE of the following diagnoses: a. Seizure disorder OR b. Anxiety disorder AND ONE of the following: 1) Patient has tried and has an inadequate response to a formulary selective serotonin reuptake inhibitor (SSRI) or serotonin norepinephrine reuptake inhibitor (SNRI) OR 2) Patient has an intolerance or hypersensitivity to a formulary SSRI or SNRI OR 3) Patient has an FDA labeled contraindication to a formulary SSRI or SNRI OR c. Alcohol withdrawal OR d. Patient has an indication that is supported in CMS approved compendia for the requested agent AND ii. Patient does NOT have any FDA labeled contraindications to the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

BENZODIAZEPINES PA - DIAZEPAM

MEDICATION(S)
DIAZEPAM 10 MG TABLET, DIAZEPAM 2 MG TABLET, DIAZEPAM 25 MG/5 ML ORAL CONC, DIAZEPAM 5 MG TABLET, DIAZEPAM 5 MG/5 ML ORAL CUP, DIAZEPAM 5 MG/5 ML SOLUTION, DIAZEPAM 5 MG/ML ORAL CONC

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
PA does NOT apply to patients less than 65 years of age. Criteria for approval require the following: 1. ONE of the following: A. BOTH of the following: i. ONE of the following: a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR b. Prescriber states the patient is currently being treated with the requested agent AND ii. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent OR B. BOTH of the following: i. Patient has ONE of the following diagnoses: a. Seizure disorder OR b. Anxiety disorder AND ONE of the following: 1) Patient has tried and had an inadequate response to a formulary selective serotonin reuptake inhibitor (SSRI) or serotonin norepinephrine reuptake inhibitor (SNRI) OR 2) Patient has an intolerance or hypersensitivity to a formulary SSRI or SNRI OR 3) Patient has an FDA labeled contraindication to a formulary SSRI or SNRI OR c. Skeletal muscle spasms OR d. Alcohol withdrawal OR e. Patient has an indication that is supported in CMS approved compendia for the requested agent AND ii. Patient does NOT have any FDA labeled contraindications to the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

BENZODIAZEPINES PA - LORAZEPAM

MEDICATION(S)
LORAZEPAM 0.5 MG TABLET, LORAZEPAM 1 MG TABLET, LORAZEPAM 2 MG TABLET, LORAZEPAM 2 MG/ML ORAL CONCENT, LORAZEPAM INTENSOL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
PA does NOT apply to patients less than 65 years of age. Criteria for approval require the following: 1. ONE of the following: A. BOTH of the following: i. ONE of the following: a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR b. Prescriber states the patient is currently being treated with the requested agent AND ii. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent OR B. BOTH of the following: i. Patient has ONE of the following diagnoses: a. Anxiety disorder AND ONE of the following: 1) Patient has tried and had an inadequate response to a formulary selective serotonin reuptake inhibitor (SSRI) or serotonin norepinephrine reuptake inhibitor (SNRI) OR 2) Patient has an intolerance or hypersensitivity to a formulary SSRI or SNRI OR 3) Patient has an FDA labeled contraindication to a formulary SSRI or SNRI OR b. Patient has an indication that is supported in CMS approved compendia for the requested agent AND ii. Patient does NOT have any FDA labeled contraindications to the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

BENZODIAZEPINES PA - OXAZEPAM

MEDICATION(S)
OXAZEPAM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
PA does NOT apply to patients less than 65 years of age. Criteria for approval require the following: 1. ONE of the following: A. BOTH of the following: i. ONE of the following: a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR b. Prescriber states the patient is currently being treated with the requested agent AND ii. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent OR B. BOTH of the following: i. Patient has ONE of the following diagnoses: a. Anxiety disorder AND ONE of the following: 1) Patient has tried and had an inadequate response to a formulary selective serotonin reuptake inhibitor (SSRI) or serotonin norepinephrine reuptake inhibitor (SNRI) OR 2) Patient has an intolerance or hypersensitivity to a formulary SSRI or SNRI OR 3) Patient has an FDA labeled contraindication to a formulary SSRI or SNRI OR b. Alcohol withdrawal OR c. Patient has an indication that is supported in CMS approved compendia for the requested agent AND ii. Patient does NOT have any FDA labeled contraindications to the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

BENZODIAZEPINES PA - SYMPAZAN

MEDICATION(S)
SYMPAZAN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
PA does NOT apply to patients less than 65 years of age. Criteria for approval require the following: 1. ONE of the following: A. BOTH of the following: i. ONE of the following: a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR b. Prescriber states the patient is currently being treated with the requested agent AND ii. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent OR B. BOTH of the following: i. Patient has ONE of the following diagnoses: a. Seizure disorder OR b. Patient has an indication that is supported in CMS approved compendia for the requested agent AND ii. Patient does NOT have any FDA labeled contraindications to the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

BEXAROTENE GEL PA

MEDICATION(S)
BEXAROTENE 1% GEL, TARGRETIN 1% GEL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require BOTH of the following: 1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR B. Prescriber states the patient is currently being treated with the requested agent OR C. ALL of the following: i. ONE of the following: 1. BOTH of the following: a. Patient has a diagnosis of stage IA or IB cutaneous T-cell lymphoma (CTCL) with cutaneous lesions AND b. ONE of the following: i. Patient has refractory or persistent disease despite a previous treatment trial with a skin-directed therapy (e.g., topical corticosteroid, topical imiquimod) OR ii. Patient has an intolerance or hypersensitivity to a previous treatment trial with a skin-directed therapy (e.g., topical corticosteroid, topical imiquimod) OR iii. Patient has an FDA labeled contraindication to a previous treatment trial with a skin-directed therapy (e.g., topical corticosteroid, topical imiquimod) OR 2. Patient has an indication that is supported in CMS approved compendia for the requested agent AND ii. Prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, oncologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND iii. Patient does NOT have any FDA labeled contraindications to the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND 3. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR B. Prescriber states the patient is currently being treated with the requested agent OR C. ALL of the following: i. Patient has had clinical benefit with the requested agent AND ii. Prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, oncologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND iii. Patient does NOT have any FDA labeled contraindications to the requested agent

PART B PREREQUISITE

N/A

BIOLOGIC IMMUNOMODULATORS PA - COSENTYX

MEDICATION(S)
COSENTYX (2 SYRINGES), COSENTYX SENSOREADY (2 PENS), COSENTYX SENSOREADY PEN, COSENTYX SYRINGE, COSENTYX UNOREADY PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR C. Patient's medication history indicates use of another biologic immunomodulator agent for the same FDA labeled indication OR D. Patient's diagnosis does NOT require a conventional prerequisite agent OR E. Patient's medication history indicates use of ONE formulary conventional prerequisite agent for the requested indication OR F. Patient has an intolerance or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication OR G. Patient has an FDA labeled contraindication to at least ONE formulary conventional prerequisite agent for the requested indication AND 3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 4. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND 4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 5. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

Use of ONE conventional prerequisite agent is required for diagnoses of psoriatic arthritis or plaque psoriasis NO prerequisites are required for diagnoses of ankylosing spondylitis, enthesitis related arthritis, hidradenitis suppurativa, or non-radiographic axial spondyloarthritis Formulary conventional agents for psoriatic arthritis include cyclosporine, leflunomide, methotrexate, or sulfasalazine Formulary conventional agents (topical or systemic) for plaque psoriasis include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids

PART B PREREQUISITE

N/A

BIOLOGIC IMMUNOMODULATORS PA - ENBREL

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

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR C. Patient's medication history indicates use of another biologic immunomodulator agent for the same FDA labeled indication OR D. Patient's diagnosis does NOT require a conventional prerequisite agent OR E. Patient's medication history indicates use of ONE formulary conventional prerequisite agent for the requested indication OR F. Patient has an intolerance or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication OR G. Patient has an FDA labeled contraindication to at least ONE formulary conventional prerequisite agent for the requested indication AND 3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 4. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND 4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 5. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

Use of ONE conventional prerequisite agent is required for diagnoses of psoriatic arthritis, plaque psoriasis, rheumatoid arthritis, juvenile psoriatic arthritis, or juvenile idiopathic arthritis NO prerequisites are required for a diagnoses of ankylosing spondylitis or severe juvenile psoriatic arthritis Formulary conventional agents for rheumatoid arthritis, juvenile idiopathic arthritis, juvenile psoriatic arthritis, or psoriatic arthritis include leflunomide, methotrexate, or sulfasalazine Formulary conventional agents (topical or systemic) for plaque psoriasis include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids

PART B PREREQUISITE

N/A

BIOLOGIC IMMUNOMODULATORS PA - HADLIMA

MEDICATION(S)
HADLIMA, HADLIMA PUSHTOUCH, HADLIMA(CF), HADLIMA(CF) PUSHTOUCH

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR C. Patient's medication history indicates use of another biologic immunomodulator agent for the same FDA labeled indication OR D. Patient's diagnosis does NOT require a conventional prerequisite agent OR E. Patient's medication history indicates use of ONE formulary conventional prerequisite agent for the requested indication OR F. Patient has an intolerance or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication OR G. Patient has an FDA labeled contraindication to at least ONE formulary conventional prerequisite agent for the requested indication AND 3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 4. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND 4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 5. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be 12 weeks for initial use for ulcerative colitis, 12 months for all others

OTHER CRITERIA

Use of ONE conventional prerequisite agent is required for diagnoses of psoriatic arthritis, plaque psoriasis, rheumatoid arthritis, juvenile idiopathic arthritis, Crohn's disease, or moderate ulcerative colitis NO prerequisites are required for diagnoses of ankylosing spondylitis, hidradenitis suppurativa, severe ulcerative colitis, or uveitis Formulary conventional agents for rheumatoid arthritis, juvenile idiopathic arthritis, or psoriatic arthritis include leflunomide, methotrexate, or sulfasalazine Formulary conventional agents (topical or systemic) for plaque psoriasis include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids Formulary conventional agents for Crohn's disease include methotrexate, sulfasalazine, corticosteroids, azathioprine, or mercaptopurine Formulary conventional agents for moderate ulcerative colitis include 5-aminosalicylates, corticosteroids, azathioprine, or mercaptopurine

PART B PREREQUISITE

N/A

BIOLOGIC IMMUNOMODULATORS PA - HUMIRA

MEDICATION(S)
HUMIRA 40 MG/0.8 ML SYRINGE, HUMIRA PEN, HUMIRA(CF), HUMIRA(CF) PEN, HUMIRA(CF) PEN CROHN'S-UC-HS, HUMIRA(CF) PEN PEDIATRIC UC, HUMIRA(CF) PEN PSOR-UV-ADOL HS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR C. Patient's medication history indicates use of another biologic immunomodulator agent for the same FDA labeled indication OR D. Patient's diagnosis does NOT require a conventional prerequisite agent OR E. Patient's medication history indicates use of ONE formulary conventional prerequisite agent for the requested indication OR F. Patient has an intolerance or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication OR G. Patient has an FDA labeled contraindication to at least ONE formulary conventional prerequisite agent for the requested indication AND 3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 4. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND 4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 5. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be 12 weeks for initial use for ulcerative colitis, 12 months for all others

OTHER CRITERIA

Use of ONE conventional prerequisite agent is required for diagnoses of psoriatic arthritis, plaque psoriasis, rheumatoid arthritis, juvenile idiopathic arthritis, Crohn's disease, or moderate ulcerative colitis NO prerequisites are required for diagnoses of ankylosing spondylitis, hidradenitis suppurativa, severe ulcerative colitis, or uveitis Formulary conventional agents for rheumatoid arthritis, juvenile idiopathic arthritis, or psoriatic arthritis include leflunomide, methotrexate, or sulfasalazine Formulary conventional agents (topical or systemic) for plaque psoriasis include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids Formulary conventional agents for Crohn's disease include methotrexate, sulfasalazine, corticosteroids, azathioprine, or mercaptopurine Formulary conventional agents for moderate ulcerative colitis include 5-aminosalicylates, corticosteroids, azathioprine, or mercaptopurine

PART B PREREQUISITE

N/A

BIOLOGIC IMMUNOMODULATORS PA - ORENCIA

MEDICATION(S)
ORENCIA, ORENCIA CLICKJECT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR C. ONE of the following: i. Patient's diagnosis is indicated for preferred biologic immunomodulator agent(s) AND ONE of the following: a. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) OR ii. The request is for an FDA labeled indication that is not covered by preferred biologic immunomodulator agent(s) AND 3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 4. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND 4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 5. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

Use of TWO preferred agents (Enbrel, Hadlima, Humira, Rinvoq tablets, or Rinvoq solution) is required for diagnosis of juvenile idiopathic arthritis Use of TWO preferred agents (Enbrel, Hadlima, Humira, or Rinvoq tablets) is required for diagnosis of rheumatoid arthritis For patients 18 years of age or over, use of TWO preferred agents (Cosentyx, Enbrel, Hadlima, Humira, Otezla, Rinvoq tablets, Rinvoq solution, Skyrizi, Stelara, or Tremfya) is required for diagnosis of psoriatic arthritis For patients between 6 and less than 18 years of age, use of TWO preferred agents (Cosentyx, Rinvoq tablets, or Rinvoq solution) is required for diagnosis of psoriatic arthritis For patients between 2 and less than 6 years of age, use of ONE preferred agent (Rinvoq tablets or Rinvoq solution) is required for diagnosis of psoriatic arthritis NO preferred agent is required for diagnosis of prophylaxis of acute graft vs host disease

PART B PREREQUISITE

N/A

BIOLOGIC IMMUNOMODULATORS PA - RENFLEXIS

MEDICATION(S)
RENFLEXIS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR C. ONE of the following: i. Patient's diagnosis is indicated for preferred biologic immunomodulator agent(s) AND ONE of the following: a. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) OR ii. The request is for an FDA labeled indication that is not covered by preferred biologic immunomodulator agent(s) AND 3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 4. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: . Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND 4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 5. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

Use of TWO preferred agents (Enbrel, Hadlima, or Humira) is required for diagnosis of rheumatoid arthritis Use of TWO preferred agents (Cosentyx, Enbrel, Hadlima, Humira, Otezla, Skyrizi, Stelara, or Tremfya) is required for diagnosis of psoriatic arthritis Use of TWO preferred agents (Cosentyx, Enbrel, Hadlima, Humira, Otezla, Skyrizi, Stelara, or Tremfya) is required for diagnosis of plaque psoriasis Use of TWO preferred agents (Cosentyx, Enbrel, Hadlima, or Humira) is required for diagnosis of ankylosing spondylitis Use of TWO preferred agents (Hadlima, Humira, Skyrizi, or Stelara) is required for diagnosis of adult Crohn’s disease Use of TWO preferred agents (Hadlima, Humira, or Stelara) is required for diagnosis of adult ulcerative colitis Use of TWO preferred agents (Hadlima and Humira) is required for diagnosis of pediatric Crohn’s disease Only the preferred agent Humira is required for diagnosis of pediatric ulcerative colitis NO preferred agent is required for diagnosis of adult fistulizing Crohn’s disease

PART B PREREQUISITE

N/A

BIOLOGIC IMMUNOMODULATORS PA - RIABNI

MEDICATION(S)
RIABNI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require BOTH of the following: 1. ONE of the following: A. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND ONE of the following: i. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR ii. Prescriber states the patient is currently being treated with the requested agent OR B. ALL of the following: i. ONE of the following: a. Patient has a diagnosis of rheumatoid arthritis AND ONE of the following: 1. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR 2. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR 3. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) OR b. Patient has another FDA labeled indication or an indication that is supported in CMS approved compendia AND ii. Patient has been screened for hepatitis B infection measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) and has begun therapy, if appropriate, prior to receiving the requested agent AND iii. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND iv. Patient does NOT have any FDA labeled limitation(s) of use that is not otherwise supported in NCCN guidelines AND 2. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan’s Prior Authorization criteria AND 2. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND 3. ONE of the following:

A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR B. Prescriber states the patient is currently being treated with the requested agent OR C. ALL of the following: i. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND ii. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND iii. Patient does NOT have any FDA labeled limitation(s) of use that is not otherwise supported in NCCN guidelines AND 4. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication Use of TWO preferred agents (Enbrel, Hadlima, Humira, or Rinvoq tablets) is required for diagnosis of rheumatoid arthritis ALL other diagnoses do NOT require any preferred agents

PART B PREREQUISITE

N/A

BIOLOGIC IMMUNOMODULATORS PA - RINVOQ SOLUTION

MEDICATION(S)
RINVOQ LQ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR C. ONE of the following: i. Patient's medication history indicates use of preferred TNF agent(s) OR ii. Patient has an intolerance or hypersensitivity to preferred TNF agent(s) OR iii. Patient has an FDA labeled contraindication to preferred TNF agent(s) OR iv. The request is for an FDA labeled indication that is not covered by preferred TNF agent(s) AND 3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 4. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND 4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 5. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

Use of ONE preferred TNF (Enbrel, Hadlima, Humira, or Simlandi) is required for diagnoses of adult psoriatic arthritis or juvenile idiopathic arthritis. NO preferred TNF agent is required for diagnosis of pediatric psoriatic arthritis

PART B PREREQUISITE

N/A

BIOLOGIC IMMUNOMODULATORS PA - RINVOQ TABLET

MEDICATION(S)
RINVOQ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR C. ONE of the following: i. BOTH of the following: a. Patient has an FDA labeled indication other than moderate to severe atopic dermatitis for the requested agent AND b. ONE of the following: 1. Patient's medication history indicates use of preferred TNF agent(s) OR 2. Patient has an intolerance or hypersensitivity to preferred TNF agent(s) OR 3. Patient has an FDA labeled contraindication to preferred TNF agent(s) OR 4. The request is for an FDA labeled indication that is not covered by preferred TNF agent(s) OR ii. Patient has a diagnosis of moderate to severe atopic dermatitis AND ONE of the following: a. Patient's medication history indicates use of TWO conventional prerequisite agents (i.e., ONE formulary topical corticosteroid AND ONE formulary topical calcineurin inhibitor) for the requested indication OR b. Patient has an intolerance or hypersensitivity to TWO conventional prerequisite agents (i.e., ONE formulary topical corticosteroid AND ONE formulary topical calcineurin inhibitor) for the requested indication OR c. Patient has an FDA labeled contraindication to TWO conventional prerequisite agents (i.e., ONE formulary topical corticosteroid AND ONE formulary topical calcineurin inhibitor) for the requested indication AND 3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 4. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND 4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 5. The requested dose is within FDA labeled dosing for the requested indication Use of ONE preferred TNF (Enbrel, Hadlima, or Humira) is required for diagnoses of ankylosing spondylitis, rheumatoid arthritis, adult psoriatic arthritis, or juvenile idiopathic arthritis Use of ONE preferred TNF (Hadlima or Humira) is required for diagnoses of ulcerative colitis or Crohn's disease Use of TWO conventional prerequisite agents are required for diagnosis of moderate to severe atopic dermatitis NO preferred TNF agents are required for diagnoses of pediatric psoriatic arthritis or non-radiographic axial spondyloarthritis

PART B PREREQUISITE

N/A

BIOLOGIC IMMUNOMODULATORS PA - RUXIENCE

MEDICATION(S)
RUXIENCE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require BOTH of the following: 1. ONE of the following: A. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND ONE of the following: i. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR ii. Prescriber states the patient is currently being treated with the requested agent OR B. ALL of the following: i. ONE of the following: a. Patient has a diagnosis of rheumatoid arthritis AND ONE of the following: 1. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR 2. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR 3. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) OR b. Patient has another FDA labeled indication or an indication that is supported in CMS approved compendia AND ii. Patient has been screened for hepatitis B infection measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) and has begun therapy, if appropriate, prior to receiving the requested agent AND iii. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND iv. Patient does NOT have any FDA labeled limitation(s) of use that is not otherwise supported in NCCN guidelines AND 2. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND 3. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR B. Prescriber states the patient is currently being treated with the requested agent OR C. ALL of the following: i. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND ii. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND iii. Patient does NOT have any FDA labeled limitation(s) of use that is not otherwise supported in NCCN guidelines AND 4. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication Use of TWO preferred agents (Enbrel, Hadlima, Humira, or Rinvoq tablets) is required for diagnosis of rheumatoid arthritis ALL other diagnoses do NOT require any preferred agents

PART B PREREQUISITE

N/A

BIOLOGIC IMMUNOMODULATORS PA - SIMLANDI

MEDICATION(S)

SIMLANDI(CF) AUTOINJECTOR

PENDING CMS APPROVAL

BIOLOGIC IMMUNOMODULATORS PA - SKYRIZI

MEDICATION(S)
SKYRIZI 150 MG/ML SYRINGE, SKYRIZI 600 MG/10 ML VIAL, SKYRIZI ON-BODY, SKYRIZI PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR C. Patient's medication history indicates use of another biologic immunomodulator agent for the same FDA labeled indication OR D. Patient's medication history indicates use of ONE formulary conventional prerequisite agent for the requested indication OR E. Patient has an intolerance or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication OR F. Patient has an FDA labeled contraindication to at least ONE formulary conventional prerequisite agent for the requested indication AND 3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 4. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND 4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 5. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

Use of ONE conventional prerequisite agent is required for diagnoses of Crohn's disease, plaque psoriasis, or psoriatic arthritis Formulary conventional agents for Crohn's disease include methotrexate, sulfasalazine, corticosteroids, azathioprine, or mercaptopurine Formulary conventional agents (topical or systemic) for plaque psoriasis include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids Formulary conventional agents for psoriatic arthritis include leflunomide, methotrexate, or sulfasalazine

PART B PREREQUISITE

N/A

BIOLOGIC IMMUNOMODULATORS PA - STELARA

MEDICATION(S)
STELARA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR C. Patient's medication history indicates use of another biologic immunomodulator agent for the same FDA labeled indication OR D. Patient's diagnosis does NOT require a conventional prerequisite agent OR E. Patient's medication history indicates use of ONE formulary conventional prerequisite agent for the requested indication OR F. Patient has an intolerance or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication OR G. Patient has an FDA labeled contraindication to at least ONE formulary conventional prerequisite agent for the requested indication AND 3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 4. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND 4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 5. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

Use of ONE conventional prerequisite agent is required for diagnoses of psoriatic arthritis, plaque psoriasis, moderate ulcerative colitis, or Crohn's disease NO prerequisites are required for diagnosis of severe ulcerative colitis Formulary conventional agents for psoriatic arthritis include cyclosporine, leflunomide, methotrexate, or sulfasalazine Formulary conventional agents (topical or systemic) for plaque psoriasis include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids Formulary conventional agents for Crohn's disease include methotrexate, sulfasalazine, corticosteroids, azathioprine, mercaptopurine Formulary conventional agents for moderate ulcerative colitis include 5-aminosalicylates, corticosteroids, azathioprine, mercaptopurine

PART B PREREQUISITE

N/A

BIOLOGIC IMMUNOMODULATORS PA - TREMFYA

MEDICATION(S)
TREMFYA 100 MG/ML INJECTOR, TREMFYA 100 MG/ML SYRINGE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR C. Patient's medication history indicates use of another biologic immunomodulator agent for the same FDA labeled indication OR D. Patient's medication history indicates use of ONE formulary conventional prerequisite agent for the requested indication OR E. Patient has an intolerance or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication OR F. Patient has an FDA labeled contraindication to at least ONE formulary conventional prerequisite agent for the requested indication AND 3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 4. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND 4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 5. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

Use of ONE conventional prerequisite agent is required for diagnoses of psoriatic arthritis or plaque psoriasis Formulary conventional agents for psoriatic arthritis include cyclosporine, leflunomide, methotrexate, or sulfasalazine Formulary conventional agents (topical or systemic) for plaque psoriasis include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids

PART B PREREQUISITE

N/A

BIVIGAM/FLEBOGAMMA/GAMMAPLEX/OCTAGAM/PRIVIGEN PA

MEDICATION(S)
GAMMAPLEX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require ONE of the following: 1. Patient has ONE of the following diagnoses: A. Primary immunodeficiency [e.g., congenital agammaglobulinemia, common variable immunodeficiency (CVID), severe combined immunodeficiency, Wiskott-Aldrich Syndrome, X-linked agammaglobulinemia (XLA), humoral immunodeficiency, IgG subclass deficiency with or without IgA deficiency] OR B. B-cell chronic lymphocytic leukemia OR multiple myeloma AND ONE of the following: i. Patient has a history of infections OR ii. Patient has evidence of specific antibody deficiency OR iii. Patient has hypogammaglobulinemia OR C. Idiopathic thrombocytopenia purpura AND ONE of the following: i. Patient has failed ONE conventional therapy [e.g., corticosteroids (e.g., methylprednisolone), or immunosuppressants (e.g., azathioprine)] OR ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR D. Dermatomyositis AND ONE of the following: i. Patient has failed ONE conventional therapy [e.g., corticosteroids (e.g., methylprednisolone) or immunosuppressants (e.g., azathioprine)] OR ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR E. Polymyositis AND ONE of the following: i. Patient has failed ONE conventional therapy [e.g., corticosteroids (e.g., methylprednisolone) or immunosuppressants (e.g., azathioprine)] OR ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR F. Severe rheumatoid arthritis AND ONE of the following: i. Patient has failed ONE conventional therapy [e.g., tumor necrosis factor antagonists (e.g., Enbrel), DMARDS (e.g., methotrexate)] OR ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR Criteria continues: see Other Criteria

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 6 months for indications in Other Criteria, 12 months for all others

OTHER CRITERIA

G. Myasthenia gravis (MG) AND ONE of the following: i. Patient is in acute myasthenic crisis OR ii. Patient has severe refractory MG (e.g., major functional disability/weakness) AND ONE of the following: a) Patient has failed ONE immunomodulator therapy (i.e., corticosteroid, pyridostigmine, or azathioprine) OR b) Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE immunomodulator therapy OR H. Multiple sclerosis (MS) AND BOTH of the following: i. Patient has a diagnosis of relapsing remitting MS (RRMS) AND ii. Patient has had an insufficient response, documented failure, or FDA labeled contraindication to TWO MS agents (e.g., Avonex, Betaseron, Copaxone, dimethyl fumarate, fingolimod, glatiramer, Glatopa, Kesimpta, Plegridy, Vumerity) OR I. Acquired von Willebrand hemophilia AND ONE of the following: i. Patient has failed ONE conventional therapy (e.g., desmopressin, von Willebrand factor replacement therapy, corticosteroids, cyclophosphamide, FEIBA, or recombinant factor VIIa) OR ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR J. Refractory pemphigus vulgaris AND ONE of the following: i. Patient has failed ONE conventional immunosuppressive therapy (e.g., azathioprine, cyclophosphamide, mycophenolate, corticosteroids) OR ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional immunosuppressive therapy OR 2. ONE of the following: A. Patient has another FDA labeled indication for the requested agent OR B. Patient has an indication that is supported in CMS approved compendia for the requested agent Indications with 6 months approval duration: Acquired von Willebrand hemophilia, Guillain-Barre Syndrome, Lambert-Eaton myasthenia syndrome, Kawasaki disease, CMV induced pneumonitis in solid organ transplant, Toxic shock syndrome due to invasive group A streptococcus, Toxic epidermal necrolysis and Stevens-Johnson syndrome Drug is also subject to Part B versus Part D review.

PART B PREREQUISITE

N/A

BUDESONIDE ORAL ER PA - ENTOCORT

MEDICATION(S)
BUDESONIDE DR, BUDESONIDE EC

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

BUDESONIDE ORAL ER PA - UCERIS

MEDICATION(S)
BUDESONIDE ER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

BYDUREON PA

MEDICATION(S)
BYDUREON BCISE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Requested agent will be used for weight loss alone

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. Patient has a diagnosis of type 2 diabetes mellitus AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR B. Prescriber states the patient is currently being treated with the requested agent within the past 180 days OR C. ALL of the following: i. ONE of the following: 1. Patient's medication history includes use of a non glucagon-like peptide-1 (GLP-1) oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) within the past 90 days OR 2. Patient had an ineffective treatment response to a non GLP-1 oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) OR 3. Patient has an intolerance or hypersensitivity to a non GLP-1 oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) OR 4. Patient has an FDA labeled contraindication to a non GLP-1 oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) AND ii. Patient does NOT have any FDA labeled contraindications to the requested agent AND iii. Patient will NOT be using the requested agent in combination with another GLP-1 agonist agent, or an agent containing a GLP-1 agonist AND iv. Patient will NOT be using the requested agent in combination with an agent containing a dipeptidyl peptidase-4 (DPP-4) inhibitor

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

CARGLUMIC PA

MEDICATION(S)
CARBAGLU, CARGLUMIC ACID

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

OFF LABEL USES
For generic carglumic acid only - Acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA)

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. Patient has a diagnosis of ONE of the following: a. Acute hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS) OR b. Chronic hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS) OR c. Acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA) AND 2. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., geneticist, nephrologist, metabolic disorders) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

CAYSTON PA

MEDICATION(S)
CAYSTON

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require ALL of the following: 1. Patient has a diagnosis of cystic fibrosis AND 2. Documentation has been provided that indicates the patient has a Pseudomonas aeruginosa respiratory infection AND 3. ONE of the following: a. Patient is NOT currently (within the past 60 days) being treated with another inhaled antibiotic (e.g., inhaled tobramycin) OR b. Patient is currently (within the past 60 days) being treated with another inhaled antibiotic (e.g., inhaled tobramycin) AND ONE of the following: i. Prescriber has confirmed that the other inhaled antibiotic will be discontinued, and that therapy will be continued only with the requested agent OR ii. Prescriber has provided information in support of another inhaled antibiotic therapy used concurrently with or alternating with (i.e., continuous alternating therapy) the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

CHENODAL PA

MEDICATION(S)
CHENODAL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. Patient has a diagnosis of radiolucent stones in a well-opacifying gallbladder AND 2. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

CHORIONIC GONADOTROPIN PA

MEDICATION(S)
CHORIONIC GONADOTROPIN, PREGNYL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Requested agent will be used to promote fertility AND requested agent will be used to treat erectile dysfunction AND FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. ONE of the following: A. Patient has a diagnosis of prepubertal cryptorchidism not due to anatomic obstruction OR B. Patient’s sex is male, with a diagnosis of hypogonadotropic hypogonadism (hypogonadism secondary to pituitary deficiency) AND BOTH of the following: i. Patient has a measured current or pretreatment total serum testosterone level that is below the testing laboratory’s lower limit of the normal range or is less than 300 ng/dL OR a free serum testosterone level that is below the testing laboratory’s lower limit of the normal range AND ii. Patient has measured luteinizing hormone (LH) AND follicle-stimulating hormone (FSH) levels that are at (low-normal) or below the testing laboratory’s normal range OR C. Patient has an indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

CINACALCET PA

MEDICATION(S)
CINACALCET HCL, SENSIPAR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has ONE of the following: A. A diagnosis of hypercalcemia due to parathyroid carcinoma OR B. A diagnosis of primary hyperparathyroidism (HPT) AND BOTH of the following: i. Patient has a pretreatment serum calcium level that is above the testing laboratory's upper limit of normal AND ii. Patient is unable to undergo parathyroidectomy OR C. Another indication that is FDA approved or supported in CMS approved compendia for the requested agent not otherwise excluded from Part D [i.e., secondary hyperparathyroidism due to end-stage renal disease (ESRD) on dialysis]

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

COLONY STIMULATING FACTORS PA - FULPHILA

MEDICATION(S)
FULPHILA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., oncologist, hematologist, infectious disease) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION
Approval will be for 6 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

COLONY STIMULATING FACTORS PA - GRANIX

MEDICATION(S)
GRANIX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., oncologist, hematologist, infectious disease) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION
Approval will be for 6 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

COLONY STIMULATING FACTORS PA - LEUKINE

MEDICATION(S)
LEUKINE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., oncologist, hematologist, infectious disease) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION
Approval will be for 6 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

COLONY STIMULATING FACTORS PA - NIVESTYM

MEDICATION(S)
NIVESTYM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., oncologist, hematologist, infectious disease) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION
Approval will be for 6 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

COLONY STIMULATING FACTORS PA - UDENYCA

MEDICATION(S)
UDENYCA, UDENYCA AUTOINJECTOR, UDENYCA ONBODY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., oncologist, hematologist, infectious disease) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION
Approval will be for 6 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

COLONY STIMULATING FACTORS PA - ZIEXTENZO

MEDICATION(S)
ZIEXTENZO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., oncologist, hematologist, infectious disease) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION
Approval will be for 6 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

CORLANOR PA

MEDICATION(S)
CORLANOR, IVABRADINE HCL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. Patient has stable, symptomatic chronic heart failure (e.g., NYHA Class II, III, IV: ACCF/AHA Class C, D) AND 2. ONE of following: A. ALL of the following: i. The requested agent is for a pediatric patient, 6 months of age or over AND ii. Patient has heart failure due to dilated cardiomyopathy (DCM) AND iii. Patient is in sinus rhythm with an elevated heart rate OR B. ALL of the following: i. The requested agent is for an adult patient AND ii. Patient has a baseline OR current left ventricular ejection fraction of 35% or less AND iii. Patient is in sinus rhythm with a resting heart rate of 70 beats or greater per minute prior to initiating therapy with the requested agent AND iv. ONE of the following: a. Patient is on a maximally tolerated dose of beta blocker (e.g., bisoprolol, carvedilol, metoprolol) OR b. Patient has an intolerance, FDA labeled contraindications, or hypersensitivity to a beta blocker

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

CRESEMBA PA

MEDICATION(S)
CRESEMBA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require the following: 1. ONE of the following: A. Patient has a diagnosis of invasive aspergillosis OR B. Patient has a diagnosis of invasive mucormycosis OR C. Patient has another indication that is supported in CMS approved compendia for the requested agent Criteria for renewal approval require BOTH of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. ONE of the following: A. Patient has a diagnosis of invasive aspergillosis and patient has continued indicators of active disease (e.g., continued radiologic findings, direct microscopy findings, histopathology findings, positive cultures, positive serum galactomannan assay) OR B. Patient has a diagnosis of invasive mucormycosis and patient has continued indicators of active disease (e.g., continued radiologic findings, direct microscopy findings, histopathology findings, positive cultures, positive serum galactomannan assay) OR C. BOTH of the following: i. Patient has another indication that is supported in CMS approved compendia for the requested agent AND ii. Patient has had clinical benefit with the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 6 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

CRYSVITA PA

MEDICATION(S)
CRYSVITA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require BOTH of the following: 1. ONE of the following: A. BOTH of the following: i. Patient has a diagnosis of X-linked hypophosphatemia (XLH) as confirmed by ONE of the following: a. Genetic testing OR b. Elevated levels of intact fibroblast growth factor 23 (FGF23) OR c. Prescriber has provided information indicating the patient has a positive family history of XLH AND ii. ONE of the following: a. Patient's epiphyseal plate has not fused OR b. Patient's epiphyseal plate has fused AND the patient is experiencing symptoms of XLH (e.g., bone pain, fractures, limited mobility) OR B. Patient has a diagnosis of tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors AND BOTH of the following: i. The requested agent is being used to treat FGF23 related hypophosphatemia AND ii. The tumor cannot be curatively surgically resected or localized AND 2. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. ONE of the following: A. Patient has a diagnosis of X-linked hypophosphatemia (XLH) OR B. Patient has a diagnosis of tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors AND 3. Patient has had clinical benefit with the requested agent (e.g., enhanced height velocity, improvement in lower extremity bowing and associated abnormalities, radiographic evidence of epiphyseal healing, improvement in bone pain, enhanced mobility, improvement in osteomalacia, improvement in fracture healing) AND 4. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
Patient is within the FDA labeled age for the requested agent for the requested indication

PRESCRIBER RESTRICTION

Prescriber is a specialist in the area of the patient’s diagnosis (e.g., nephrologist, endocrinologist) or the prescriber has consulted with a specialist in the area of the patient’s diagnosis

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

CYSTADROPS PA

MEDICATION(S)
CYSTADROPS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has an FDA labeled indication for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., ophthalmologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

CYSTARAN PA

MEDICATION(S)
CYSTARAN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has an FDA labeled indication for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., ophthalmologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

CYSTINOSIS AGENTS PA - CYSTAGON

MEDICATION(S)
CYSTAGON

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of nephropathic cystinosis AND 2. Prescriber has performed a baseline white blood cell (WBC) cystine level test AND 3. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of nephropathic cystinosis AND 3. Patient has had clinical benefit with the requested agent (e.g., decrease in WBC cystine levels from baseline) AND 4. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

DALFAMPRIDINE PA

MEDICATION(S)
AMPYRA, DALFAMPRIDINE ER

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require BOTH of the following: 1. Patient has a diagnosis of multiple sclerosis (MS) AND 2. ONE of the following: A. The requested agent will be used in combination with a disease modifying agent [e.g., dimethyl fumarate, glatiramer (e.g., Copaxone)] OR B. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a disease modifying agent OR C. Prescriber has provided information indicating that a disease modifying agent is not clinically appropriate for the patient Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of multiple sclerosis (MS) AND 3. ONE of the following: A. The requested agent will be used in combination with a disease modifying agent [e.g., dimethyl fumarate, glatiramer (e.g., Copaxone)] OR B. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a disease modifying agent OR C. Prescriber has provided information indicating that a disease modifying agent is not clinically appropriate for the patient AND 4. Patient has had improvements or stabilization from baseline in timed walking speed (timed 25-foot walk)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION
Initial approval will be for 3 months, renewal approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

DAYVIGO PA

MEDICATION(S)
DAYVIGO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has an FDA labeled indication for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

DROXIDOPA PA

MEDICATION(S)
DROXIDOPA, NORTHERA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of neurogenic orthostatic hypotension (nOH) AND 2. Prescriber has performed baseline blood pressure readings while the patient is sitting or supine (lying face up), AND also within three minutes of standing from a supine position AND 3. Patient has a decrease of at least 20 mmHg in systolic blood pressure or 10 mmHg diastolic blood pressure within three minutes after standing AND 4. Patient has persistent and consistent symptoms of neurogenic orthostatic hypotension (nOH) caused by ONE of the following: A. Primary autonomic failure [Parkinson's disease (PD), multiple system atrophy, or pure autonomic failure] OR B. Dopamine beta-hydroxylase deficiency OR C. Non-diabetic autonomic neuropathy AND 5. Prescriber has assessed the severity of the patient's baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out AND 6. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of neurogenic orthostatic hypotension (nOH) AND 3. Patient has had improvements or stabilization with the requested agent as indicated by improvement in severity from baseline symptoms of ONE of the following: A. Dizziness B. Lightheadedness C. Feeling faint D. Feeling like the patient may black out AND 4. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, neurologist) or the

prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION

Approval will be 1 month for initial, 3 months for renewal

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

DUPIXENT PA

MEDICATION(S)
DUPIXENT PEN, DUPIXENT SYRINGE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require BOTH of the following: 1. ONE of the following: A. Patient has a diagnosis of moderate-to-severe atopic dermatitis AND ALL of the following: i. ONE of the following: a. Patient has tried and failed a topical steroid (e.g., triamcinolone) OR b. Patient has an intolerance, hypersensitivity, or an FDA labeled contraindication to a topical steroid AND ii. For patients 2 years of age or over, ONE of the following: a. Patient has tried and failed a topical calcineurin inhibitor (e.g., tacrolimus) OR b. Patient has an intolerance, hypersensitivity, or an FDA labeled contraindication to a topical calcineurin inhibitor AND iii. Patient will NOT be using the requested agent in combination with another biologic agent or a JAK inhibitor for the requested indication OR B. Patient has a diagnosis of moderate-to-severe asthma with an eosinophilic phenotype or oral corticosteroid dependent asthma AND BOTH of the following: i. Patient is currently being treated with AND will continue asthma control therapy (e.g., ICS, ICS/LABA, LRTA, LAMA, theophylline) in combination with the requested agent AND ii. Patient will NOT be using the requested agent in combination with Xolair or with an injectable interleukin 5 (IL-5) inhibitor (e.g., Cinqair, Fasenra, Nucala) for the requested indication OR C. Patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND the following: i. BOTH of the following: a. ONE of the following: 1. Patient has tried and had an inadequate response to an oral systemic corticosteroid AND an intranasal corticosteroid (e.g., fluticasone) OR 2. Patient has an intolerance, hypersensitivity, or an FDA labeled contraindication to an oral systemic corticosteroid AND an intranasal corticosteroid AND Initial criteria continues: see Other Criteria

AGE RESTRICTION
For diagnosis of moderate-to-severe atopic dermatitis, patient is 6 months of age or over. For diagnosis of moderate-to-severe asthma with an eosinophilic phenotype or oral corticosteroid dependent asthma, patient is 6 years of age or over. For diagnosis of CRSwNP, patient is 18 years of age or over. For

diagnosis of EoE, patient is 1 year of age or over. For diagnosis of PN, patient is 18 years of age or over.

PRESCRIBER RESTRICTION

Prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, dermatologist, immunologist, gastroenterologist, otolaryngologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

b. Patient will continue standard maintenance therapy (e.g., intranasal corticosteroid) in combination with the requested agent OR D. Patient has a diagnosis of eosinophilic esophagitis (EoE) confirmed by esophageal biopsy OR E. Patient has a diagnosis of prurigo nodularis (PN) AND 2. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. ONE of the following: A. Patient has a diagnosis of moderate-to-severe atopic dermatitis AND the following: i. Patient will NOT be using the requested agent in combination with another biologic agent or a JAK inhibitor for the requested indication OR B. Patient has a diagnosis of moderate-to-severe asthma with an eosinophilic phenotype or oral corticosteroid dependent asthma AND BOTH of the following: i. Patient is currently being treated with AND will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent AND ii. Patient will NOT be using the requested agent in combination with Xolair or with an injectable interleukin 5 (IL-5) inhibitor (e.g., Cinqair, Fasenra, Nucala) for the requested indication OR C. Patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND the following: i. Patient will continue standard maintenance therapy (e.g., intranasal corticosteroid) in combination with the requested agent OR D. Patient has a diagnosis of eosinophilic esophagitis (EoE) OR E. Patient has a diagnosis of prurigo nodularis (PN) AND 3. Patient has had clinical benefit with the requested agent AND 4. The requested dose is within FDA labeled dosing for the requested indication

PART B PREREQUISITE

N/A

EMGALITY PA

MEDICATION(S)
EMGALITY PEN, EMGALITY SYRINGE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require the following: 1. ONE of the following: A. Patient has a diagnosis of migraine AND ALL of the following: i. The requested agent is being used for migraine prophylaxis AND ii. Patient has 4 or more migraine headache days per month AND iii. Patient will NOT be using the requested agent in combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis OR B. Patient has a diagnosis of episodic cluster headache AND BOTH of the following: i. Patient has had at least 5 cluster headache attacks AND ii. Patient has had at least two cluster periods lasting 7 days to one year and separated by pain-free remission periods of 3 months or more Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. ONE of the following: A. ALL of the following: i. Patient has a diagnosis of migraine AND ii. The requested agent is being used for migraine prophylaxis AND iii. Patient will NOT be using the requested agent in combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis OR B. Patient has a diagnosis of episodic cluster headache AND 3. Patient has had clinical benefit with the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

EMSAM PA

MEDICATION(S)
EMSAM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require BOTH of the following: 1. ONE of the following: A. Patient has a diagnosis of major depressive disorder (MDD) OR B. Patient has an indication that is supported in CMS approved compendia for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR B. Prescriber states the patient is currently being treated with the requested agent OR C. BOTH of the following: i. ONE of the following: a. BOTH of the following: i. Patient has a diagnosis of major depressive disorder (MDD) AND ii. ONE of the following: 1. Patient has tried and had an inadequate response to at least two different oral antidepressants (e.g., SSRIs, SNRIs, mirtazapine, bupropion) OR 2. Patient has an intolerance or hypersensitivity to at least two different oral antidepressants (e.g., SSRIs, SNRIs, mirtazapine, bupropion) OR 3. Patient has an FDA labeled contraindication to at least two different oral antidepressants (e.g., SSRIs, SNRIs, mirtazapine, bupropion) OR b. Patient has an indication that is supported in CMS approved compendia for the requested agent AND ii. Patient does NOT have any FDA labeled contraindications to the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA

Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. ONE of the following: A. Patient has a diagnosis of major depressive disorder (MDD) OR B. Patient has an indication that is supported in CMS approved compendia for the requested agent AND 3. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR B. Prescriber states the patient is currently being treated with the requested agent OR C. BOTH of the following: i. Patient has had clinical benefit with the requested agent AND ii. Patient does NOT have any FDA labeled contraindications to the requested agent

PART B PREREQUISITE

N/A

ENDARI PA

MEDICATION(S)
ENDARI, L-GLUTAMINE 5 GRAM POWDER PKT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of sickle cell disease AND 2. Patient is using the requested agent to reduce the acute complications of sickle cell disease AND 3. ONE of the following: A. Patient has tried and had an inadequate response to maximally tolerated dose of hydroxyurea OR B. Patient has an intolerance or hypersensitivity to hydroxyurea OR C. Patient has an FDA labeled contraindication to hydroxyurea AND 4. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of sickle cell disease AND 3. Patient is using the requested agent to reduce the acute complications of sickle cell disease AND 4. Patient has had clinical benefit with the requested agent AND 5. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
Patient is within the FDA labeled age for the requested agent

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

EPIDIOLEX PA

MEDICATION(S)
EPIDIOLEX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. Patient has a diagnosis of seizures associated with ONE of the following: A. Lennox-Gastaut syndrome OR B. Dravet syndrome OR C. Tuberous sclerosis complex AND 2. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
Patient is within the FDA labeled age for the requested agent

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ERYTHROPOIETIN STIMULATING AGENTS PA - ARANESP

MEDICATION(S)

ARANESP 10 MCG/0.4 ML SYRINGE, ARANESP 100 MCG/0.5 ML SYRINGE, ARANESP 100 MCG/ML VIAL, ARANESP 150 MCG/0.3 ML SYRINGE, ARANESP 200 MCG/0.4 ML SYRINGE, ARANESP 200 MCG/ML VIAL, ARANESP 25 MCG/0.42 ML SYRING, ARANESP 25 MCG/ML VIAL, ARANESP 300 MCG/0.6 ML SYRINGE, ARANESP 40 MCG/0.4 ML SYRINGE, ARANESP 40 MCG/ML VIAL, ARANESP 500 MCG/1 ML SYRINGE, ARANESP 60 MCG/0.3 ML SYRINGE, ARANESP 60 MCG/ML VIAL

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION

Criteria for approval require BOTH of the following: 1. The requested agent is being prescribed for ONE of the following: A. Anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy AND ALL of the following: i. Patient's hemoglobin level is less than 10 g/dL for patients initiating ESA therapy OR less than 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) AND ii. Patient is being concurrently treated with chemotherapy with or without radiation (there must be a minimum of 2 additional months of planned chemotherapy) AND iii. The intent of chemotherapy is non-curative OR B. Anemia associated with chronic kidney disease in a patient NOT on dialysis AND ALL of the following: i. Patient's hemoglobin level is less than 10 g/dL for patients initiating ESA therapy OR 11 g/dL or less for patients stabilized on therapy (measured within the previous 4 weeks) AND ii. The rate of hemoglobin decline indicates the likelihood of requiring a RBC transfusion AND iii. The intent of therapy is to reduce the risk of alloimmunization and/or other RBC transfusion related risks OR C. Anemia due to myelodysplastic syndrome AND the patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy OR less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) OR D. Another indication that is supported in CMS approved compendia for the requested agent AND the patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy OR less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) AND 2. Patient's transferrin saturation and serum ferritin have been

evaluated Drug is also subject to Part B versus Part D review.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

6 months for chemotherapy, 12 months for other indications

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ERYTHROPOIETIN STIMULATING AGENTS PA - EPOGEN/PROCRIT

MEDICATION(S)
PROCRIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. The requested agent is being prescribed for ONE of the following: A. To reduce the possibility of allogeneic blood transfusion in a surgery patient AND the patient's hemoglobin level is greater than 10 g/dL but less than or equal to 13 g/dL OR B. Anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy AND ALL of the following: i. Patient's hemoglobin level is less than 10 g/dL for patients initiating ESA therapy OR less than 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) AND ii. Patient is being concurrently treated with chemotherapy with or without radiation (there must be a minimum of 2 additional months of planned chemotherapy) AND iii. The intent of chemotherapy is non-curative OR C. Anemia associated with chronic kidney disease in a patient NOT on dialysis AND ALL of the following: i. Patient's hemoglobin level is less than 10 g/dL for patients initiating ESA therapy OR 11 g/dL or less for patients stabilized on therapy (measured within the previous 4 weeks) AND ii. The rate of hemoglobin decline indicates the likelihood of requiring a RBC transfusion AND iii. The intent of therapy is to reduce the risk of alloimmunization and/or other RBC transfusion related risks OR D. Anemia due to myelodysplastic syndrome AND the patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy OR less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) OR E. Anemia resulting from zidovudine treatment of HIV infection AND the patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy OR less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) OR Initial criteria continues: see Other Criteria

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 month for surgery (reduce transfusion possibility), 6 months for chemo, 12 months for other

OTHER CRITERIA

F. Another indication that is supported in CMS approved compendia for the requested agent AND the patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy OR less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) AND 2. Patient's transferrin saturation and serum ferritin have been evaluated Drug is also subject to Part B versus Part D review.

PART B PREREQUISITE

N/A

ERYTHROPOIETIN STIMULATING AGENTS PA - RETACRIT

MEDICATION(S)
RETACRIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. The requested agent is being prescribed for ONE of the following: A. To reduce the possibility of allogeneic blood transfusion in a surgery patient AND the patient's hemoglobin level is greater than 10 g/dL but less than or equal to 13 g/dL OR B. Anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy AND ALL of the following: i. Patient's hemoglobin level is less than 10 g/dL for patients initiating ESA therapy OR less than 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) AND ii. Patient is being concurrently treated with chemotherapy with or without radiation (there must be a minimum of 2 additional months of planned chemotherapy) AND iii. The intent of chemotherapy is non-curative OR C. Anemia associated with chronic kidney disease in a patient NOT on dialysis AND ALL of the following: i. Patient's hemoglobin level is less than 10 g/dL for patients initiating ESA therapy OR 11 g/dL or less for patients stabilized on therapy (measured within the previous 4 weeks) AND ii. The rate of hemoglobin decline indicates the likelihood of requiring a RBC transfusion AND iii. The intent of therapy is to reduce the risk of alloimmunization and/or other RBC transfusion related risks OR D. Anemia resulting from zidovudine treatment of HIV infection AND the patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy OR less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) OR E. Another indication that is supported in CMS approved compendia for the requested agent AND the patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy OR less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) AND 2. Patient's transferrin saturation and serum ferritin have been evaluated Drug is also subject to Part B versus Part D review.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1 month for surgery (reduce transfusion possibility), 6 months for chemo, 12 months for other

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

EYSUVIS PA

MEDICATION(S)
EYSUVIS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require ALL of the following: 1. Patient has a diagnosis of dry eye disease AND 2. The requested agent will be used for short-term (up to two weeks) treatment AND 3. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 1 month

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

FASENRA PA

MEDICATION(S)
FASENRA, FASENRA PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of severe asthma with an eosinophilic phenotype AND 2. Patient is currently being treated with AND will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent AND 3. Patient will NOT be using the requested agent in combination with Xolair, Dupixent, or with another injectable interleukin 5 (IL-5) inhibitor (e.g., Cinqair, Nucala) for the requested indication AND 4. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of severe asthma with an eosinophilic phenotype AND 3. Patient has had clinical benefit with the requested agent AND 4. Patient is currently being treated with AND will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent AND 5. Patient will NOT be using the requested agent in combination with Xolair, Dupixent, or with another injectable interleukin 5 (IL-5) inhibitor (e.g., Cinqair, Nucala) for the requested indication AND 6. The requested dose is within the FDA labeled dosing for the requested indication

AGE RESTRICTION
Patient is 6 years of age or over

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

FENTANYL ORAL PA - FENTANYL LOZENGE

MEDICATION(S)
FENTANYL CIT OTFC 1,200 MCG, FENTANYL CIT OTFC 1,600 MCG, FENTANYL CITRATE OTFC 200 MCG, FENTANYL CITRATE OTFC 400 MCG, FENTANYL CITRATE OTFC 600 MCG, FENTANYL CITRATE OTFC 800 MCG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. ONE of the following: a. Patient has a documented diagnosis (i.e., medical records) of chronic cancer pain due to an active malignancy AND BOTH of the following: i. Prescriber has provided the patient's type of cancer AND ii. There is evidence of a claim that the patient is currently being treated with a long-acting opioid with the requested agent within the past 90 days OR b. Patient has a diagnosis that is supported in CMS approved compendia for the requested agent AND 2. Patient will NOT be using the requested agent in combination with any other oral or nasal fentanyl agent

AGE RESTRICTION
Patient is 16 years of age or over

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

FINTEPLA PA

MEDICATION(S)
FINTEPLA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. Patient has a diagnosis of seizures associated with Dravet syndrome (DS) or Lennox-Gastaut syndrome (LGS) AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR B. Prescriber states the patient is currently being treated with the requested agent OR C. ALL of the following: i. An echocardiogram assessment will be obtained before and during treatment with the requested agent, to evaluate for valvular heart disease and pulmonary arterial hypertension AND ii. Prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND iii. Patient does NOT have any FDA labeled contraindications to the requested agent

AGE RESTRICTION
Patient is within the FDA labeled age for the requested agent

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

FLUCYTOSINE PA

MEDICATION(S)
FLUCYTOSINE 250 MG CAPSULE, FLUCYTOSINE 500 MG CAPSULE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require ALL of the following: 1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND 2. ONE of the following: A. The requested agent will be used in combination with amphotericin B OR B. Prescriber has provided information in support of therapy without concurrent amphotericin B for the requested indication AND 3. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., infectious disease) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION
Approval will be for 10 weeks

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

FOCALIN PA

MEDICATION(S)
DEXMETHYLPHENIDATE HCL, FOCALIN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has an FDA labeled indication for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

GAMMAGARD/GAMMAKED/GAMUNEX-C PA

MEDICATION(S)
GAMMAGARD LIQUID, GAMMAGARD S-D, GAMUNEX-C

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require ONE of the following: 1. Patient has ONE of the following diagnoses: A. Primary immunodeficiency [e.g., congenital agammaglobulinemia, common variable immunodeficiency (CVID), severe combined immunodeficiency, Wiskott-Aldrich Syndrome, X-linked agammaglobulinemia (XLA), humoral immunodeficiency, IgG subclass deficiency with or without IgA deficiency] OR B. B-cell chronic lymphocytic leukemia OR multiple myeloma AND ONE of the following: i. Patient has a history of infections OR ii. Patient has evidence of specific antibody deficiency OR iii. Patient has hypogammaglobulinemia OR C. Idiopathic thrombocytopenia purpura AND ONE of the following: i. Patient has failed ONE conventional therapy [e.g., corticosteroids (e.g., methylprednisolone), or immunosuppressants (e.g., azathioprine)] OR ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR D. Dermatomyositis AND ONE of the following: i. Patient has failed ONE conventional therapy [e.g., corticosteroids (e.g., methylprednisolone) or immunosuppressants (e.g., azathioprine)] OR ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR E. Polymyositis AND ONE of the following: i. Patient has failed ONE conventional therapy [e.g., corticosteroids (e.g., methylprednisolone) or immunosuppressants (e.g., azathioprine)] OR ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR F. Severe rheumatoid arthritis AND ONE of the following: i. Patient has failed ONE conventional therapy [e.g., tumor necrosis factor antagonists (e.g., Enbrel), DMARDS (e.g., methotrexate)] OR ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR Criteria continues: see Other Criteria

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 6 months for indications in Other Criteria, 12 months for all others

OTHER CRITERIA

G. Myasthenia gravis (MG) AND ONE of the following: i. Patient is in acute myasthenic crisis OR ii. Patient has severe refractory MG (e.g., major functional disability/weakness) AND ONE of the following: a) Patient has failed ONE immunomodulator therapy (i.e., corticosteroid, pyridostigmine, or azathioprine) OR b) Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE immunomodulator therapy OR H. Multiple sclerosis (MS) AND BOTH of the following: i. Patient has a diagnosis of relapsing remitting MS (RRMS) AND ii. Patient has had an insufficient response, documented failure, or FDA labeled contraindication to TWO MS agents (e.g., Avonex, Betaseron, Copaxone, dimethyl fumarate, fingolimod, glatiramer, Glatopa, Kesimpta, Plegridy, Vumerity) OR I. Acquired von Willebrand hemophilia AND ONE of the following: i. Patient has failed ONE conventional therapy (e.g., desmopressin, von Willebrand factor replacement therapy, corticosteroids, cyclophosphamide, FEIBA, or recombinant factor VIIa) OR ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR J. Refractory pemphigus vulgaris AND ONE of the following: i. Patient has failed ONE conventional immunosuppressive therapy (e.g., azathioprine, cyclophosphamide, mycophenolate, corticosteroids) OR ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional immunosuppressive therapy OR 2. ONE of the following: A. Patient has another FDA labeled indication for the requested agent OR B. Patient has an indication that is supported in CMS approved compendia for the requested agent Indications with 6 months approval duration: Acquired von Willebrand hemophilia, Guillain-Barre Syndrome, Lambert-Eaton myasthenia syndrome, Kawasaki disease, CMV induced pneumonitis in solid organ transplant, Toxic shock syndrome due to invasive group A streptococcus, Toxic epidermal necrolysis and Stevens-Johnson syndrome Drug is also subject to Part B versus Part D review.

PART B PREREQUISITE

N/A

GATTEX PA

MEDICATION(S)
GATTEX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of short bowel syndrome (SBS) AND 2. Patient is dependent on parenteral nutrition OR intravenous (PN/IV) fluids AND 3. ONE of the following: A. Patient is aged 1 year to 17 years AND BOTH of the following: i. A fecal occult blood test has been performed within 6 months prior to initiating treatment with the requested agent AND ii. ONE of the following: a. There was no unexplained blood in the stool OR b. There was unexplained blood in the stool AND a colonoscopy or a sigmoidoscopy was performed OR B. Patient is 18 years of age or over AND BOTH of the following: i. Patient has had a colonoscopy within 6 months prior to initiating treatment with the requested agent AND ii. If polyps were present at this colonoscopy, the polyps were removed AND 4. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of short bowel syndrome (SBS) AND 3. Patient has had a reduction from baseline in parenteral nutrition OR intravenous (PN/IV) fluids AND 4. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION

Approval will be 6 months for initial, 12 months for renewal

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

GAUCHER ENZYME REPLACEMENT PA - CEREZYME

MEDICATION(S)
CEREZYME

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of Gaucher disease type 1 (GD1) confirmed by ONE of the following: A. A baseline (prior to therapy for the requested indication) glucocerebrosidase enzyme activity of less than or equal to 15% of mean normal in peripheral blood leukocytes, fibroblasts, or other nucleated cells OR B. Confirmation of genetic mutation of glucocerebrosidase (GBA) gene with two disease-causing alleles AND 2. Prescriber has drawn baseline (prior to therapy for the requested indication) measurements of hemoglobin, platelet count, liver volume, and spleen volume AND 3. Prior to any treatment for the intended diagnosis, the patient has had at least ONE of the following clinical presentations: A. Anemia [defined as mean hemoglobin (Hb) level below the testing laboratory's lower limit of the normal range based on age and gender] OR B. Thrombocytopenia (defined as a platelet count of less than 100,000 per microliter) OR C. Hepatomegaly OR D. Splenomegaly OR E. Growth failure (i.e., growth velocity below the standard mean for age) OR F. Evidence of bone disease with other causes ruled out AND 4. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of Gaucher disease type 1 (GD1) AND 3. Patient has had improvement and/or stabilization from baseline (prior to therapy for the requested indication) in at least ONE of the following: A. Hemoglobin (Hb) level OR B. Platelet count OR C. Liver volume OR D. Spleen volume OR E. Growth velocity OR F. Bone pain or disease AND 4. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

Prescriber is a specialist in the area of the patient’s diagnosis (e.g., endocrinologist, geneticist, hematologist, specialist in metabolic diseases) or the prescriber has consulted with a specialist in the area of the patient’s diagnosis

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

GAUCHER ENZYME REPLACEMENT PA - ELELYSO

MEDICATION(S)
ELELYSO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of Gaucher disease type 1 (GD1) confirmed by ONE of the following: A. A baseline (prior to therapy for the requested indication) glucocerebrosidase enzyme activity of less than or equal to 15% of mean normal in peripheral blood leukocytes, fibroblasts, or other nucleated cells OR B. Confirmation of genetic mutation of glucocerebrosidase (GBA) gene with two disease-causing alleles AND 2. Prescriber has drawn baseline (prior to therapy for the requested indication) measurements of hemoglobin, platelet count, liver volume, and spleen volume AND 3. Prior to any treatment for the intended diagnosis, the patient has had at least ONE of the following clinical presentations: A. Anemia [defined as mean hemoglobin (Hb) level below the testing laboratory's lower limit of the normal range based on age and gender] OR B. Thrombocytopenia (defined as a platelet count of less than 100,000 per microliter) OR C. Hepatomegaly OR D. Splenomegaly OR E. Growth failure (i.e., growth velocity below the standard mean for age) OR F. Evidence of bone disease with other causes ruled out AND 4. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of Gaucher disease type 1 (GD1) AND 3. Patient has had improvement and/or stabilization from baseline (prior to therapy for the requested indication) in at least ONE of the following: A. Hemoglobin (Hb) level OR B. Platelet count OR C. Liver volume OR D. Spleen volume OR E. Growth velocity OR F. Bone pain or disease AND 4. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

Prescriber is a specialist in the area of the patient’s diagnosis (e.g., endocrinologist, geneticist, hematologist, specialist in metabolic diseases) or the prescriber has consulted with a specialist in the area of the patient’s diagnosis

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

GAUCHER ENZYME REPLACEMENT PA - VPRIV

MEDICATION(S)
VPRIV

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of Gaucher disease type 1 (GD1) confirmed by ONE of the following: A. A baseline (prior to therapy for the requested indication) glucocerebrosidase enzyme activity of less than or equal to 15% of mean normal in peripheral blood leukocytes, fibroblasts, or other nucleated cells OR B. Confirmation of genetic mutation of glucocerebrosidase (GBA) gene with two disease-causing alleles AND 2. Prescriber has drawn baseline (prior to therapy for the requested indication) measurements of hemoglobin, platelet count, liver volume, and spleen volume AND 3. Prior to any treatment for the intended diagnosis, the patient has had at least ONE of the following clinical presentations: A. Anemia [defined as mean hemoglobin (Hb) level below the testing laboratory's lower limit of the normal range based on age and gender] OR B. Thrombocytopenia (defined as a platelet count of less than 100,000 per microliter) OR C. Hepatomegaly OR D. Splenomegaly OR E. Growth failure (i.e., growth velocity below the standard mean for age) OR F. Evidence of bone disease with other causes ruled out AND 4. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of Gaucher disease type 1 (GD1) AND 3. Patient has had improvement and/or stabilization from baseline (prior to therapy for the requested indication) in at least ONE of the following: A. Hemoglobin (Hb) level OR B. Platelet count OR C. Liver volume OR D. Spleen volume OR E. Growth velocity OR F. Bone pain or disease AND 4. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

Prescriber is a specialist in the area of the patient’s diagnosis (e.g., endocrinologist, geneticist, hematologist, specialist in metabolic diseases) or the prescriber has consulted with a specialist in the area of the patient’s diagnosis

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

GAUZE PADS PA

MEDICATION(S)
GAUZE PADS & DRESSINGS - PADS 2 X 2

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
This program will be implemented as a dynamic PA. Criteria for approval require BOTH of the following: 1. The requested medical supply product will be used in the delivery of insulin to the body AND 2. Patient's medication history includes use of insulin within the past 180 days

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

GROWTH HORMONE PA - OMNITROPE

MEDICATION(S)
OMNITROPE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
For Children - Criteria for initial approval require the following: 1. ONE of the following: A. Patient has a diagnosis of Turner Syndrome OR B. Patient has a diagnosis of Prader-Willi Syndrome OR C. Patient has a diagnosis of panhypopituitarism AND BOTH of the following: i. Deficiencies in 3 or more pituitary axes AND ii. Measured serum IGF-1 (insulin-like growth factor-1) levels are below the age and sex-appropriate reference range when off GH therapy OR D. Patient has a diagnosis of growth hormone deficiency (GHD) or short stature AND BOTH of the following: i. Patient has ONE of the following: a. Height more than 2 standard deviations (SD) below the mean for age and sex OR b. Height more than 1.5 SD below the midparental height OR c. A decrease in height SD of more than 0.5 over one year in children at least 2 years of age OR d. Height velocity more than 2 SD below the mean over one year or more than 1.5 SD sustained over two years AND ii. Failure of at least 2 growth hormone (GH) stimulation tests (e.g., peak GH value of less than 10 mcg/L after stimulation, or otherwise considered abnormal as determined by testing lab) OR E. Patient has a diagnosis of small for gestational age (SGA) AND ALL of the following: i. Patient is at least 2 years of age AND ii. Documented birth weight and/or length that is 2 or more SD below the mean for gestational age AND iii. At 24 months of age, the patient fails to manifest catch-up growth evidenced by a height that remains 2 or more SD below the mean for age and sex

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

For Children - Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the preferred agent through the plan's Prior Authorization criteria AND 2. Patient has been diagnosed with ONE of the following: A. Growth Hormone Deficiency, Short Stature OR B. Panhypopituitarism OR C. Prader-Willi Syndrome OR D. Small for Gestational Age (SGA) OR E. Turner Syndrome AND 3. ALL of the following: A. Patient does NOT have closed epiphyses AND B. Patient is being monitored for adverse effects of therapy with the requested agent AND C. Patient's height has increased or height velocity has improved since initiation or last approval of the requested agent For Adults - Criteria for initial approval require the following: 1. Patient has been diagnosed with ONE of the following: A. Childhood growth hormone deficiency (GHD) with genetic or organic origin AND ONE of the following: i. Low IGF-1 (insulin-like growth factor-1) level without GH replacement therapy OR ii. Failure of at least one growth hormone (GH) stimulation test as an adult (e.g., peak GH value of 5 mcg/L or lower after stimulation, or otherwise considered abnormal as determined by testing lab) OR B. Acquired adult GHD secondary to structural lesions or trauma AND ONE of the following: i. Patient has a diagnosis of panhypopituitarism AND BOTH of the following: a. Deficiencies in 3 or more pituitary axes AND b. Low IGF-1 level without GH replacement therapy OR ii. Patient has failed at least one growth hormone (GH) stimulation test as an adult OR C. Idiopathic GHD (adult or childhood onset) AND the patient has failed at least two growth hormone (GH) stimulation tests as an adult For Adults - Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the preferred agent through the plan's Prior Authorization criteria AND 2. Patient has been diagnosed with ONE of the following: A. Childhood growth hormone deficiency (GHD) with genetic or organic origin OR B. Acquired adult GHD secondary to structural lesions or trauma OR C. Idiopathic GHD (adult or childhood onset) AND 3. Patient is being monitored for adverse effects of therapy with the requested agent AND 4. Patient's IGF-1 level has been evaluated to confirm the appropriateness of the current dose AND 5. Patient has had clinical benefit with the requested agent (i.e., body composition, hip-to-waist ratio, cardiovascular health, bone mineral density, serum cholesterol, physical strength, or quality of life)

PART B PREREQUISITE

N/A

HAE PA - CINRYZE

MEDICATION(S)
CINRYZE

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

OFF LABEL USES
Acute HAE attacks

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of hereditary angioedema (HAE) which has been confirmed via two confirmatory tests of C1-INH antigenic level, C1-INH functional level, and C4 level as follows: a. Hereditary angioedema (HAE) due to C1INH deficiency [HAE-C1INH (Type I)]: decreased quantities of C4 and C1-INH (antigenic and functional level) OR b. Hereditary angioedema (HAE) due to C1INH deficiency [HAE-C1INH (Type II)]: decreased quantities of C4 and C1-INH function (C1-INH protein level may be normal) OR c. Hereditary angioedema (HAE) with normal C1INH [HAE-nI-C1INH (Type III)]: Normal levels of C4 and C1-INH [antigenic and functional level (at baseline and during an attack)] AND ONE of the following: i. BOTH of the following: 1. Family history of angioedema AND 2. ALL other causes of angioedema have been ruled out OR ii. Patient demonstrates a Factor XII mutation, angiopoietin-1 (ANGPT1) mutation, plasminogen (PLG) mutation, kininogen1 mutation, heparan sulfate 3-O-sulfotransferase 6 gene mutation, or myoferlin gene mutation that is associated with the disease AND 2. Medications known to cause angioedema (e.g., ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate AND 3. ONE of the following: a. The requested agent will be used to treat acute HAE attacks AND the patient will NOT be using the requested agent in combination with another HAE agent indicated for treatment of acute HAE attacks OR b. The requested agent will be used for prophylaxis against HAE attacks AND the patient will NOT be using the requested agent in combination with another HAE agent indicated for prophylaxis against HAE attacks

AGE RESTRICTION
Patient is within the FDA labeled age for the requested agent

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of hereditary angioedema (HAE) AND ONE of the following: a. The requested agent will be used to treat acute HAE attacks AND the patient will NOT be using the requested agent in combination with another HAE agent indicated for treatment of acute HAE attacks OR b. The requested agent will be used for prophylaxis against HAE attacks AND the patient will NOT be using the requested agent in combination with another HAE agent indicated for prophylaxis against HAE attacks AND 3. Patient has had a decrease in the frequency or severity of acute attacks or has had stabilization of disease from use of the requested agent

PART B PREREQUISITE

N/A

HAE PA - HAEGARDA

MEDICATION(S)
HAEGARDA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of hereditary angioedema (HAE) which has been confirmed via two confirmatory tests of C1-INH antigenic level, C1-INH functional level, and C4 level as follows: a. Hereditary angioedema (HAE) due to C1INH deficiency [HAE-C1INH (Type I)]: decreased quantities of C4 and C1-INH (antigenic and functional level) OR b. Hereditary angioedema (HAE) due to C1INH deficiency [HAE-C1INH (Type II)]: decreased quantities of C4 and C1-INH function (C1-INH protein level may be normal) OR c. Hereditary angioedema (HAE) with normal C1INH [HAE-nI-C1INH (Type III)]: Normal levels of C4 and C1-INH [antigenic and functional level (at baseline and during an attack)] AND ONE of the following: i. BOTH of the following: 1. Family history of angioedema AND 2. ALL other causes of angioedema have been ruled out OR ii. Patient demonstrates a Factor XII mutation, angiopoietin-1 (ANGPT1) mutation, plasminogen (PLG) mutation, kininogen1 mutation, heparan sulfate 3-O-sulfotransferase 6 gene mutation, or myoferlin gene mutation that is associated with the disease AND 2. Medications known to cause angioedema (e.g., ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate AND 3. The requested agent will be used for prophylaxis against HAE attacks AND 4. Patient will NOT be using the requested agent in combination with another HAE agent indicated for prophylaxis against HAE attacks

AGE RESTRICTION
Patient is within the FDA labeled age for the requested agent

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of hereditary angioedema (HAE) AND 3. The requested agent is being used for prophylaxis against HAE attacks AND 4. Patient has had a decrease in the frequency or severity of acute attacks or has had stabilization of disease from use of the requested agent AND 5. Patient will NOT be using the requested agent in combination with another HAE agent indicated for prophylaxis against HAE attacks

PART B PREREQUISITE

N/A

HAE PA - ICATIBANT

MEDICATION(S)
FIRAZYR, ICATIBANT, SAJAZIR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of hereditary angioedema (HAE) which has been confirmed via two confirmatory tests of C1-INH antigenic level, C1-INH functional level, and C4 level as follows: a. Hereditary angioedema (HAE) due to C1INH deficiency [HAE-C1INH (Type I)]: decreased quantities of C4 and C1-INH (antigenic and functional level) OR b. Hereditary angioedema (HAE) due to C1INH deficiency [HAE-C1INH (Type II)]: decreased quantities of C4 and C1-INH function (C1-INH protein level may be normal) OR c. Hereditary angioedema (HAE) with normal C1INH [HAE-nI-C1INH (Type III)]: Normal levels of C4 and C1-INH [antigenic and functional level (at baseline and during an attack)] AND ONE of the following: i. BOTH of the following: 1. Family history of angioedema AND 2. ALL other causes of angioedema have been ruled out OR ii. Patient demonstrates a Factor XII mutation, angiopoietin-1 (ANGPT1) mutation, plasminogen (PLG) mutation, kininogen1 mutation, heparan sulfate 3-O-sulfotransferase 6 gene mutation, or myoferlin gene mutation that is associated with the disease AND 2. Medications known to cause angioedema (e.g., ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate AND 3. The requested agent will be used to treat acute HAE attacks AND 4. Patient will NOT be using the requested agent in combination with another HAE agent indicated for treatment of acute HAE attacks

AGE RESTRICTION
Patient is within the FDA labeled age for the requested agent

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of hereditary angioedema (HAE) AND 3. The requested agent will be used to treat acute HAE attacks AND 4. Patient will NOT be using the requested agent in combination with another HAE agent indicated for treatment of acute HAE attacks AND 5. Patient has had a decrease in the frequency or severity of acute attacks or stabilization of disease from use of the requested agent

PART B PREREQUISITE

N/A

HIGH RISK MEDICATION PA - ALL STARTS

MEDICATION(S)

BENZTROPINE MES 0.5 MG TAB, BENZTROPINE MES 1 MG TABLET, BENZTROPINE MES 2 MG TABLET, CLEMASTINE FUM 2.68 MG TABLET, CYPROHEPTADINE 2 MG/5 ML SOLN, CYPROHEPTADINE 2 MG/5 ML SYRUP, CYPROHEPTADINE 4 MG TABLET, CYPROHEPTADINE 4 MG/10 ML SYRP, DICYCLOMINE 10 MG CAPSULE, DICYCLOMINE 10 MG/5 ML SOLN, DICYCLOMINE 20 MG TABLET, DIPHENOXYLATE-ATROP 2.5-0.025, HYDROXYZINE 10 MG/5 ML SOLN, HYDROXYZINE 10 MG/5 ML SYRUP, HYDROXYZINE 50 MG/25 ML CUP, HYDROXYZINE HCL 10 MG TABLET, HYDROXYZINE HCL 25 MG TABLET, HYDROXYZINE HCL 50 MG TABLET, HYDROXYZINE PAMOATE, PROMETHAZINE 12.5 MG SUPPOS, PROMETHAZINE 12.5 MG TABLET, PROMETHAZINE 25 MG SUPPOSITORY, PROMETHAZINE 25 MG TABLET, PROMETHAZINE 50 MG TABLET, PROMETHAZINE 6.25 MG/5 ML CUP, PROMETHAZINE 6.25 MG/5 ML SOLN, PROMETHAZINE 6.25 MG/5 ML SYRP, PROMETHEGAN 12.5 MG SUPPOS, PROMETHEGAN 25 MG SUPPOSITORY, SCOPOLAMINE, TRIHEXYPHENIDYL 2 MG TABLET, TRIHEXYPHENIDYL 5 MG TABLET

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

PA does NOT apply to patients less than 65 years of age. Criteria for approval require ALL of the following: 1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested high-risk medication AND 2. Prescriber has indicated that the benefits of the requested high-risk medication outweigh the risks for the patient AND 3. Prescriber has indicated that the risks and potential side effects of the requested high-risk medication have been discussed with the patient

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

HOFH PA - JUXTAPID

MEDICATION(S)
JUXTAPID 10 MG CAPSULE, JUXTAPID 20 MG CAPSULE, JUXTAPID 30 MG CAPSULE, JUXTAPID 5 MG CAPSULE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) AND 2. Patient's diagnosis was confirmed by ONE of the following: A. Genetic confirmation of bi-allelic pathogenic/likely pathogenic variants on different chromosomes at the LDLR, Apo-B, PCSK9, or LDLRAP1 genes or greater than or equal to 2 such variants at different loci OR B. History of untreated LDL-C greater than 400 mg/dL (greater than 10 mmol/L) AND ONE of the following: i. Patient has cutaneous or tendon xanthomas before the age of 10 years OR ii. Untreated elevated LDL-C levels consistent with heterozygous familial hypercholesterolemia (HeFH) in both parents (or in digenic form, one parent may have normal LDL-C levels and the other may have LDL-C levels consistent with HoFH) AND 3. ONE of the following: A. Patient is currently being treated with a lipid-lowering regimen in the last 90 days (i.e., rosuvastatin in combination with ezetimibe OR atorvastatin in combination with ezetimibe) OR B. Patient has an intolerance or hypersensitivity to a lipid-lowering regimen (i.e., rosuvastatin in combination with ezetimibe OR atorvastatin in combination with ezetimibe) OR C. Patient has an FDA labeled contraindication to a lipid-lowering regimen (i.e., rosuvastatin in combination with ezetimibe OR atorvastatin in combination with ezetimibe)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, endocrinologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) AND 3. Patient has had clinical benefit with the requested agent AND 4. ONE of the following: A. Patient is currently being treated with a lipid-lowering regimen in the last 90 days (i.e., rosuvastatin in combination with ezetimibe OR atorvastatin in combination with ezetimibe) OR B. Patient has an intolerance or hypersensitivity to a lipid-lowering regimen (i.e., rosuvastatin in combination with ezetimibe OR atorvastatin in combination with ezetimibe) OR C. Patient has an FDA labeled contraindication to a lipid-lowering regimen (i.e., rosuvastatin in combination with ezetimibe OR atorvastatin in combination with ezetimibe)

PART B PREREQUISITE

N/A

IMIQUIMOD PA

MEDICATION(S)
IMIQUIMOD 5% CREAM PACKET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has ONE of the following diagnoses: A. Actinic keratosis OR B. Superficial basal cell carcinoma OR C. External genital and/or perianal warts/condyloma acuminata OR D. Squamous cell carcinoma OR E. Basal cell carcinoma OR F. Another indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
4 months for Actinic keratosis, other diagnoses - see Other Criteria

OTHER CRITERIA
2 months for Superficial basal cell carcinoma, Squamous cell carcinoma, or Basal cell carcinoma 4 months for External genital and/or perianal warts/condyloma acuminata 12 months for All other diagnoses

PART B PREREQUISITE
N/A

INBRIJA PA

MEDICATION(S)
INBRIJA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. The requested agent will be used for intermittent treatment of OFF episodes in patients with Parkinson's disease AND 2. The requested agent will be used in combination with carbidopa/levodopa

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

INJECTABLE ONCOLOGY PA

MEDICATION(S)
KANJINTI, MVASI, ONTRUZANT, TRAZIMERA, ZIRABEV

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR B. Prescriber states the patient is currently being treated with the requested agent OR C. ALL of the following: i. Genetic testing has been completed, if required, for therapy with the requested agent and results indicate the requested agent is appropriate AND ii. ONE of the following: a. The requested agent is FDA labeled or supported by CMS approved compendia as first-line therapy for the requested indication OR b. Patient has tried appropriate FDA labeled or CMS approved compendia supported therapy that are indicated as first-line therapy for the requested indication OR c. Patient has an intolerance or hypersensitivity to the first-line therapy for the requested indication OR d. Patient has an FDA labeled contraindication to the first-line therapy for the requested indication AND iii. Patient does NOT have any FDA labeled contraindications to the requested agent AND iv. Patient does NOT have any FDA labeled limitations of use that is not otherwise supported in NCCN guidelines May also be subject to Part B versus Part D review.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

INSULIN PEN NEEDLE PA

MEDICATION(S)
INSULIN PEN NEEDLE, NEEDLES, INSULIN DISP., SAFETY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
This program will be implemented as a dynamic PA. Criteria for approval require BOTH of the following: 1. The requested medical supply product will be used in the delivery of insulin to the body AND 2. Patient's medication history includes use of insulin within the past 180 days

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

INSULIN SYRINGE_NEEDLE PA

MEDICATION(S)
INSULIN SYRINGE (DISP) U-100 0.3 ML, INSULIN SYRINGE (DISP) U-100 1 ML, INSULIN SYRINGE (DISP) U-100 1/2 ML, NEEDLES, INSULIN DISP., SAFETY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
This program will be implemented as a dynamic PA. Criteria for approval require BOTH of the following: 1. The requested medical supply product will be used in the delivery of insulin to the body AND 2. Patient's medication history includes use of insulin within the past 180 days

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

IRON CHELATING AGENTS PA - EXJADE

MEDICATION(S)
DEFERASIROX 125 MG TB FOR SUSP, DEFERASIROX 250 MG TB FOR SUSP, DEFERASIROX 500 MG TB FOR SUSP, EXJADE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require BOTH of the following: 1. ONE of the following: A. Patient has a diagnosis of chronic iron overload due to a non-transfusion dependent thalassemia syndrome AND ONE of the following: i. A liver iron (Fe) concentration (LIC) of at least 5 mg Fe per gram of dry weight OR ii. A serum ferritin greater than 300 mcg/L OR iii. MRI confirmation of iron deposition OR B. Patient has a diagnosis of chronic iron overload due to blood transfusions AND 2. Patient will NOT be using the requested agent in combination with another iron chelating agent (e.g., deferiprone) for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. ONE of the following: A. Patient has a diagnosis of chronic iron overload due to a non-transfusion dependent thalassemia syndrome OR B. Patient has a diagnosis of chronic iron overload due to blood transfusions AND 3. Patient has had clinical benefit with the requested agent AND 4. Patient will NOT be using the requested agent in combination with another iron chelating agent (e.g., deferiprone) for the requested indication

AGE RESTRICTION
Patient is within the FDA labeled age for the requested agent for the requested indication

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

IRON CHELATING AGENTS PA - JADENU

MEDICATION(S)
DEFERASIROX 180 MG GRANULE PKT, DEFERASIROX 180 MG TABLET, DEFERASIROX 360 MG GRANULE PKT, DEFERASIROX 360 MG TABLET, DEFERASIROX 90 MG GRANULE PKT, DEFERASIROX 90 MG TABLET, JADENU, JADENU SPRINKLE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require BOTH of the following: 1. ONE of the following: A. Patient has a diagnosis of chronic iron overload due to a non-transfusion dependent thalassemia syndrome AND ONE of the following: i. A liver iron (Fe) concentration (LIC) of at least 5 mg Fe per gram of dry weight OR ii. A serum ferritin greater than 300 mcg/L OR iii. MRI confirmation of iron deposition OR B. Patient has a diagnosis of chronic iron overload due to blood transfusions AND 2. Patient will NOT be using the requested agent in combination with another iron chelating agent (e.g., deferiprone) for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. ONE of the following: A. Patient has a diagnosis of chronic iron overload due to a non-transfusion dependent thalassemia syndrome OR B. Patient has a diagnosis of chronic iron overload due to blood transfusions AND 3. Patient has had clinical benefit with the requested agent AND 4. Patient will NOT be using the requested agent in combination with another iron chelating agent (e.g., deferiprone) for the requested indication

AGE RESTRICTION
Patient is within the FDA labeled age for the requested agent for the requested indication

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

IVERMECTIN CREAM PA

MEDICATION(S)
IVERMECTIN 1% CREAM, SOOLANTRA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

IVERMECTIN TABLET PA

MEDICATION(S)
IVERMECTIN 3 MG TABLET, STROMECTOL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND 2. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 4 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

KALYDECO PA

MEDICATION(S)
KALYDECO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of cystic fibrosis AND 2. ONE of the following: A. Patient has ONE of the CFTR gene mutations or a mutation in the CFTR gene that is responsive based on in vitro data, as indicated in the FDA label, confirmed by genetic testing OR B. Patient has another CFTR gene mutation(s) that is responsive to the requested agent, as indicated in the FDA label, confirmed by genetic testing AND 3. Patient is NOT homozygous for the F508del mutation AND 4. Patient will NOT be using the requested agent in combination with another CFTR modulator agent for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of cystic fibrosis AND 3. Patient has had improvement or stabilization with the requested agent [e.g., improvement in FEV1 from baseline, increase in weight/BMI, improvement from baseline Cystic Fibrosis Questionnaire-Revised (CFQ-R) Respiratory Domain score, improvements in respiratory symptoms (cough, sputum production, and difficulty breathing), and/or reduced number of pulmonary exacerbations] AND 4. Patient will NOT be using the requested agent in combination with another CFTR modulator agent for the requested indication

AGE RESTRICTION
Patient is within the FDA labeled age for the requested agent

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., cystic fibrosis, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

KERENDIA PA

MEDICATION(S)
KERENDIA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has an FDA labeled indication for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

LEUPROLIDE PA

MEDICATION(S)
ELIGARD, LEUPROLIDE 2WK 14 MG/2.8 ML KT, LEUPROLIDE 2WK 14 MG/2.8 ML VL, LEUPROLIDE DEPOT, LUPRON DEPOT 3.75 MG KIT, LUPRON DEPOT 7.5 MG KIT, LUPRON DEPOT-4 MONTH KIT, LUPRON DEPOT 3.75MG (LUPANETA), LUPRON DEPOT-PED 11.25 MG 3MO, LUPRON DEPOT-PED 45 MG 6MO KIT, LUPRON DEPOT-PED 7.5 MG KIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require ALL of the following: 1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR B. Prescriber states the patient is currently being treated with the requested agent OR C. BOTH of the following: i. Patient is NOT currently being treated with the requested agent AND ii. Patient does NOT have any FDA labeled contraindications to the requested agent AND 3. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

LIDOCAINE TOPICAL PA - LIDOCAINE OINTMENT

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
Criteria for approval require the following: 1. The requested agent will be used for ONE of the following: A. Anesthesia of accessible mucous membranes of the oropharynx OR B. Anesthetic lubricant for intubation OR C. Temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites OR D. Another indication that is supported in CMS approved compendia for the requested agent AND ONE of the following: i. Patient has tried and had an inadequate response to a conventional therapy [e.g., gabapentin, pregabalin, oral prescription NSAID (non-steroidal anti-inflammatory drug)] for the requested indication OR ii. Patient has an intolerance or hypersensitivity to a conventional therapy OR iii. Patient has an FDA labeled contraindication to a conventional therapy

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

LIDOCAINE TOPICAL PA - LIDOCAINE PATCH

MEDICATION(S)
DERMACINRX LIDOCAN, LIDOCAINE 5% PATCH, LIDOCAN II, LIDOCAN III, LIDOCAN IV, LIDOCAN V, LIDODERM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. Patient has ONE of the following diagnoses: A. Pain associated with postherpetic neuralgia (PHN) OR B. Pain associated with diabetic neuropathy OR C. Neuropathic pain associated with cancer, or cancer treatment OR D. Another diagnosis that is supported in CMS approved compendia for the requested agent AND 2. ONE of the following: A. Patient has tried and had an inadequate response to a conventional therapy [e.g., gabapentin, pregabalin, oral prescription NSAID (non-steroidal anti-inflammatory drug)] for the requested indication OR B. Patient has an intolerance or hypersensitivity to a conventional therapy OR C. Patient has an FDA labeled contraindication to a conventional therapy

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

LIDOCAINE TOPICAL PA - LIDOCAINE SOLUTION

MEDICATION(S)
LIDOCAINE HCL 4% SOLUTION, LIDOCAINE HCL LARYNGOTRACHEAL 4% SOLUTION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. The requested agent will be used for ONE of the following: A. Topical anesthesia of accessible mucous membranes of the oral and nasal cavities OR B. Topical anesthesia of accessible mucous membranes of proximal portions of the digestive tract OR C. Another indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

LIDOCAINE TOPICAL PA - LIDOCAINE/PRILOCAINE CREAM

MEDICATION(S)
LIDOCAINE-PRILOCAINE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. The requested agent will be used for ONE of the following: A. Local analgesia on normal intact skin OR B. Topical anesthetic for dermal procedures OR C. Adjunctive anesthesia prior to local anesthetic infiltration in adult male genital skin OR D. Anesthesia for minor procedures on female external genitalia OR E. Another indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

LIDOCAINE TOPICAL PA - ZTLIDO

MEDICATION(S)
ZTLIDO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require ALL of the following: 1. Patient has ONE of the following diagnoses: A. Pain associated with postherpetic neuralgia (PHN) OR B. Neuropathic pain associated with cancer, or cancer treatment OR C. Another diagnosis that is supported in CMS approved compendia for the requested agent AND 2. ONE of the following: A. Patient has tried and had an inadequate response to generic lidocaine 5% patch OR B. Patient has an intolerance or hypersensitivity to generic lidocaine 5% patch OR C. Patient has an FDA labeled contraindication to generic lidocaine 5% patch AND 3. ONE of the following: A. Patient has tried and had an inadequate response to a conventional therapy [e.g., gabapentin, pregabalin, oral prescription NSAID (non-steroidal anti-inflammatory drug)] for the requested indication OR B. Patient has an intolerance or hypersensitivity to a conventional therapy OR C. Patient has an FDA labeled contraindication to a conventional therapy

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

LINEZOLID PA

MEDICATION(S)
LINEZOLID, ZYVOX 100 MG/5 ML SUSPENSION, ZYVOX 600 MG TABLET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require ALL of the following: 1. Patient has an FDA labeled indication for the requested agent AND ONE of the following: a. The requested agent is prescribed by an infectious disease specialist or the prescriber has consulted with an infectious disease specialist on treatment of this patient OR b. Patient has a documented infection due to vancomycin-resistant Enterococcus faecium OR c. Patient has a diagnosis of pneumonia caused by Staphylococcus aureus or Streptococcus pneumoniae AND ONE of the following: i. Patient has a documented infection that is resistant to TWO of the following: beta-lactams, macrolides, clindamycin, tetracyclines, or co-trimoxazole, OR that is resistant to vancomycin OR ii. Patient has an intolerance or hypersensitivity to TWO of the following: beta-lactams, macrolides, clindamycin, tetracyclines, or co-trimoxazole OR iii. Patient has an FDA labeled contraindication to TWO of the following: beta-lactams, macrolides, clindamycin, tetracyclines, or co-trimoxazole OR iv. Patient has an intolerance or hypersensitivity to vancomycin OR v. Patient has an FDA labeled contraindication to vancomycin OR d. Patient has a documented skin and skin structure infection, including diabetic foot infections, caused by Staphylococcus aureus, Streptococcus pyogenes, or Streptococcus agalactiae AND ONE of the following: i. Patient has a documented infection that is resistant to TWO of the following: beta-lactams, macrolides, clindamycin, tetracyclines, or co-trimoxazole, OR that is resistant to vancomycin at the site of infection OR ii. Patient has an intolerance or hypersensitivity to TWO of the following: beta-lactams, macrolides, clindamycin, tetracyclines, or co-trimoxazole OR iii. Patient has an FDA labeled contraindication to TWO of the following: beta-lactams, macrolides, clindamycin, tetracyclines, or co-trimoxazole OR Criteria continues: see Other Criteria

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 3 months

OTHER CRITERIA

iv. Patient has an intolerance or hypersensitivity to vancomycin OR v. Patient has an FDA labeled contraindication to vancomycin AND 2. Patient will NOT be using the requested agent in combination with Sivextro (tedizolid) for the same infection AND 3. The requested dose is within FDA labeled dosing for the requested indication

PART B PREREQUISITE

N/A

LUMRYZ PA

MEDICATION(S)
LUMRYZ

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. ONE of the following: A. Patient has a diagnosis of narcolepsy with cataplexy OR B. Patient has a diagnosis of narcolepsy with excessive daytime sleepiness AND BOTH of the following: i. ONE of the following: a. Patient has tried and had an inadequate response to modafinil or armodafinil OR b. Patient has an intolerance or hypersensitivity to modafinil or armodafinil OR c. Patient has an FDA labeled contraindication to modafinil or armodafinil AND ii. ONE of the following: a. Patient has tried and had an inadequate response to ONE standard stimulant agent (e.g., methylphenidate) OR b. Patient has an intolerance or hypersensitivity to ONE standard stimulant agent (e.g., methylphenidate) OR c. Patient has an FDA labeled contraindication to ONE standard stimulant agent (e.g., methylphenidate) OR C. Patient has another indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
Patient is 18 years of age or over

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

MAVYRET PA

MEDICATION(S)
MAVYRET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require ALL of the following: 1. ONE of the following: A. Patient has a diagnosis of hepatitis C confirmed by serological markers OR B. Patient is a hepatitis C virus (HCV) - uninfected solid organ transplant recipient AND BOTH of the following: i. Patient received an HCV - viremic donor organ AND ii. The requested agent is being used for prophylaxis AND 2. Prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection and if positive, will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent AND 3. The requested agent will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling or AASLD/IDSA guidelines for the patient's diagnosis and genotype AND 4. The requested dose is within FDA labeled dosing or supported in AASLD/IDSA guideline dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist or infectious disease) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION
Duration of therapy: Based on FDA approved labeling or AASLD/IDSA guideline supported

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

MEMANTINE ER PA

MEDICATION(S)
MEMANTINE HCL ER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
PA does NOT apply to patients greater than or equal to 30 years of age Criteria for approval require the following: 1. Patient is younger than 30 years of age AND ONE of the following: A. Patient has a diagnosis of moderate to severe dementia of the Alzheimer's type OR B. Patient has an indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

MEMANTINE PA

MEDICATION(S)
MEMANTINE 5-10 MG TITRATION PK, MEMANTINE HCL 10 MG TABLET, MEMANTINE HCL 2 MG/ML SOLUTION, MEMANTINE HCL 5 MG TABLET, NAMENDA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
PA does NOT apply to patients greater than or equal to 30 years of age Criteria for approval require the following: 1. Patient is younger than 30 years of age AND ONE of the following: A. Patient has a diagnosis of moderate to severe dementia of the Alzheimer's type OR B. Patient has an indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

METHYLIN PA

MEDICATION(S)
METHYLPHENIDATE 10 MG/5 ML SOL, METHYLPHENIDATE 5 MG/5 ML SOLN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has an FDA labeled indication for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

METHYLPHENIDATE ER TABLET PA

MEDICATION(S)
METHYLPHENIDATE ER 20 MG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has an FDA labeled indication for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

MIFEPRISTONE PA

MEDICATION(S)
KORLYM, MIFEPRISTONE 300 MG TABLET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of Cushing's syndrome AND 2. ONE of the following: A. Patient has type 2 diabetes mellitus OR B. Patient has glucose intolerance as defined by a 2-hour glucose tolerance test plasma glucose value of 140-199 mg/dL AND 3. ONE of the following: A. Patient had an inadequate response to surgical resection OR B. Patient is NOT a candidate for surgical resection Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of Cushing's syndrome AND 3. Patient has had clinical benefit with the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

MIGRANAL PA

MEDICATION(S)
DIHYDROERGOTAMINE 4 MG/ML SPRY, MIGRANAL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. The requested agent will be used for the treatment of acute migraine with or without aura AND 2. ONE of the following: A. Patient has tried and had an inadequate response to TWO triptan agents with differing active ingredients (e.g., sumatriptan, rizatriptan) OR B. Patient has an intolerance or hypersensitivity to TWO triptan agents with differing active ingredients OR C. Patient has an FDA labeled contraindication to TWO triptan agents with differing active ingredients AND 3. Patient will NOT be using the requested agent in combination with another acute migraine agent (e.g., triptan, 5HT-1F, acute CGRP) Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. The requested agent will be used for the treatment of acute migraine with or without aura AND 3. Patient has had clinical benefit with the requested agent AND 4. Patient will NOT be using the requested agent in combination with another acute migraine agent (e.g., triptan, 5HT-1F, acute CGRP)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

MODAFINIL PA

MEDICATION(S)
MODAFINIL 100 MG TABLET, MODAFINIL 200 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND 2. Patient will NOT be using the requested agent in combination with another target agent (i.e., armodafinil)

AGE RESTRICTION
Patient is 17 years of age or over

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

MOUNJARO PA

MEDICATION(S)
MOUNJARO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Requested agent will be used for weight loss alone

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. Patient has a diagnosis of type 2 diabetes mellitus AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR B. Prescriber states the patient is currently being treated with the requested agent within the past 180 days OR C. ALL of the following: i. ONE of the following: 1. Patient's medication history includes use of a non glucagon-like peptide-1 (GLP-1) oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) within the past 90 days OR 2. Patient had an ineffective treatment response to a non GLP-1 oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) OR 3. Patient has an intolerance or hypersensitivity to a non GLP-1 oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) OR 4. Patient has an FDA labeled contraindication to a non GLP-1 oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) AND ii. Patient does NOT have any FDA labeled contraindications to the requested agent AND iii. Patient will NOT be using the requested agent in combination with another GLP-1 agonist agent, or an agent containing a GLP-1 agonist AND iv. Patient will NOT be using the requested agent in combination with an agent containing a dipeptidyl peptidase-4 (DPP-4) inhibitor

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

MS PA - AVONEX

MEDICATION(S)
AVONEX 30 MCG/0.5 ML SYRINGE, AVONEX PREFILLED SYR 30 MCG KT, AVONEX PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require BOTH of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical benefit with the requested agent AND 4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

MS PA - BETASERON

MEDICATION(S)
BETASERON

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require BOTH of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical benefit with the requested agent AND 4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

MS PA - DIMETHYL FUMARATE

MEDICATION(S)
DIMETHYL FUMARATE, TECFIDERA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require BOTH of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical benefit with the requested agent AND 4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

MS PA - FINGOLIMOD

MEDICATION(S)
FINGOLIMOD, GILENYA 0.5 MG CAPSULE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication AND 3. Prescriber has performed an electrocardiogram within 6 months prior to initiating treatment Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical benefit with the requested agent AND 4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

MS PA - GLATIRAMER

MEDICATION(S)
COPAXONE, GLATIRAMER ACETATE, GLATOPA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require BOTH of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical benefit with the requested agent AND 4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

MS PA - KESIMPTA

MEDICATION(S)
KESIMPTA PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require BOTH of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical benefit with the requested agent AND 4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

MS PA - PLEGRIDY

MEDICATION(S)
PLEGRIDY, PLEGRIDY PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require BOTH of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical benefit with the requested agent AND 4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

MS PA - VUMERITY

MEDICATION(S)
VUMERITY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require BOTH of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical benefit with the requested agent AND 4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

MYALEPT PA

MEDICATION(S)
MYALEPT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has leptin deficiency associated with a diagnosis of either congenital generalized lipodystrophy (CGL) or acquired generalized lipodystrophy (AGL) AND 2. Prescriber has provided the patient's baseline levels for HbA1C, triglycerides, and fasting insulin, measured prior to beginning therapy with the requested agent AND 3. Patient also has at least ONE of the complications related to lipodystrophy: diabetes mellitus, hypertriglyceridemia (200 mg/dL or higher), and/or high fasting insulin (30 microunits/mL or higher) AND 4. Patient has tried and had an inadequate response to maximum tolerable dosing of a conventional agent for the additional diagnosis AND 5. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has leptin deficiency associated with a diagnosis of either congenital generalized lipodystrophy (CGL) or acquired generalized lipodystrophy (AGL) AND 3. Patient has had improvement or stabilization with the requested agent as indicated by change from baseline level of at least ONE of the following: A. HbA1C B. Triglycerides C. Fasting insulin AND 4. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

Conventional agent examples include: Hypertriglyceridemia: statins, fenofibrates, Omega-3-Acid Ethyl Esters (generic Lovaza) Diabetes/high fasting insulin: insulin, sulfonylurea/sulfonylurea combination, metformin/metformin combination

PART B PREREQUISITE

N/A

NUEDEXTA PA

MEDICATION(S)
NUEDEXTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. ONE of the following: A. Patient has a diagnosis of pseudobulbar affect OR B. Patient has an indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

NUPLAZID PA

MEDICATION(S)
NUPLAZID 10 MG TABLET, NUPLAZID 34 MG CAPSULE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has an FDA labeled indication for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

NURTEC PA

MEDICATION(S)
NURTEC ODT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require BOTH of the following: 1. Patient has a diagnosis of migraine AND 2. ONE of the following: A. The requested agent is being used for the treatment of acute migraine with or without aura AND BOTH of the following: i. ONE of the following: a. Patient has tried and had an inadequate response to a triptan (e.g., sumatriptan, rizatriptan) agent OR b. Patient has an intolerance, or hypersensitivity to a triptan OR c. Patient has an FDA labeled contraindication to a triptan AND ii. Patient will NOT be using the requested agent in combination with another acute migraine agent (e.g., triptan, 5HT-1F, ergotamine, acute CGRP) OR B. The requested agent is being used for migraine prophylaxis AND BOTH of the following: i. Patient has 4 or more migraine headache days per month AND ii. Patient will NOT be using the requested agent in combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of migraine AND 3. ONE of the following: A. The requested agent is being used for the treatment of acute migraine with or without aura AND BOTH of the following: i. Patient has had clinical benefit with the requested agent AND ii. Patient will NOT be using the requested agent in combination with another acute migraine agent (e.g., triptan, 5HT-1F, ergotamine, acute CGRP) OR B. The requested agent is being used for migraine prophylaxis AND BOTH of the following: i. Patient has had clinical benefit with the requested agent AND ii. Patient will NOT be using the requested agent in combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

OCALIVA PA

MEDICATION(S)
OCALIVA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of primary biliary cholangitis (PBC) confirmed by at least TWO of the following: A. There is biochemical evidence of cholestasis with an alkaline phosphatase (ALP) elevation B. Presence of antimitochondrial antibody (AMA): a titer greater than 1:80 OR a level that is above the testing laboratory's upper limit of the normal range C. If the AMA is negative or present only in low titer (less than or equal to 1:80), presence of other PBC-specific autoantibodies, including sp100 or gp210 D. Histologic evidence of nonsuppurative destruction cholangitis and destruction of interlobular bile ducts AND 2. ONE of the following: A. Patient does NOT have cirrhosis OR B. Patient has compensated cirrhosis with NO evidence of portal hypertension AND 3. Prescriber has measured the patient's alkaline phosphatase (ALP) level AND total bilirubin level AND 4. ONE of the following: A. BOTH of the following: i. Patient has tried and had an inadequate response to ursodiol AND ii. The requested agent will be used in combination with ursodiol OR B. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ursodiol

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA

Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of primary biliary cholangitis (PBC) AND 3. ONE of the following: A. Patient does NOT have cirrhosis OR B. Patient has compensated cirrhosis with NO evidence of portal hypertension AND 4. ONE of the following: A. The requested agent will be used in combination with ursodiol OR B. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ursodiol AND 5. Patient has had improvements or stabilization with the requested agent as indicated by BOTH of the following: A. Decrease in alkaline phosphatase (ALP) level from baseline AND B. Total bilirubin is less than or equal to the upper limit of normal (ULN)

PART B PREREQUISITE

N/A

OFEV PA

MEDICATION(S)
OFEV

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require the following: 1. ONE of the following: A. BOTH of the following: i. Patient has a diagnosis of idiopathic pulmonary fibrosis (IPF) AND ii. Patient has no known explanation for interstitial lung disease (ILD) or pulmonary fibrosis (e.g., radiation, drugs, metal dusts, sarcoidosis, or any connective tissue disease known to cause ILD) OR B. BOTH of the following: i. Patient has a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) AND ii. Patient's diagnosis has been confirmed on high-resolution computed tomography (HRCT) or chest radiography scans OR C. BOTH of the following: i. Patient has a diagnosis of chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype AND ii. Patient's diagnosis has been confirmed on high-resolution computed tomography (HRCT) Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of ONE of the following: A. Idiopathic pulmonary fibrosis (IPF) OR B. Systemic sclerosis-associated interstitial lung disease (SSc-ILD) OR C. Chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype AND 3. Patient has had clinical benefit with the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., pathologist, pulmonologist, radiologist, rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

OMNIPOD PA

MEDICATION(S)
OMNIPOD 5 DEXG7G6 INTRO(GEN 5), OMNIPOD 5 DEXG7G6 PODS (GEN 5), OMNIPOD 5 G6-G7 INTRO KT(GEN5), OMNIPOD 5 G6-G7 PODS (GEN 5), OMNIPOD CLASSIC PDM KIT(GEN 3), OMNIPOD CLASSIC PODS (GEN 3), OMNIPOD DASH INTRO KIT (GEN 4), OMNIPOD DASH PDM KIT (GEN 4), OMNIPOD DASH PODS (GEN 4), OMNIPOD GO PODS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of diabetes mellitus AND 2. Patient is on an insulin regimen of 3 or more injections per day AND 3. ONE of the following: A. Patient is testing glucose levels 4 or more times per day OR B. Patient is using a continuous glucose monitor (CGM) Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan’s Prior Authorization criteria AND 2. Patient has a diagnosis of diabetes mellitus AND 3. Patient has had clinical benefit with the requested agent (e.g., stable or improved glycemic control)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

OPIOIDS ER PA - BUPRENORPHINE PAIN

MEDICATION(S)
BELBUCA, BUPRENORPHINE, BUTRANS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. ONE of the following: A. Patient has a diagnosis of chronic cancer-related pain OR B. Patient has a diagnosis of pain due to sickle cell disease OR C. Patient is undergoing treatment of chronic non-cancer pain AND ONE of the following: i. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR ii. Prescriber states the patient is currently being treated with the requested agent within the past 90 days OR iii. ALL of the following: a. Prescriber has completed a formal, consultative evaluation including BOTH of the following: 1. Diagnosis AND 2. A medical history which includes previous and current pharmacological and non-pharmacological therapy for the requested diagnosis AND b. The requested agent is NOT prescribed as an as-needed (prn) analgesic AND c. Prescriber has confirmed that a patient-specific pain management plan is on file for the patient AND d. ONE of the following: 1. Patient's medication history includes use of an immediate-acting opioid OR 2. Patient has an intolerance or hypersensitivity to an immediate-acting opioid OR 3. Patient has an FDA labeled contraindication to an immediate-acting opioid AND e. Prescriber has reviewed the patient's records in the state's prescription drug monitoring program (PDMP) AND has determined that the opioid dosages and combinations of opioids and other controlled substances within the patient's records do NOT indicate the patient is at high risk for overdose AND f. Patient does NOT have any FDA labeled contraindications to the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

OPIOIDS ER PA - FENTANYL PATCH

MEDICATION(S)
FENTANYL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. ONE of the following: A. Patient has a diagnosis of chronic cancer-related pain OR B. Patient has a diagnosis of pain due to sickle cell disease OR C. Patient is undergoing treatment of chronic non-cancer pain AND ONE of the following: i. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR ii. Prescriber states the patient is currently being treated with the requested agent within the past 90 days OR iii. ALL of the following: a. Prescriber has completed a formal, consultative evaluation including BOTH of the following: 1. Diagnosis AND 2. A medical history which includes previous and current pharmacological and non-pharmacological therapy for the requested diagnosis AND b. The requested agent is NOT prescribed as an as-needed (prn) analgesic AND c. Prescriber has confirmed that a patient-specific pain management plan is on file for the patient AND d. ONE of the following: 1. Patient's medication history includes use of an immediate-acting opioid OR 2. Patient has an intolerance or hypersensitivity to an immediate-acting opioid OR 3. Patient has an FDA labeled contraindication to an immediate-acting opioid AND e. Prescriber has reviewed the patient's records in the state's prescription drug monitoring program (PDMP) AND has determined that the opioid dosages and combinations of opioids and other controlled substances within the patient's records do NOT indicate the patient is at high risk for overdose AND f. Patient does NOT have any FDA labeled contraindications to the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

OPIOIDS ER PA - HYDROCODONE

MEDICATION(S)
HYDROCODONE ER 10 MG CAPSULE, HYDROCODONE ER 15 MG CAPSULE, HYDROCODONE ER 20 MG CAPSULE, HYDROCODONE ER 30 MG CAPSULE, HYDROCODONE ER 40 MG CAPSULE, HYDROCODONE ER 50 MG CAPSULE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. ONE of the following: A. Patient has a diagnosis of chronic cancer-related pain OR B. Patient has a diagnosis of pain due to sickle cell disease OR C. Patient is undergoing treatment of chronic non-cancer pain AND ONE of the following: i. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR ii. Prescriber states the patient is currently being treated with the requested agent within the past 90 days OR iii. ALL of the following: a. Prescriber has completed a formal, consultative evaluation including BOTH of the following: 1. Diagnosis AND 2. A medical history which includes previous and current pharmacological and non-pharmacological therapy for the requested diagnosis AND b. The requested agent is NOT prescribed as an as-needed (prn) analgesic AND c. Prescriber has confirmed that a patient-specific pain management plan is on file for the patient AND d. ONE of the following: 1. Patient's medication history includes use of an immediate-acting opioid OR 2. Patient has an intolerance or hypersensitivity to an immediate-acting opioid OR 3. Patient has an FDA labeled contraindication to an immediate-acting opioid AND e. Prescriber has reviewed the patient's records in the state's prescription drug monitoring program (PDMP) AND has determined that the opioid dosages and combinations of opioids and other controlled substances within the patient's records do NOT indicate the patient is at high risk for overdose AND f. Patient does NOT have any FDA labeled contraindications to the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

OPIOIDS ER PA - MORPHINE

MEDICATION(S)
MORPHINE SULF ER 100 MG TABLET, MORPHINE SULF ER 15 MG TABLET, MORPHINE SULF ER 200 MG TABLET, MORPHINE SULF ER 30 MG TABLET, MORPHINE SULF ER 60 MG TABLET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. ONE of the following: A. Patient has a diagnosis of chronic cancer-related pain OR B. Patient has a diagnosis of pain due to sickle cell disease OR C. Patient is undergoing treatment of chronic non-cancer pain AND ONE of the following: i. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR ii. Prescriber states the patient is currently being treated with the requested agent within the past 90 days OR iii. ALL of the following: a. Prescriber has completed a formal, consultative evaluation including BOTH of the following: 1. Diagnosis AND 2. A medical history which includes previous and current pharmacological and non-pharmacological therapy for the requested diagnosis AND b. The requested agent is NOT prescribed as an as-needed (prn) analgesic AND c. Prescriber has confirmed that a patient-specific pain management plan is on file for the patient AND d. ONE of the following: 1. Patient's medication history includes use of an immediate-acting opioid OR 2. Patient has an intolerance or hypersensitivity to an immediate-acting opioid OR 3. Patient has an FDA labeled contraindication to an immediate-acting opioid AND e. Prescriber has reviewed the patient's records in the state's prescription drug monitoring program (PDMP) AND has determined that the opioid dosages and combinations of opioids and other controlled substances within the patient's records do NOT indicate the patient is at high risk for overdose AND f. Patient does NOT have any FDA labeled contraindications to the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

OPIOIDS ER PA - TRAMADOL

MEDICATION(S)
TRAMADOL HCL ER 100 MG TABLET, TRAMADOL HCL ER 200 MG TABLET, TRAMADOL HCL ER 300 MG TABLET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. ONE of the following: A. Patient has a diagnosis of chronic cancer-related pain OR B. Patient has a diagnosis of pain due to sickle cell disease OR C. Patient is undergoing treatment of chronic non-cancer pain AND ONE of the following: i. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR ii. Prescriber states the patient is currently being treated with the requested agent within the past 90 days OR iii. ALL of the following: a. Prescriber has completed a formal, consultative evaluation including BOTH of the following: 1. Diagnosis AND 2. A medical history which includes previous and current pharmacological and non-pharmacological therapy for the requested diagnosis AND b. The requested agent is NOT prescribed as an as-needed (prn) analgesic AND c. Prescriber has confirmed that a patient-specific pain management plan is on file for the patient AND d. ONE of the following: 1. Patient's medication history includes use of an immediate-acting opioid OR 2. Patient has an intolerance or hypersensitivity to an immediate-acting opioid OR 3. Patient has an FDA labeled contraindication to an immediate-acting opioid AND e. Prescriber has reviewed the patient's records in the state's prescription drug monitoring program (PDMP) AND has determined that the opioid dosages and combinations of opioids and other controlled substances within the patient's records do NOT indicate the patient is at high risk for overdose AND f. Patient does NOT have any FDA labeled contraindications to the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ORAL IMMUNOTHERAPY AGENTS PA - ORALAIR

MEDICATION(S)
ORALAIR 300 IR ADULT SAMPLE KT, ORALAIR 300 IR STARTER PACK, ORALAIR 300 IR SUBLINGUAL TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require ALL of the following: 1. Patient has a diagnosis of allergic rhinitis, with or without conjunctivitis AND 2. Patient's diagnosis is confirmed with ONE of the following: A. Positive skin test to ONE of the pollen extracts included in the requested agent OR B. IgE specific antibodies to ONE of the extracts included in the requested agent: Sweet vernal, orchard, perennial rye, Timothy, or Kentucky blue grass AND 3. ONE of the following: A. Patient has tried and had an inadequate response to an intranasal corticosteroid AND one other standard allergy agent (e.g., oral or intranasal antihistamines, oral or intranasal corticosteroids, leukotriene inhibitors, note: two separate intranasal corticosteroids meet this criteria) OR B. Patient has an intolerance or hypersensitivity to therapy with an intranasal corticosteroid AND one other standard allergy agent OR C. Patient has an FDA labeled contraindication to therapy with an intranasal corticosteroid AND one other standard allergy agent AND 4. Patient will NOT be using the requested agent in combination with a subcutaneous injectable immunotherapy agent AND 5. The requested agent will be started, or has already been started, 3 to 4 months before the expected onset of the applicable pollen season AND 6. The first dose is given in the clinic/hospital under direct supervision from the provider for a period of at least 30 minutes AND 7. Patient has been prescribed epinephrine auto-injector for at home emergency use

AGE RESTRICTION
Patient is within the FDA labeled age for the requested agent

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ORKAMBI PA

MEDICATION(S)
ORKAMBI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of cystic fibrosis AND 2. ONE of the following: A. Patient has the presence of the F508del mutation on both alleles (homozygous) of the CFTR gene confirmed by genetic testing OR B. Patient has another CFTR gene mutation(s) that is responsive to the requested agent, as indicated in the FDA label, confirmed by genetic testing AND 3. Patient will NOT be using the requested agent in combination with another CFTR modulator agent for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of cystic fibrosis AND 3. Patient has had improvement or stabilization with the requested agent [e.g., improvement in FEV1 from baseline, increase in weight/BMI, improvement from baseline Cystic Fibrosis Questionnaire-Revised (CFQ-R) Respiratory Domain score, improvements in respiratory symptoms (cough, sputum production, and difficulty breathing), and/or reduced number of pulmonary exacerbations] AND 4. Patient will NOT be using the requested agent in combination with another CFTR modulator agent for the requested indication

AGE RESTRICTION
Patient is within the FDA labeled age for the requested agent

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., cystic fibrosis, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

OTEZLA PA

MEDICATION(S)
OTEZLA 10-20 MG STARTER 28 DAY, OTEZLA 10-20-30MG START 28 DAY, OTEZLA 20 MG TABLET, OTEZLA 30 MG TABLET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require BOTH of the following: 1. ONE of the following: A. BOTH of the following: i. Patient has ONE of the following diagnoses: 1. Plaque psoriasis OR 2. Active psoriatic arthritis AND ii. ONE of the following: 1. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR 2. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR 3. Patient's medication history indicates use of a biologic immunomodulator agent for the same FDA labeled indication OR 4. Patient has tried and had an inadequate response to at least ONE conventional prerequisite agent for the requested indication OR 5. Patient has an intolerance or hypersensitivity to at least ONE conventional prerequisite agent for the requested indication OR 6. Patient has an FDA labeled contraindication to at least ONE conventional prerequisite agent for the requested indication OR B. Patient has a diagnosis of oral ulcers associated with Behcet's disease (BD) AND 2. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has ONE of the following diagnoses: A. Plaque psoriasis OR B. Active psoriatic arthritis OR C. Oral ulcers associated with Behcet's disease (BD) AND 3. Patient has had clinical benefit with the requested agent (slowing of disease progression or decrease in symptom severity and/or frequency) AND 4. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

Formulary conventional agent required for diagnoses of plaque psoriasis or active psoriatic arthritis Formulary conventional agents for plaque psoriasis include cyclosporine, methotrexate, tazarotene, topical calcitriol, or topical corticosteroids Formulary conventional agents for active psoriatic arthritis include cyclosporine, leflunomide, methotrexate, or sulfasalazine NO prerequisites are required for a diagnosis of oral ulcers associated with Behcet's disease (BD)

PART B PREREQUISITE

N/A

OZEMPIC PA

MEDICATION(S)
OZEMPIC 0.25-0.5 MG/DOSE PEN, OZEMPIC 1 MG/DOSE (4 MG/3 ML), OZEMPIC 2 MG/DOSE (8 MG/3 ML)

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Requested agent will be used for weight loss alone

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. Patient has a diagnosis of type 2 diabetes mellitus AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR B. Prescriber states the patient is currently being treated with the requested agent within the past 180 days OR C. ALL of the following: i. ONE of the following: 1. Patient's medication history includes use of a non glucagon-like peptide-1 (GLP-1) oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) within the past 90 days OR 2. Patient had an ineffective treatment response to a non GLP-1 oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) OR 3. Patient has an intolerance or hypersensitivity to a non GLP-1 oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) OR 4. Patient has an FDA labeled contraindication to a non GLP-1 oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) OR 5. BOTH of the following: a. Patient has a diagnosis of established cardiovascular disease [e.g., myocardial infarction, stroke, any revascularization procedure, transient ischemic attack, unstable angina, amputation, symptomatic or asymptomatic coronary artery disease] AND b. The requested agent will be used to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) AND ii. Patient does NOT have any FDA labeled contraindications to the requested agent AND iii. Patient will NOT be using the requested agent in combination with another GLP-1 agonist agent, or an agent containing a GLP-1 agonist AND iv. Patient will NOT be using the requested agent in combination with an agent containing a dipeptidyl peptidase-4 (DPP-4) inhibitor

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

PALYNZIQ PA

MEDICATION(S)
PALYNZIQ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of phenylketonuria (PKU) AND 2. Patient has a baseline blood Phe level greater than 600 micromol/L (10 mg/dL) AND 3. Patient will NOT be using the requested agent in combination with sapropterin for the requested indication AND 4. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of phenylketonuria (PKU) AND 3. ONE of the following: a. Patient's blood Phe levels are being maintained within the acceptable range OR b. Patient has had a decrease in blood Phe level from baseline AND 4. Patient will NOT be using the requested agent in combination with sapropterin for the requested indication AND 5. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., metabolic or genetic disorders) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION
Approval will be 9 months for initial, 12 months for renewal

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

PANRETIN PA

MEDICATION(S)
PANRETIN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. ONE of the following: A. Patient has a diagnosis of cutaneous lesions associated with AIDS-related Kaposi's sarcoma (KS) OR B. Patient has an indication that is supported in CMS approved compendia for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR B. Prescriber states the patient is currently being treated with the requested agent OR C. ALL of the following: i. ONE of the following: 1. BOTH of the following: a. Patient has a diagnosis of cutaneous lesions associated with AIDS-related Kaposi's sarcoma (KS) AND b. Patient does NOT require systemic anti-Kaposi's sarcoma therapy OR 2. Patient has an indication that is supported in CMS approved compendia for the requested agent AND ii. Prescriber is a specialist in the area of the patient's diagnosis (e.g., oncologist, dermatologist, infectious disease) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND iii. Patient does NOT have any FDA labeled contraindications to the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

PART D VS PART B

MEDICATION(S)

ACETYLCYSTEINE 10% VIAL, ACETYLCYSTEINE 20% VIAL, ACYCLOVIR 1,000 MG/20 ML VIAL, ACYCLOVIR 500 MG/10 ML VIAL, ALBUTEROL 100 MG/20 ML SOLN, ALBUTEROL 15 MG/3 ML SOLUTION, ALBUTEROL 2.5 MG/0.5 ML SOL, ALBUTEROL 20 MG/4 ML SOLUTION, ALBUTEROL 25 MG/5 ML SOLUTION, ALBUTEROL 5 MG/ML SOLUTION, ALBUTEROL 75 MG/15 ML SOLN, ALBUTEROL SUL 0.63 MG/3 ML SOL, ALBUTEROL SUL 1.25 MG/3 ML SOL, ALBUTEROL SUL 2.5 MG/3 ML SOLN, AMBISOME, AMPHOTERICIN B, AMPHOTERICIN B LIPOSOME, APREPITANT, ASTAGRAF XL, ATGAM, AZASAN, AZATHIOPRINE, BUDESONIDE 0.25 MG/2 ML SUSP, BUDESONIDE 0.5 MG/2 ML SUSP, BUDESONIDE 1 MG/2 ML INH SUSP, CELLCEPT 200 MG/ML ORAL SUSP, CELLCEPT 250 MG CAPSULE, CELLCEPT 500 MG TABLET, CROMOLYN 20 MG/2 ML NEB SOLN, CYCLOPHOSPHAMIDE 25 MG CAPSULE, CYCLOPHOSPHAMIDE 25 MG TABLET, CYCLOPHOSPHAMIDE 50 MG CAPSULE, CYCLOPHOSPHAMIDE 50 MG TABLET, CYCLOSPORINE 100 MG CAPSULE, CYCLOSPORINE 25 MG CAPSULE, CYCLOSPORINE MODIFIED, DRONABINOL, EMEND 80 MG CAPSULE, EMEND TRIPACK, ENGERIX-B ADULT, ENGERIX-B PEDIATRIC-ADOLESCENT, ENVARSUS XR, EVEROLIMUS 0.25 MG TABLET, EVEROLIMUS 0.5 MG TABLET, EVEROLIMUS 0.75 MG TABLET, EVEROLIMUS 1 MG TABLET, GENGRAF, GRANISETRON HCL 1 MG TABLET, HEPLISAV-B 20 MCG/0.5 ML SYRNG, HUMULIN R U-500, HYDROMORPHONE 10 MG/ML AMPULE, HYDROMORPHONE 10 MG/ML VIAL, HYDROMORPHONE 50 MG/5 ML AMP, HYDROMORPHONE 50 MG/5 ML VIAL, HYDROMORPHONE 500 MG/50 ML VL, IMOVAX RABIES VACCINE, IMURAN, INTRALIPID 20% IV FAT EMUL, IPRATROPIUM BR 0.02% SOLN, IPRATROPIUM-ALBUTEROL, JYNNEOS, JYNNEOS (NATIONAL STOCKPILE), MYCOPHENOLATE 200 MG/ML SUSP, MYCOPHENOLATE 250 MG CAPSULE, MYCOPHENOLATE 500 MG TABLET, MYCOPHENOLIC ACID, MYFORTIC 180 MG TABLET, MYHIBBIN, NEBUPENT, NEORAL, NUTRILIPID, PENTAMIDINE 300 MG INHAL POWDR, PREHEVBRIO, PROGRAF 0.2 MG GRANULE PACKET, PROGRAF 0.5 MG CAPSULE, PROGRAF 1 MG CAPSULE, PROGRAF 1 MG GRANULE PACKET, PROGRAF 5 MG CAPSULE, PULMOZYME, RABAVERT, RAPAMUNE 1 MG/ML ORAL SOLN, RECOMBIVAX HB, SANDIMMUNE 100 MG CAPSULE, SANDIMMUNE 100 MG/ML SOLN, SANDIMMUNE 25 MG CAPSULE, SIROLIMUS 0.5 MG TABLET, SIROLIMUS 1 MG TABLET, SIROLIMUS 1 MG/ML SOLUTION, SIROLIMUS 2 MG TABLET, TACROLIMUS 0.5 MG CAPSULE (IR), TACROLIMUS 1 MG CAPSULE (IR), TACROLIMUS 5 MG CAPSULE (IR), TDVAX, TENIVAC, THYMOGLOBULIN, TRAVASOL, TROPHAMINE, XATMEP, 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.

PEGYLATED INTERFERON PA

MEDICATION(S)
PEGASYS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. ONE of the following: A. Patient has a diagnosis of chronic hepatitis B AND BOTH of the following: i. The chronic hepatitis B infection has been confirmed by serological markers AND ii. Patient has NOT been administered the requested agent for more than 48 weeks for the treatment of chronic hepatitis B OR B. BOTH of the following: i. Patient has a diagnosis of chronic hepatitis C confirmed by serological markers AND ii. The requested agent will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling for the patient's diagnosis and genotype OR C. Patient has an indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months for all other diagnoses. For hep B, hep C see Other Criteria

OTHER CRITERIA
No prior peginterferon alfa use, approve 48 weeks for hepatitis B infection. Prior peginterferon alfa use, approve remainder of 48 weeks of total therapy for hepatitis B infection Duration of therapy for hepatitis C: Based on FDA approved labeling

PART B PREREQUISITE

N/A

PIRFENIDONE PA

MEDICATION(S)
ESBRIET, PIRFENIDONE 267 MG CAPSULE, PIRFENIDONE 267 MG TABLET, PIRFENIDONE 801 MG TABLET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require BOTH of the following: 1. Patient has a diagnosis of idiopathic pulmonary fibrosis (IPF) AND 2. Patient has no known explanation for interstitial lung disease (ILD) or pulmonary fibrosis (e.g., radiation, drugs, metal dusts, sarcoidosis, or any connective tissue disease known to cause ILD) Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of idiopathic pulmonary fibrosis (IPF) AND 3. Patient has had clinical benefit with the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., pathologist, pulmonologist, radiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

POSACONAZOLE PA

MEDICATION(S)
NOXAFIL, POSACONAZOLE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require the following: 1. ONE of the following: A. Patient has a diagnosis of oropharyngeal candidiasis AND ONE of the following: i. Patient has tried and had an inadequate response to fluconazole or an alternative antifungal agent OR ii. Patient has an intolerance or hypersensitivity to fluconazole or an alternative antifungal agent OR iii. Patient has an FDA labeled contraindication to fluconazole or an alternative antifungal agent OR B. The requested agent is being prescribed for prophylaxis of invasive Aspergillus or Candida AND patient is severely immunocompromised, such as a hematopoietic stem cell transplant [HSCT] recipient, or hematologic malignancy with prolonged neutropenia from chemotherapy, or is a high-risk solid organ (lung, heart-lung, liver, pancreas, small bowel) transplant patient, or long term use of high dose corticosteroids (greater than 1 mg/kg/day of prednisone or equivalent) OR C. Patient has a diagnosis of invasive Aspergillus AND ONE of the following: i. Patient has tried and had an inadequate response to an alternative antifungal agent OR ii. Patient has an intolerance or hypersensitivity to an alternative antifungal agent OR iii. Patient has an FDA labeled contraindication to an alternative antifungal agent OR D. Patient has another indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

One month for oropharyngeal candidiasis, 6 months for all other indications

OTHER CRITERIA

Criteria for renewal approval require BOTH of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. ONE of the following: A. The requested agent is being prescribed for prophylaxis of invasive Aspergillus or Candida and patient continues to be severely immunocompromised, such as a hematopoietic stem cell transplant [HSCT] recipient, or hematologic malignancy with prolonged neutropenia from chemotherapy, or is a high-risk solid organ (lung, heart-lung, liver, pancreas, small bowel) transplant patient, or long term use of high dose corticosteroids (greater than 1 mg/kg/day of prednisone or equivalent) OR B. Patient has a diagnosis of invasive Aspergillus AND patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) OR C. BOTH of the following: i. Patient has a diagnosis of oropharyngeal candidiasis AND ii. Patient has had clinical benefit with the requested agent OR D. BOTH of the following: i. Patient has another indication that is supported in CMS approved compendia for the requested agent AND ii. Patient has had clinical benefit with the requested agent

PART B PREREQUISITE

N/A

PROLIA PA

MEDICATION(S)
PROLIA

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

OFF LABEL USES
Osteopenia (osteoporosis prophylaxis)

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require ALL of: 1. ONE of: A. Patient's (pt) sex is male or the pt is postmenopausal with a diagnosis of osteoporosis AND BOTH of: i. Pt's diagnosis was confirmed by ONE of: 1. A fragility fracture in the hip or spine OR 2. A T-score of -2.5 or lower OR 3. A T-score of -1.0 to -2.5 AND ONE of: a. A fragility fracture of the proximal humerus, pelvis, or distal forearm OR b. A FRAX 10-year probability for major osteoporotic fracture of 20% or greater OR c. A FRAX 10-year probability of hip fracture of 3% or greater AND ii. ONE of: 1. Pt is at a very high fracture risk as defined by ONE of: a. Pt had a recent fracture (within the past 12 months) OR b. Pt had fractures while on FDA approved osteoporosis therapy OR c. Pt has had multiple fractures OR d. Pt had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) OR e. Pt has a very low T-score (less than -3.0) OR f. Pt is at high risk for falls or has a history of injurious falls OR g. Pt has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm OR 2. ONE of: a. Pt's medication history includes use of a bisphosphonate OR b. Pt has an intolerance, FDA labeled contraindication, or hypersensitivity to a bisphosphonate OR B. Pt is requesting the agent for osteopenia (osteoporosis prophylaxis) AND ALL of: i. ONE of: 1. Pt's sex is male and the pt is 50 years of age or over OR 2. Pt is postmenopausal AND ii. Pt has a T-score between -1.0 to -2.50 AND iii. ONE of: a. A fragility fracture of the proximal humerus, pelvis, or distal forearm OR b. 10-year probability of a hip fracture 3% and greater per FRAX OR c. 10-year probability of a major OP-related fracture 20% and greater per FRAX AND iv. ONE of: a. Pt's medication history includes use of a bisphosphonate OR Criteria continues: See Other Criteria

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

b. Pt has an intolerance, FDA labeled contraindication, or hypersensitivity to a bisphosphonate OR C. Pt's sex is a female with a diagnosis of breast cancer who is receiving aromatase inhibitor therapy AND ONE of: i. Pt's medication history includes use of a bisphosphonate OR ii. Pt has an intolerance, FDA labeled contraindication, or hypersensitivity to a bisphosphonate OR D. Pt's sex is male with a diagnosis of prostate cancer receiving androgen deprivation therapy (ADT) AND ONE of: i. Pt's medication history includes use of a bisphosphonate OR ii. Pt has an intolerance, FDA labeled contraindication, or hypersensitivity to a bisphosphonate OR E. Pt has a diagnosis of glucocorticoid-induced osteoporosis AND ALL of: i. Pt is either initiating or continuing systemic glucocorticoids in a daily dose equivalent to 7.5 mg or greater of prednisone AND ii. Pt is expected to remain on glucocorticoids for at least 6 months AND iii. Pt's diagnosis was confirmed by ONE of: 1. A fragility fracture in the hip or spine OR 2. A T-score of -2.5 or lower OR 3. A T-score of -1.0 to -2.5 AND ONE of the following: a. A fragility fracture of the proximal humerus, pelvis, or distal forearm OR b. A FRAX 10-year probability for major osteoporotic fracture of 20% or greater OR c. A FRAX 10-year probability of hip fracture of 3% or greater AND iv. ONE of: 1. Pt is at a very high fracture risk as defined by ONE of the following: a. Pt had a recent fracture (within the past 12 months) OR b. Pt had fractures while on FDA approved osteoporosis therapy OR c. Pt has had multiple fractures OR d. Pt had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) OR e. Pt has a very low T-score (less than -3.0) OR f. Pt is at high risk for falls or has a history of injurious falls OR g. Pt has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm OR 2. ONE of: a. Pt's medication history includes use of a bisphosphonate OR b. Pt has an intolerance, FDA labeled contraindication, or hypersensitivity to a bisphosphonate AND 2. ONE of: A. Pt has a pretreatment or current calcium level that is NOT below the lower limit of the testing laboratory's normal range OR B. Pt has a pretreatment or current calcium level that is below the lower limit of the testing laboratory's normal range AND it will be corrected prior to use of the requested agent OR C. Prescriber has indicated that the pt is not at risk for hypocalcemia (not including risk associated with the requested agent) AND 3. Pt will NOT be using the requested agent in combination with a bisphosphonate, another form of denosumab (e.g., Xgeva), romosozumab-aqqg, or parathyroid hormone analog (e.g., abaloparatide, teriparatide) for the requested indication AND 4. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

PART B PREREQUISITE

N/A

PROMACTA PA

MEDICATION(S)
PROMACTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require BOTH of the following: 1. ONE of the following: A. Patient (pt) has a diagnosis of persistent or chronic immune (idiopathic) thrombocytopenia (ITP) AND ONE of the following: i. Pt has tried and had an insufficient response to a corticosteroid or immunoglobulin (IVIg or anti-D) OR ii. Pt has an intolerance or hypersensitivity to a corticosteroid or immunoglobulin (IVIg or anti-D) OR iii. Pt has an FDA labeled contraindication to a corticosteroid or immunoglobulin (IVIg or anti-D) OR iv. Pt has had an insufficient response to a splenectomy OR B. Pt has a diagnosis of hepatitis C associated thrombocytopenia AND ONE of the following: i. Pt's platelet count is less than 75 x 10^9/L AND the intent is to increase platelet counts sufficiently to initiate interferon therapy OR ii. Pt is on concomitant therapy with interferon therapy AND is at risk for discontinuing hepatitis C therapy due to thrombocytopenia OR C. Pt has a diagnosis of severe aplastic anemia (SAA) AND ALL of the following: i. Pt has at least 2 of the following blood criteria: 1. Neutrophils less than 0.5 X 10^9/L OR 2. Platelets less than 30 X 10^9/L OR 3. Reticulocyte count less than 60 X 10^9/L AND ii. Pt has at least 1 of the following marrow criteria: 1. Severe hypocellularity is less than 25% OR 2. Moderate hypocellularity is 25-50% with hematopoietic cells representing less than 30% of residual cells AND iii. ONE of the following: 1. Pt has tried and had an insufficient response to BOTH antithymocyte globulin (ATG) AND cyclosporine therapy OR 2. BOTH of the following: a. Pt will be using the requested agent as first-line treatment (i.e., has not been treated with ATG and/or cyclosporine) AND b. Pt will use the requested agent in combination with standard immunosuppressive therapy (i.e., ATG AND cyclosporine) OR Initial criteria continues: see Other Criteria

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: 6 months for ITP. Renewal: 12 months for ITP. Other indications, see Other Criteria.

OTHER CRITERIA

D. Pt has another indication that is supported in CMS approved compendia for the requested agent AND 2. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Pt has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. ONE of the following: A. Pt has a diagnosis of persistent or chronic immune (idiopathic) thrombocytopenia (ITP) AND ONE of the following: i. Pt's platelet count is 50 x 10^9/L or greater OR ii. Pt's platelet count has increased sufficiently to avoid clinically significant bleeding OR B. Pt has a diagnosis of hepatitis C associated thrombocytopenia AND BOTH of the following: i. ONE of the following: 1. Pt will be initiating hepatitis C therapy with interferon therapy OR 2. Pt will be maintaining hepatitis C therapy with interferon therapy at the same time as the requested agent AND ii. ONE of the following: 1. Pt's platelet count is 90 x 10^9/L or greater OR 2. Pt's platelet count has increased sufficiently to initiate or maintain interferon therapy for the treatment of hepatitis C OR C. Pt has a diagnosis of severe aplastic anemia (SAA) AND the pt has had clinical benefit with the requested agent OR D. Pt has another indication that is supported in CMS approved compendia and the pt has had clinical benefit with the requested agent AND 3. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication Initial: 48 weeks for hepatitis C associated thrombocytopenia, 6 months for first-line therapy in severe aplastic anemia, 16 weeks for SAA, 12 months for All other indications Renewal: 48 weeks for hepatitis C associated thrombocytopenia, 12 months for SAA, 12 months for All other indications

PART B PREREQUISITE

N/A

PULMONARY HYPERTENSION PA - ADEMPAS

MEDICATION(S)
ADEMPAS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require the following: 1. ONE of the following: A. BOTH of the following: i. ONE of the following: a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR b. Prescriber states the patient is currently being treated with the requested agent within the past 90 days AND ii. Patient has an FDA labeled indication for the requested agent OR B. Patient has a diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH), WHO Group 4, as determined by a ventilation-perfusion scan and a confirmatory selective pulmonary angiography AND ALL of the following: i. ONE of the following: a. Patient is NOT a candidate for surgery OR b. Patient has had pulmonary endarterectomy AND has persistent or recurrent disease AND ii. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND iv. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units OR C. Patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization AND ALL of the following: i. Patient's World Health Organization (WHO) functional class is II or greater AND ii. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND iv. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units AND Initial criteria continues: see Other Criteria

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

v. ONE of the following: a. The requested agent will be utilized as monotherapy OR b. The requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy), AND BOTH of the following: 1. Patient has unacceptable or deteriorating clinical status despite established pharmacotherapy AND 2. The requested agent is in a different therapeutic class OR c. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), AND ALL of the following: 1. ONE of the following: i. A prostanoid has been started as one of the agents in the triple therapy OR ii. Patient has an intolerance or hypersensitivity to a prostanoid OR iii. Patient has an FDA labeled contraindication to a prostanoid AND 2. Patient has unacceptable or deteriorating clinical status despite established pharmacotherapy AND 3. All three agents in the triple therapy are from a different therapeutic class Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical benefit with the requested agent

PART B PREREQUISITE

N/A

PULMONARY HYPERTENSION PA - AMBRISENTAN

MEDICATION(S)
AMBRISENTAN, LETAIRIS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require the following: 1. ONE of the following: A. BOTH of the following: i. ONE of the following: a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR b. Prescriber states the patient is currently being treated with the requested agent within the past 90 days AND ii. Patient has an FDA labeled indication for the requested agent OR B. Patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization AND ALL of the following: i. Patient's World Health Organization (WHO) functional class is II or greater AND ii. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND iv. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units AND v. ONE of the following: a. The requested agent will be utilized as monotherapy OR b. The requested agent will be used in combination with a phosphodiesterase 5 (PDE5) inhibitor for dual therapy ONLY OR c. The requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy), [except for dual therapy requests for a phosphodiesterase 5 (PDE 5) inhibitor plus an endothelin receptor antagonist (ERA)], AND BOTH of the following: 1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND 2. The requested agent is in a different therapeutic class OR Initial criteria continues: see Other Criteria

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

d. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), AND ALL of the following: 1. ONE of the following: i. A prostanoid has been started as one of the agents in the triple therapy OR ii. Patient has an intolerance or hypersensitivity to a prostanoid OR iii. Patient has an FDA labeled contraindication to a prostanoid AND 2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND 3. All three agents in the triple therapy are from a different therapeutic class OR e. The requested agent will be utilized as part of triple therapy in a treatment naive patient AND BOTH of the following: 1. Patient is classified as WHO functional class IV AND 2. The three agents being utilized consist of: ERA plus PDE5i plus prostanoid Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical benefit with the requested agent

PART B PREREQUISITE

N/A

PULMONARY HYPERTENSION PA - BOSENTAN

MEDICATION(S)
BOSENTAN, TRACLEER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Elevated liver enzymes accompanied by signs or symptoms of liver dysfunction/injury or a bilirubin level of 2 times the ULN (upper limit of normal) or greater AND FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require the following: 1. ONE of the following: A. BOTH of the following: i. ONE of the following: a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR b. Prescriber states the patient is currently being treated with the requested agent within the past 90 days AND ii. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent OR B. Patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1, as determined by right heart catheterization, AND ALL of the following: i. Patient's World Health Organization (WHO) functional class is II or greater AND ii. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND iv. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units AND v. ONE of the following: a. The requested agent will be utilized as monotherapy OR b. The requested agent will be used in combination with a phosphodiesterase 5 (PDE5) inhibitor for dual therapy ONLY OR c. The requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy), [except for dual therapy requests for a phosphodiesterase 5 inhibitor (PDE5) plus an endothelin receptor antagonist (ERA)], AND BOTH of the following: 1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND 2. The requested agent is in a different therapeutic class OR Initial criteria continues: see Other Criteria

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

d. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), AND ALL of the following: 1. ONE of the following: i. A prostanoid has been started as one of the agents in the triple therapy OR ii. Patient has an intolerance or hypersensitivity to a prostanoid OR iii. Patient has an FDA labeled contraindication to a prostanoid AND 2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND 3. All three agents in the triple therapy are from a different therapeutic class OR e. The requested agent will be utilized as part of triple therapy in a treatment naive patient AND BOTH of the following: 1. Patient is classified as WHO functional class IV AND 2. The three agents being utilized consist of: ERA plus PDE5i plus prostanoid OR C. Patient has an indication that is supported in CMS approved compendia for the requested agent Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND 3. Patient has had clinical benefit with the requested agent

PART B PREREQUISITE

N/A

PULMONARY HYPERTENSION PA - OPSUMIT

MEDICATION(S)
OPSUMIT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require the following: 1. ONE of the following: A. BOTH of the following: i. ONE of the following: a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR b. Prescriber states the patient is currently being treated with the requested agent within the past 90 days AND ii. Patient has an FDA labeled indication for the requested agent OR B. Patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization AND ALL of the following: i. Patient's World Health Organization (WHO) functional class is II or greater AND ii. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND iv. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units AND v. ONE of the following: a. The requested agent will be utilized as monotherapy OR b. The requested agent will be used in combination with a phosphodiesterase 5 (PDE5) inhibitor for dual therapy ONLY OR c. The requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy), [except for dual therapy requests for a phosphodiesterase 5 (PDE 5) inhibitor plus an endothelin receptor antagonist (ERA)], AND BOTH of the following: 1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND 2. The requested agent is in a different therapeutic class OR Initial criteria continues: see Other Criteria

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

d. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), AND ALL of the following: 1. ONE of the following: i. A prostanoid has been started as one of the agents in the triple therapy OR ii. Patient has an intolerance or hypersensitivity to a prostanoid OR iii. Patient has an FDA labeled contraindication to a prostanoid AND 2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND 3. All three agents in the triple therapy are from a different therapeutic class OR e. The requested agent will be utilized as part of triple therapy in a treatment naive patient AND BOTH of the following: 1. Patient is classified as WHO functional class IV AND 2. The three agents being utilized consist of: ERA plus PDE5i plus prostanoid Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical benefit with the requested agent

PART B PREREQUISITE

N/A

PULMONARY HYPERTENSION PA - SILDENAFIL

MEDICATION(S)
SILDENAFIL 20 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrently taking another phosphodiesterase 5 (PDE 5) inhibitor with the requested agent AND FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require the following: 1. ONE of the following: A. BOTH of the following: i. ONE of the following: a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR b. Prescriber states the patient is currently being treated with the requested agent within the past 90 days AND ii. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent OR B. Patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization AND ALL of the following: i. Patient's World Health Organization (WHO) functional class is II or greater AND ii. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND iv. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units AND v. ONE of the following: a. The requested agent will be utilized as monotherapy OR b. The requested agent will be used in combination with an endothelin receptor antagonist (ERA) for dual therapy ONLY OR c. The requested agent will be utilized for add-on therapy to existing monotherapy, [except for dual requests for a phosphodiesterase 5 (PDE5) inhibitor plus an endothelin receptor antagonist (ERA)], AND BOTH of the following: 1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND 2. The requested agent is in a different therapeutic class OR Initial criteria continues: see Other Criteria

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

d. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy) AND ALL of the following: 1. ONE of the following: i. A prostanoid has been started as one of the agents in the triple therapy OR ii. Patient has an intolerance or hypersensitivity to a prostanoid OR iii. Patient has an FDA labeled contraindication to a prostanoid AND 2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND 3. All three agents in the triple therapy are from a different therapeutic class OR e. The requested agent will be utilized as part of triple therapy in a treatment naive patient AND BOTH of the following: 1. Patient is classified as WHO functional class IV AND 2. The three agents being utilized consist of: ERA plus PDE5i plus prostanoid OR C. Patient has an indication that is supported in CMS approved compendia for the requested agent Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND 3. Patient has had clinical benefit with the requested agent

PART B PREREQUISITE

N/A

PULMONARY HYPERTENSION PA - TADALAFIL

MEDICATION(S)
ADCIRCA, TADALAFIL 20 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrently taking another phosphodiesterase 5 (PDE 5) inhibitor with the requested agent AND FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require the following: 1. ONE of the following: A. BOTH of the following: i. ONE of the following: a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR b. Prescriber states the patient is currently being treated with the requested agent within the past 90 days AND ii. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent OR B. Patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization AND ALL of the following: i. Patient's World Health Organization (WHO) functional class is II or greater AND ii. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND iv. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units AND v. ONE of the following: a. The requested agent will be utilized as monotherapy OR b. The requested agent will be used in combination with an endothelin receptor antagonist (ERA) for dual therapy ONLY OR c. The requested agent will be utilized for add-on therapy to existing monotherapy, [except for dual requests for a phosphodiesterase 5 (PDE5) inhibitor plus an endothelin receptor antagonist (ERA)], AND BOTH of the following: 1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND 2. The requested agent is in a different therapeutic class OR Initial criteria continues: see Other Criteria

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

d. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy) AND ALL of the following: 1. ONE of the following: i. A prostanoid has been started as one of the agents in the triple therapy OR ii. Patient has an intolerance or hypersensitivity to a prostanoid OR iii. Patient has an FDA labeled contraindication to a prostanoid AND 2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND 3. All three agents in the triple therapy are from a different therapeutic class OR e. The requested agent will be utilized as part of triple therapy in a treatment naive patient AND BOTH of the following: 1. Patient is classified as WHO functional class IV AND 2. The three agents being utilized consist of: ERA plus PDE5i plus prostanoid OR C. Patient has an indication that is supported in CMS approved compendia for the requested agent Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND 3. Patient has had clinical benefit with the requested agent

PART B PREREQUISITE

N/A

PULMONARY HYPERTENSION PA - VENTAVIS

MEDICATION(S)
VENTAVIS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require the following: 1. ONE of the following: A. BOTH of the following: i. ONE of the following: a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR b. Prescriber states the patient is currently being treated with the requested agent within the past 90 days AND ii. Patient has an FDA labeled indication for the requested agent OR B. Patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization AND ALL of the following: i. Patient's World Health Organization (WHO) functional class is II or greater AND ii. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND iv. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units AND v. ONE of the following: a. The requested agent will be utilized as monotherapy OR b. The requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy), AND BOTH of the following: 1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND 2. The requested agent is in a different therapeutic class OR c. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), AND ALL of the following: 1. Patient is WHO functional class III or IV AND 2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND 3. All three agents in the triple therapy are from a different therapeutic class OR d. The requested agent will be utilized as part of triple therapy in a treatment naive patient AND BOTH of the following: 1. Patient is classified as WHO functional class IV AND 2. The three agents being utilized consist of: ERA plus PDE5i plus prostanoid

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical benefit with the requested agent Drug is also subject to Part B versus Part D review.

PART B PREREQUISITE

N/A

PYRIMETHAMINE PA

MEDICATION(S)
DARAPRIM, PYRIMETHAMINE 25 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND 2. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 6 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

QUININE PA

MEDICATION(S)
QUININE SULFATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has ONE of the following diagnoses: A. Uncomplicated malaria OR B. Babesiosis OR C. An indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
7 days for malaria, 10 days for babesiosis, 12 months for all other diagnoses

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

REGRANEX PA

MEDICATION(S)
REGRANEX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. ONE of the following: A. BOTH of the following: i. Patient has a diagnosis of lower extremity diabetic neuropathic ulcer(s) that extends into the subcutaneous tissue or beyond AND ii. The ulcer(s) intended for treatment has an adequate blood supply OR B. Patient has an indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

RELISTOR INJ PA

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

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require ALL of the following: 1. ONE of the following diagnoses: A. Patient has opioid-induced constipation (OIC) with advanced illness or pain caused by active cancer and is receiving palliative care OR B. Patient has opioid induced constipation (OIC) and chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment AND 2. Patient has chronic use of an opioid agent in the past 90 days AND 3. ONE of the following: A. Patient has tried and had an inadequate response to lactulose OR B. Patient has an intolerance or hypersensitivity to lactulose OR C. Patient has an FDA labeled contraindication to lactulose

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

RELISTOR TABLET PA

MEDICATION(S)
RELISTOR 150 MG TABLET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require ALL of the following: 1. Patient has opioid-induced constipation (OIC) and chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment AND 2. Patient has chronic use of an opioid agent in the past 90 days AND 3. ONE of the following: A. Patient has tried and had an inadequate response to lactulose OR B. Patient has an intolerance or hypersensitivity to lactulose OR C. Patient has an FDA labeled contraindication to lactulose

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

REPATHA PA

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has ONE of the following: A. A diagnosis of heterozygous familial hypercholesterolemia (HeFH) AND ONE of the following: i. Genetic confirmation of one mutant allele at the LDLR, Apo-B, PCSK9, or 1/LDLRAP1 gene OR ii. ONE of the following: a. Patient is 18 years of age or older AND has a pretreatment LDL-C greater than 190 mg/dL (greater than 4.9 mmol/L) OR b. Patient is between the ages of 10 and less than 18 years AND has a pretreatment LDL-C greater than 155 mg/dL (greater than 4.0 mmol/L) OR iii. Patient has clinical manifestations of HeFH (e.g., cutaneous xanthomas, tendon xanthomas, corneal arcus, tuberous xanthoma, or xanthelasma) OR iv. Patient has "definite" or "possible" familial hypercholesterolemia as defined by the Simon Broome criteria OR v. Patient has a Dutch Lipid Clinic Network criteria score of greater than 5 OR vi. Patient has a treated low-density lipoprotein cholesterol (LDL-C) level greater than or equal to 100 mg/dL after treatment with antihyperlipidemic agents but prior to PCSK9 inhibitor therapy OR B. A diagnosis of homozygous familial hypercholesterolemia (HoFH) AND ONE of the following: i. Genetic confirmation of bi-allelic pathogenic/likely pathogenic variants on different chromosomes at the LDLR, Apo-B, PCSK9, or LDLRAP1 genes or greater than or equal to 2 such variants at different loci OR ii. History of untreated LDL-C greater than 400 mg/dL (greater than 10 mmol/L) AND ONE of the following: a. Cutaneous or tendon xanthomas before the age of 10 years OR b. Untreated elevated LDL-C levels consistent with heterozygous familial hypercholesterolemia (HeFH) in both parents (or in digenic form, one parent may have normal LDL-C levels and the other may have LDL-C levels consistent with HoFH) OR Initial criteria continues: see Other Criteria

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

The agent was prescribed by, or in consultation with, a cardiologist, an endocrinologist, and/or a physician who focuses in the treatment of cardiovascular (CV) risk management and/or lipid disorders

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

C. A diagnosis of established cardiovascular disease [acute coronary syndrome (ACS), history of myocardial infarction (MI), stable or unstable angina, coronary or other arterial revascularization stroke, transient ischemic attack (TIA), peripheral artery disease (PAD) including aortic aneurysm] AND the requested agent will be used to reduce the risk of myocardial infarction, stroke OR D. A diagnosis of primary hyperlipidemia (not associated with HeFH, HoFH, or established cardiovascular disease) OR E. Patient has another indication that is supported in CMS approved compendia for the requested agent AND 2. ONE of the following: A. Patient has tried and had an inadequate response to a high-intensity statin (i.e., rosuvastatin 20-40 mg or atorvastatin 40-80 mg) OR B. Patient has an intolerance to TWO different statins OR C. Patient has an FDA labeled contraindication to a statin AND 3. Patient will NOT be using the requested agent in combination with another PCSK9 agent Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND 3. Patient has had clinical benefit with the requested agent AND 4. Patient will NOT be using the requested agent in combination with another PCSK9 agent

PART B PREREQUISITE

N/A

REZUROCK PA

MEDICATION(S)
REZUROCK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require BOTH of the following: 1. Patient has a diagnosis of chronic graft-versus-host disease (chronic GVHD) AND 2. Patient has failed at least two prior lines of systemic therapy Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of chronic graft-versus-host disease (chronic GVHD) AND 3. Patient has had clinical benefit with the requested agent

AGE RESTRICTION
Patient is within the FDA labeled age for the requested agent

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, oncologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

RITALIN PA

MEDICATION(S)
METHYLPHENIDATE 10 MG TABLET, METHYLPHENIDATE 20 MG TABLET, METHYLPHENIDATE 5 MG TABLET, RITALIN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has an FDA labeled indication for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ROFLUMILAST PA

MEDICATION(S)
DALIRESP, ROFLUMILAST

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. ONE of the following: A. Patient has tried and had an inadequate response to an agent from TWO of the following categories: i. long-acting beta-2 agonist (LABA) [e.g., salmeterol] ii. long-acting muscarinic antagonist (LAMA) [e.g., umeclidinium] iii. inhaled corticosteroid (ICS) [e.g., fluticasone] OR B. Patient has an intolerance or hypersensitivity to an agent from TWO of the following categories: i. long-acting beta-2 agonist (LABA) [e.g., salmeterol] ii. long-acting muscarinic antagonist (LAMA) [e.g., umeclidinium] iii. inhaled corticosteroid (ICS) [e.g., fluticasone] OR C. Patient has an FDA labeled contraindication to an agent from TWO of the following categories: i. long-acting beta-2 agonist (LABA) [e.g., salmeterol] ii. long-acting muscarinic antagonist (LAMA) [e.g., umeclidinium] iii. inhaled corticosteroid (ICS) [e.g., fluticasone]

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

RYBELSUS PA

MEDICATION(S)
RYBELSUS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Requested agent will be used for weight loss alone

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. Patient has a diagnosis of type 2 diabetes mellitus AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR B. Prescriber states the patient is currently being treated with the requested agent within the past 180 days OR C. ALL of the following: i. ONE of the following: 1. Patient's medication history includes use of a non glucagon-like peptide-1 (GLP-1) oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) within the past 90 days OR 2. Patient had an ineffective treatment response to a non GLP-1 oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) OR 3. Patient has an intolerance or hypersensitivity to a non GLP-1 oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) OR 4. Patient has an FDA labeled contraindication to a non GLP-1 oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) AND ii. Patient does NOT have any FDA labeled contraindications to the requested agent AND iii. Patient will NOT be using the requested agent in combination with another GLP-1 agonist agent, or an agent containing a GLP-1 agonist AND iv. Patient will NOT be using the requested agent in combination with an agent containing a dipeptidyl peptidase-4 (DPP-4) inhibitor

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

SAMSCA PA

MEDICATION(S)
SAMSCA, TOLVAPTAN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Any underlying liver disease, including cirrhosis AND FDA labeled contraindications to the request agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require ALL of the following: 1. The requested agent was initiated (or re-initiated) in the hospital AND 2. Prior to initiating the requested agent, the patient has or had a diagnosis of clinically significant hypervolemic or euvolemic hyponatremia defined by ONE of the following: A. Serum sodium is less than 125 mEq/L OR B. Serum sodium is 125 mEq/L or greater AND patient has symptomatic hyponatremia that has resisted correction with fluid restriction AND 3. Medications known to cause hyponatremia have been evaluated and discontinued when appropriate AND 4. Patient has NOT already received 30 days of therapy with the requested agent following the most recent hospitalization for initiation of therapy AND 5. The requested dose is within the FDA labeled dosing for the requested indication (Recommended starting dose is 15 mg once daily. Dosage may be increased at intervals greater than or equal to 24 hours to 30 mg once daily, and to a maximum of 60 mg once daily as needed to raise serum sodium. Do not administer for more than 30 days to minimize the risk of liver injury.)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 30 days

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

SAPROPTERIN PA

MEDICATION(S)
KUVAN, SAPROPTERIN DIHYDROCHLORIDE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of phenylketonuria (PKU) AND 2. Prescriber has submitted a baseline blood Phe level measured prior to initiation of therapy with the requested agent, which is above the recommended levels indicated for the patient's age range or condition AND 3. Patient will NOT be using the requested agent in combination with Palynziq (pegvaliase-pqpz) for the requested indication AND 4. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of phenylketonuria (PKU) AND 3. ONE of the following: a. Patient's blood Phe levels are being maintained within the acceptable range OR b. Patient has had a decrease in blood Phe level from baseline AND 4. Patient will NOT be using the requested agent in combination with Palynziq (pegvaliase-pqpz) for the requested indication AND 5. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., metabolic or genetic disorders) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION
Initial: 2 months if dose is 5 to less than 20 mg/kg/day, 1 month if 20 mg/kg/day Renewal: 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

SELF - ADMINISTERED ONCOLOGY PA

MEDICATION(S)

ABIRATERONE ACETATE 250 MG TAB, AFINITOR, AFINITOR DISPERZ, AKEEGA, ALECENSA, ALUNBRIG, AUGTYRO 40 MG CAPSULE, AYVAKIT, BALVERSA, BESREMI, BEXAROTENE 75 MG CAPSULE, BOSULIF, BRAFTOVI 75 MG CAPSULE, BRUKINSA, CABOMETYX, CALQUENCE, CAPRELSA, COMETRIQ, COPIKTRA, COTELLIC, DAURISMO, ERIVEDGE, ERLEADA, ERLOTINIB HCL 100 MG TABLET, ERLOTINIB HCL 150 MG TABLET, ERLOTINIB HCL 25 MG TABLET, EVEROLIMUS 10 MG TABLET, EVEROLIMUS 2 MG TAB FOR SUSP, EVEROLIMUS 2.5 MG TABLET, EVEROLIMUS 3 MG TAB FOR SUSP, EVEROLIMUS 5 MG TAB FOR SUSP, EVEROLIMUS 5 MG TABLET, EVEROLIMUS 7.5 MG TABLET, EXKIVITY, FOTIVDA, FRUZAQLA, GAVRETO, GEFITINIB, GILOTRIF, GLEEVEC, IBRANCE, ICLUSIG, IDHIFA, IMATINIB MESYLATE, IMBRUVICA 140 MG CAPSULE, IMBRUVICA 420 MG TABLET, IMBRUVICA 70 MG CAPSULE, IMBRUVICA 70 MG/ML SUSPENSION, INLYTA, INQOVI, INREBIC, IRESSA, IWILFIN, JAKAFI, JAYPIRCA, KISQALI, KISQALI FEMARA CO-PACK, KOSELUGO, KRAZATI, LAPATINIB, LAZCLUZE, LENALIDOMIDE, LENVIMA, LONSURF, LORBRENA, LUMAKRAS 120 MG TABLET, LUMAKRAS 320 MG TABLET, LYNPARZA, LYTGOBI, MATULANE, MEKINIST, MEKTOVI, NERLYNX, NEXAVAR, NINLARO, NUBEQA, ODOMZO, OGSIVEO, OJEMDA, OJJAARA, ONUREG, ORGOVYX, ORSERDU, PAZOPANIB HCL, PEMAZYRE, PIQRAY, POMALYST, QINLOCK, RETEVMO, REZLIDHIA, ROZLYTREK, RUBRACA, RYDAPT, SCEMBLIX, SORAFENIB, SPRYCEL, STIVARGA, SUNITINIB MALATE, SUTENT, TABRECTA, TAFINLAR, TAGRISSO, TALZENNA, TARGRETIN 75 MG CAPSULE, TASIGNA, TAZVERIK, TEPMETKO, THALOMID, TIBSOVO, TORPENZ, TRETINOIN 10 MG CAPSULE, TRUQAP, TUKYSA, TURALIO 125 MG CAPSULE, TYKERB, VANFLYTA, VENCLEXTA, VENCLEXTA STARTING PACK, VERZENIO, VITRAKVI, VIZIMPRO, VONJO, VORANIGO, VOTRIENT, WELIREG, XALKORI, XOSPATA, XPOVIO, XTANDI, YONSA, ZEJULA 100 MG TABLET, ZEJULA 200 MG TABLET, ZEJULA 300 MG TABLET, ZELBORAF, ZOLINZA, ZYDELIG, ZYKADIA 150 MG TABLET

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Criteria for approval require BOTH of the following: 1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR B. Prescriber states the patient is currently being treated with the requested agent OR C. ALL of the following: i. Genetic testing has been completed, if required, for therapy with the requested agent and results indicate the requested agent is appropriate AND ii. Patient does NOT have any FDA labeled contraindications to the requested agent AND iii. ONE of the following: a. The requested agent is FDA labeled or supported by CMS approved compendia as a first-line therapy for the requested indication OR b. Patient has tried appropriate FDA labeled or CMS approved compendia supported therapy that are indicated as first-line therapy for the requested indication OR c. Patient has an intolerance or hypersensitivity to the first-line therapy for the requested indication OR d. Patient has an FDA labeled contraindication to the first-line therapy for the requested indication AND iv. Patient does NOT have any FDA labeled limitations of use that is not otherwise supported in NCCN guidelines AND Criteria continues: see Other Criteria

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

v. ONE of the following: a. The requested agent is not Bosulif OR b. The requested agent is Bosulif AND ONE of the following: 1. Patient's medication history indicates use of imatinib OR dasatinib for the requested indication (if applicable) OR 2. Patient has an intolerance or hypersensitivity to imatinib OR dasatinib OR 3. Patient has an FDA labeled contraindication to imatinib OR dasatinib OR 4. CMS approved compendia does not support the use of imatinib OR dasatinib for the requested indication OR 5. Prescriber has provided information in support of use of Bosulif over imatinib OR dasatinib for the requested indication AND vi. ONE of the following: a. The requested agent is not Calquence OR b. The requested agent is Calquence AND ONE of the following: 1. Patient's medication history indicates use of Brukinsa OR Imbruvica for the requested indication (if applicable) OR 2. Patient has an intolerance or hypersensitivity to Brukinsa OR Imbruvica OR 3. Patient has an FDA labeled contraindication to Brukinsa OR Imbruvica OR 4. CMS approved compendia do not support the use of Brukinsa OR Imbruvica for the requested indication OR 5. Prescriber has provided information in support of use of

Calquence over Brukinsa OR Imbruvica for the requested indication

PART B PREREQUISITE

N/A

SIGNIFOR LAR PA

MEDICATION(S)
SIGNIFOR LAR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Severe hepatic impairment (i.e., Child Pugh C)

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require the following: 1. ONE of the following: A. Patient has a diagnosis of acromegaly AND ONE of the following: i. Patient had an inadequate response to surgery as indicated by growth hormone and serum IGF-1 levels that are above the reference ranges for the patient's gender and age OR ii. Patient is NOT a candidate for surgery OR B. Patient has a diagnosis of Cushing's disease (CD) AND ONE of the following: i. Patient had an inadequate response to pituitary surgical resection OR ii. Patient is NOT a candidate for pituitary surgical resection OR C. Patient has an indication that is supported in CMS approved compendia for the requested agent Criteria for renewal approval require BOTH of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. ONE of the following: A. Patient has a diagnosis of acromegaly AND ONE of the following: i. Patient has growth hormone and serum IGF-1 levels that are within normal limits for patient's gender and age reference range OR ii. Patient has had clinical improvement (e.g., reduction in tumor size, decreased headaches, improved cardiovascular or respiratory symptoms) OR B. Patient has a diagnosis of Cushing's disease (CD) AND BOTH of the following: i. Patient has a urinary free cortisol level less than or equal to the upper limit of normal AND ii. Patient has had improvement in at least ONE of the following clinical signs and symptoms: 1. Fasting plasma glucose OR 2. Hemoglobin A1c OR 3. Hypertension OR 4. Weight OR C. BOTH of the following: i. Patient has an indication that is supported in CMS approved compendia for the requested agent AND ii. Patient has had clinical benefit with the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial: Acromegaly - 6 months, CD - 7 months, All other diagnoses - 12 months, Renewal: 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

SIGNIFOR PA

MEDICATION(S)
SIGNIFOR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Severe hepatic impairment (i.e., Child Pugh C)

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require the following: 1. ONE of the following: A. Patient has a diagnosis of Cushing's disease (CD) AND ONE of the following: i. Patient had an inadequate response to pituitary surgical resection OR ii. Patient is NOT a candidate for pituitary surgical resection OR B. Patient has an indication that is supported in CMS approved compendia for the requested agent Criteria for renewal approval require BOTH of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. ONE of the following: A. Patient has a diagnosis of Cushing's disease (CD) AND BOTH of the following: i. Patient has a urinary free cortisol level less than or equal to the upper limit of normal AND ii. Patient has had improvement in at least ONE of the following clinical signs and symptoms: 1. Fasting plasma glucose OR 2. Hemoglobin A1c OR 3. Hypertension OR 4. Weight OR B. BOTH of the following: i. Patient has an indication that is supported in CMS approved compendia for the requested agent AND ii. Patient has had clinical benefit with the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial approval: 6 months for CD, 12 months for all other diagnoses, Renewal approval: 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

SIVEXTRO PA

MEDICATION(S)
SIVEXTRO 200 MG TABLET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require ALL of the following: 1. Patient has ONE of the following: A. BOTH of the following: i. A documented acute bacterial skin and skin structure infection (ABSSSI) defined as a bacterial infection of the skin with a lesion size area of at least 75 cm2 (lesion size measured by the area of redness, edema, or induration) AND ii. The infection is due to Staphylococcus aureus, Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus, Streptococcus intermedius, Streptococcus constellatus, or Enterococcus faecalis OR B. Another indication that is supported in CMS approved compendia for the requested agent AND 2. ONE of the following: A. The requested agent is prescribed by an infectious disease specialist or the prescriber has consulted with an infectious disease specialist on treatment of this patient OR B. The requested agent is NOT prescribed by an infectious disease specialist or the prescriber has NOT consulted with an infectious disease specialist on treatment of this patient AND ONE of the following: i. There is documentation of resistance to TWO of the following: beta-lactams, macrolides, clindamycin, tetracycline, or co-trimoxazole at the site of infection OR ii. Patient has an intolerance or hypersensitivity to TWO of the following: beta-lactams, macrolides, clindamycin, tetracyclines, or co-trimoxazole OR iii. Patient has an FDA labeled contraindication to TWO of the following: beta-lactams, macrolides, clindamycin, tetracyclines, or co-trimoxazole OR iv. There is documentation of resistance to vancomycin at the site of infection OR v. Patient has an intolerance or hypersensitivity to vancomycin OR vi. Patient has an FDA labeled contraindication to vancomycin AND 3. Patient will NOT be using the requested agent in combination with linezolid for the same infection AND 4. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

AGE RESTRICTION
Patient is within the FDA labeled age for the requested agent

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be 6 days for ABSSSI or 30 days for all other indications

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

SODIUM OXYBATE PA

MEDICATION(S)
SODIUM OXYBATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. ONE of the following: A. Patient has a diagnosis of narcolepsy with cataplexy OR B. Patient has a diagnosis of narcolepsy with excessive daytime sleepiness AND BOTH of the following: i. ONE of the following: a. Patient is under 18 years of age OR b. ONE of the following: 1. Patient has tried and had an inadequate response to modafinil or armodafinil OR 2. Patient has an intolerance or hypersensitivity to modafinil or armodafinil OR 3. Patient has an FDA labeled contraindication to modafinil or armodafinil AND ii. ONE of the following: a. Patient has tried and had an inadequate response to ONE standard stimulant agent (e.g., methylphenidate) OR b. Patient has an intolerance or hypersensitivity to ONE standard stimulant agent (e.g., methylphenidate) OR c. Patient has an FDA labeled contraindication to ONE standard stimulant agent (e.g., methylphenidate) OR C. Patient has another indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
Patient is 7 years of age or over

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

SOMATOSTATIN ANALOGS PA - LANREOTIDE

MEDICATION(S)
SOMATULINE DEPOT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require BOTH of the following: 1. ONE of the following: A. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND ONE of the following: i. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR ii. Prescriber states the patient is currently being treated with the requested agent OR B. ONE of the following: i. Patient has a diagnosis of acromegaly AND ONE of the following: a. Patient is not a candidate for surgical resection or pituitary radiation therapy OR b. The requested agent is for adjunctive therapy with pituitary radiation therapy OR c. Patient had an inadequate response to surgery or pituitary radiation therapy as indicated by growth hormone levels or serum IGF-1 levels that are above the reference range OR ii. Patient has a diagnosis of gastroenteropancreatic neuroendocrine tumors AND BOTH of the following: a. The tumors are well or moderately differentiated AND b. ONE of the following: 1. The tumors are unresectable, locally advanced OR 2. Patient has metastatic disease OR iii. Patient has a diagnosis of carcinoid syndrome OR iv. Patient has another indication that is supported in CMS approved compendia for the requested agent AND 2. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

Approval will be 6 months for initial, 12 months for renewal

OTHER CRITERIA

Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND 3. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR B. Prescriber states the patient is currently being treated with the requested agent OR C. BOTH of the following: i. ONE of the following: 1. Patient has a diagnosis of acromegaly OR

2. Patient has a diagnosis of metastatic OR unresectable, locally advanced, well or moderately differentiated gastroenteropancreatic neuroendocrine tumors OR 3. Patient has a diagnosis of carcinoid syndrome OR 4. Patient has another indication that is supported in CMS approved compendia for the requested agent AND ii. Patient has had clinical benefit with the requested agent AND 4. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

PART B PREREQUISITE

N/A

SOMATOSTATIN ANALOGS PA - OCTREOTIDE

MEDICATION(S)
OCTREOTIDE ACETATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require BOTH of the following: 1. ONE of the following: A. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND ONE of the following: i. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR ii. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR B. ONE of the following: i. Patient has a diagnosis of acromegaly AND ONE of the following: a. Patient is not a candidate for surgical resection or pituitary radiation therapy OR b. The requested agent is for adjunctive therapy with pituitary radiation therapy OR c. Patient had an inadequate response to surgery or pituitary radiation therapy as indicated by growth hormone levels or serum IGF-1 levels that are above the reference range OR ii. Patient has severe diarrhea and/or flushing episodes associated with metastatic carcinoid tumors OR iii. Patient has profuse watery diarrhea associated with Vasoactive Intestinal Peptide (VIP) secreting tumors OR iv. Patient has a diagnosis of dumping syndrome AND ONE of the following: a. Patient has tried and had an inadequate response to acarbose OR b. Patient has an intolerance or hypersensitivity to acarbose OR c. Patient has an FDA labeled contraindication to acarbose OR v. Patient has another indication that is supported in CMS approved compendia for the requested agent AND 2. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be 6 months for initial, 12 months for renewal

OTHER CRITERIA

Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. ONE of the following: A. Patient has a diagnosis of acromegaly OR B. Patient has severe diarrhea and/or flushing episodes associated with metastatic carcinoid tumors OR C. Patient has profuse watery diarrhea associated with Vasoactive Intestinal Peptide (VIP) secreting tumors OR D. Patient has a diagnosis of dumping syndrome OR E. Patient has another indication that is supported in CMS approved compendia for the requested agent AND 3. Patient has had clinical benefit with the requested agent AND 4. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

PART B PREREQUISITE

N/A

SOMATOSTATIN ANALOGS PA - SANDOSTATIN LAR

MEDICATION(S)
SANDOSTATIN LAR DEPOT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. ONE of the following: A. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND ONE of the following: i. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR ii. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR B. ONE of the following: i. Patient has a diagnosis of acromegaly AND ONE of the following: a. Patient is not a candidate for surgical resection or pituitary radiation therapy OR b. The requested agent is for adjunctive therapy with pituitary radiation therapy OR c. Patient had an inadequate response to surgery or pituitary radiation therapy as indicated by growth hormone levels or serum IGF-1 levels that are above the reference range OR ii. Patient has severe diarrhea and/or flushing episodes associated with metastatic carcinoid tumors OR iii. Patient has profuse watery diarrhea associated with Vasoactive Intestinal Peptide (VIP) secreting tumors OR iv. Patient has a diagnosis of dumping syndrome AND ONE of the following: a. Patient has tried and had an inadequate response to acarbose OR b. Patient has an intolerance or hypersensitivity to acarbose OR c. Patient has an FDA labeled contraindication to acarbose OR v. Patient has another indication that is supported in CMS approved compendia for the requested agent AND 2. Patient has responded to and tolerated octreotide for a minimum of 2 weeks prior to starting therapy with Sandostatin LAR AND 3. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be 6 months for initial, 12 months for renewal

OTHER CRITERIA

Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan’s Prior Authorization criteria AND . ONE of the following: A. Patient has a diagnosis of acromegaly OR B. Patient has severe diarrhea and/or flushing episodes associated with metastatic carcinoid tumors OR C. Patient has profuse watery diarrhea associated with Vasoactive Intestinal Peptide (VIP) secreting tumors OR D. Patient has a diagnosis of dumping syndrome OR E. Patient has another indication that is supported in CMS approved compendia for the requested agent AND 3. Patient has had clinical benefit with the requested agent AND 4. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

PART B PREREQUISITE

N/A

SOMATOSTATIN ANALOGS PA - SOMAVERT

MEDICATION(S)
SOMAVERT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require BOTH of the following: 1. Patient has a diagnosis of acromegaly AND ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR C. BOTH of the following: i. ONE of the following: a. Patient is not a candidate for surgical resection or pituitary radiation therapy OR b. The requested agent is for adjunctive therapy with pituitary radiation therapy OR c. Patient had an inadequate response to surgery or pituitary radiation therapy as indicated by serum IGF-1 levels that are above the reference range AND ii. ONE of the following: a. Patient has tried and had an inadequate response to octreotide or Somatuline Depot (lanreotide) OR b. Patient has an intolerance or hypersensitivity to octreotide or Somatuline Depot (lanreotide) OR c. Patient has an FDA labeled contraindication to octreotide or Somatuline Depot (lanreotide) AND 2. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of acromegaly AND 3. Patient has had clinical benefit with the requested agent AND 4. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

Approval will be 6 months for initial, 12 months for renewal

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

STRENSIQ PA

MEDICATION(S)
STRENSIQ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has ONE of the following diagnoses: A. Perinatal or infantile-onset hypophosphatasia OR B. Juvenile-onset hypophosphatasia AND 2. Patient has documentation (i.e., medical records) of clinical manifestations to support the diagnosis of hypophosphatasia at the age of onset prior to age 18 (e.g., vitamin B6-dependent seizures, skeletal abnormalities such as rachitic chest deformity leading to respiratory problems or bowed arms/legs, “failure to thrive”) AND 3. Patient has documentation (i.e., medical records) of radiographic imaging to support the diagnosis of hypophosphatasia at the age of onset prior to age 18 (e.g., infantile rickets, alveolar bone loss, craniosynostosis, fractures) AND 4. Patient has documentation (i.e., medical records) of confirmed mutation(s) in the ALPL gene that encodes the tissue non-specific isoenzyme of alkaline phosphatase (TNSALP) AND 5. Patient has documentation (i.e., medical records) of a measured total serum alkaline phosphatase (ALP) level that is below the normal lab reference range for age and sex AND 6. Patient has documentation (i.e., medical records) of ONE of the following: A. Elevated urine concentration of phosphoethanolamine (PEA) OR B. Elevated serum concentration of pyridoxal 5'-phosphate (PLP) in the absence of vitamin supplements within one week prior to the test OR C. Elevated urinary inorganic pyrophosphate (PPi) AND 7. The requested dose is within FDA labeled dosing (based on the patient’s weight) for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient’s diagnosis (e.g., endocrinologist or geneticist with expertise in metabolic bone diseases) or the prescriber has consulted with a specialist in the area of

the patient’s diagnosis

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan’s Prior Authorization criteria AND 2. Patient has ONE of the following diagnoses: A. Perinatal or infantile-onset hypophosphatasia OR B. Juvenile-onset hypophosphatasia AND 3. There is documentation (i.e., medical records) that the patient has had a decrease from baseline (before treatment with the requested agent) in at least ONE of the following levels: A. Urine concentration of phosphoethanolamine (PEA) OR B. Serum concentration of pyridoxal 5'-phosphate (PLP) in the absence of vitamin supplements within one week prior to the test OR C. Urinary inorganic pyrophosphate (PPi) AND 4. Patient has documentation (i.e., medical records) of clinical improvement and/or stabilization with the requested agent (e.g., improvement in respiratory status, growth, pain, radiographic findings, other symptoms associated with the disease) AND 5. The requested dose is within FDA labeled dosing (based on the patient’s weight) for the requested indication

PART B PREREQUISITE
N/A

SUBSTRATE REDUCTION THERAPY PA - MIGLUSTAT

MEDICATION(S)
MIGLUSTAT, YARGESA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of Gaucher disease type 1 (GD1) confirmed by ONE of the following: A. A baseline (prior to therapy for the requested indication) glucocerebrosidase enzyme activity of less than or equal to 15% of mean normal in peripheral blood leukocytes, fibroblasts, or other nucleated cells OR B. Confirmation of genetic mutation of the glucocerebrosidase (GBA) gene with two disease-causing alleles AND 2. Prescriber has drawn baseline (prior to therapy for the requested indication) measurements of hemoglobin level, platelet count, liver volume, and spleen volume AND 3. Prior to any treatment for the intended diagnosis, the patient has had at least ONE of the following clinical presentations: A. Anemia [defined as mean hemoglobin (Hb) level below the testing laboratory's lower limit of the normal range based on age and gender] OR B. Thrombocytopenia (defined as platelet count of less than 100,000 per microliter) OR C. Hepatomegaly OR D. Splenomegaly OR E. Growth failure (i.e., growth velocity is below the standard mean for age) OR F. Evidence of bone disease with other causes ruled out Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of Gaucher disease type 1 (GD1) AND 3. Patient has had improvements or stabilization with the requested agent as indicated by ONE of the following: A. Spleen volume OR B. Hemoglobin level OR C. Liver volume OR D. Platelet count OR E. Growth OR F. Bone pain or crisis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist,

hematologist, hepatologist, specialist in metabolic diseases) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

TASIMELTEON CAPSULE PA

MEDICATION(S)
HETLIOZ, TASIMELTEON

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. ONE of the following: A. BOTH of the following: i. Patient has a diagnosis of Non-24-hour sleep-wake disorder AND ii. Patient is totally blind (i.e., no light perception) OR B. BOTH of the following: i. Patient has a diagnosis of Smith-Magenis Syndrome (SMS) confirmed by the presence of ONE of the following genetic mutations: A. A heterozygous deletion of 17p11.2 OR B. A heterozygous pathogenic variant involving RAI1 AND ii. The requested agent is being used to treat nighttime sleep disturbances associated with SMS

AGE RESTRICTION
For diagnosis of Non-24-hour sleep-wake disorder, patient is 18 years of age or over. For diagnosis of Smith-Magenis Syndrome (SMS), patient is 16 years of age or over.

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, sleep specialist, psychiatrist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

TERIPARATIDE PA

MEDICATION(S)
FORTEO, TERIPARATIDE 620 MCG/2.48 ML

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require ALL of the following: 1. Patient has ONE of the following: A. Postmenopausal osteoporosis OR B. Patient's sex is male with primary or hypogonadal osteoporosis OR C. Osteoporosis with sustained systemic glucocorticoid therapy AND 2. Patient's diagnosis was confirmed by ONE of the following: A. A fragility fracture in the hip or spine OR B. A T-score of -2.5 or lower OR C. A T-score of -1.0 to -2.5 AND ONE of the following: i. A fragility fracture of the proximal humerus, pelvis, or distal forearm OR ii. A FRAX 10-year probability for major osteoporotic fracture of 20% or greater OR iii. A FRAX 10-year probability of hip fracture of 3% or greater AND 3. ONE of the following: A. Patient is at a very high fracture risk as defined by ONE of the following: i. Patient had a recent fracture (within the past 12 months) OR ii. Patient had fractures while on FDA approved osteoporosis therapy OR iii. Patient has had multiple fractures OR iv. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) OR v. Patient has a very low T-score (less than -3.0) OR vi. Patient is at high risk for falls or has a history of injurious falls OR vii. Patient has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm OR B. ONE of the following: i. Patient has tried and had an inadequate response to a bisphosphonate OR ii. Patient has an intolerance or hypersensitivity to a bisphosphonate OR iii. Patient has an FDA labeled contraindication to a bisphosphonate AND 4. Patient will NOT be using the requested agent in combination with a bisphosphonate, denosumab (e.g., Prolia, Xgeva), romosozumab-aqqg, or another parathyroid hormone analog (e.g., abaloparatide) for the requested indication AND Criteria continues: see Other Criteria

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

No prior teriparatide and/or Tymlos use approve 2 years, Prior use - see Other Criteria

OTHER CRITERIA

5. The requested dose is within FDA labeled dosing for the requested indication AND 6. ONE of the following: A. Patient has never received treatment with teriparatide or Tymlos (abaloparatide) OR B. Patient has been previously treated with teriparatide or Tymlos (abaloparatide) AND ONE of the following: i. The total cumulative duration of treatment with teriparatide and Tymlos (abaloparatide) has NOT exceeded 2 years OR ii. Patient has received 2 years or more of treatment with teriparatide, or a combination of teriparatide and Tymlos (abaloparatide), and remains at or has returned to having a high risk for fracture Prior teriparatide and/or Tymlos use approve remainder of 2 years of total cumulative therapy. Approve 1 year if patient has received 2 years or more teriparatide or a combination of teriparatide and Tymlos (abaloparatide)

PART B PREREQUISITE

N/A

TETRABENAZINE PA

MEDICATION(S)
TETRABENAZINE, XENAZINE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require ALL of the following: 1. ONE of the following: A. Patient has a diagnosis of chorea associated with Huntington's disease OR B. Patient has an indication that is supported in CMS approved compendia for the requested agent AND 2. ONE of the following: A. Patient does NOT have a current diagnosis of depression OR B. Patient has a current diagnosis of depression and is being treated for depression AND 3. ONE of the following: A. Patient does NOT have a diagnosis of suicidal ideation and/or behavior OR B. Patient has a diagnosis of suicidal ideation and/or behavior and must NOT be actively suicidal AND 4. Patient will NOT be using the requested agent in combination with a monoamine oxidase inhibitor (MAOI) AND 5. Patient will NOT be using the requested agent in combination with reserpine

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

TOBRAMYCIN NEB PA

MEDICATION(S)
TOBRAMYCIN 300 MG/5 ML AMPULE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require ALL of the following: 1. Patient has a diagnosis of cystic fibrosis AND 2. Documentation has been provided that indicates the patient has a Pseudomonas aeruginosa respiratory infection AND 3. ONE of the following: a. Patient is NOT currently (within the past 60 days) being treated with another inhaled antibiotic (e.g., inhaled aztreonam) OR b. Patient is currently (within the past 60 days) being treated with another inhaled antibiotic (e.g., inhaled aztreonam) AND ONE of the following: i. Prescriber has confirmed that the other inhaled antibiotic will be discontinued, and that therapy will be continued only with the requested agent OR ii. Prescriber has provided information in support of another inhaled antibiotic therapy used concurrently with or alternating with (i.e., continuous alternating therapy) the requested agent Drug is also subject to Part B versus Part D review.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

TOPICAL DICLOFENAC 3% GEL PA

MEDICATION(S)
DICLOFENAC SODIUM 3% GEL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has a diagnosis of actinic keratosis (AK)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 3 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

TOPICAL DOXEPIN PA

MEDICATION(S)
DOXEPIN 5% CREAM, PRUDOXIN, ZONALON

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. ONE of the following: a. Patient has a diagnosis of moderate pruritus associated with atopic dermatitis AND ONE of the following: i. Patient has tried and had an inadequate response to a topical corticosteroid (e.g., hydrocortisone, triamcinolone) OR ii. Patient has an intolerance or hypersensitivity to a topical corticosteroid OR iii. Patient has an FDA labeled contraindication to a topical corticosteroid OR b. Patient has a diagnosis of moderate pruritus associated with lichen simplex chronicus AND ONE of the following: i. Patient has tried and had an inadequate response to a topical corticosteroid (e.g., hydrocortisone, triamcinolone) OR ii. Patient has an intolerance or hypersensitivity to a topical corticosteroid OR iii. Patient has an FDA labeled contraindication to a topical corticosteroid

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 8 days

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

TOPICAL NSAID PA - PENNSAID

MEDICATION(S)
DICLOFENAC 1.5% TOPICAL SOLN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. ONE of the following: a. Patient has an FDA labeled indication for the requested agent OR b. Patient has an indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 months for acute pain, 12 months for all other diagnoses

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

TOPICAL RETINOIDS PA - TAZAROTENE

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

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Requested agent will be used for cosmetic purposes

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. ONE of the following: a. Patient has an FDA labeled indication for the requested agent OR b. Patient has an indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

TOPICAL RETINOIDS PA - TRETINOIN

MEDICATION(S)
AVITA, RETIN-A, TRETINOIN 0.01% GEL, TRETINOIN 0.025% CREAM, TRETINOIN 0.025% GEL, TRETINOIN 0.05% CREAM, TRETINOIN 0.1% CREAM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Requested agent will be used for cosmetic purposes

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. ONE of the following: a. Patient has an FDA labeled indication for the requested agent OR b. Patient has an indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

TRELSTAR PA

MEDICATION(S)
TRELSTAR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require ALL of the following: 1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR B. Prescriber states the patient is currently being treated with the requested agent OR C. BOTH of the following: i. Patient is NOT currently being treated with the requested agent AND ii. Patient does NOT have any FDA labeled contraindications to the requested agent AND 3. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

TRIENTINE PA

MEDICATION(S)
SYPRINE, TRIENTINE HCL 250 MG CAPSULE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require BOTH of the following: 1. Patient has a diagnosis of Wilson's disease confirmed by ONE of the following: A. Confirmation of genetic mutation of the ATP7B gene OR B. Patient has TWO or more of the following: i. Presence of hepatic abnormality (e.g., acute liver failure, cirrhosis, fatty liver) ii. Presence of Kayser-Fleischer rings iii. Serum ceruloplasmin level less than 20 mg/dL iv. Basal urinary copper excretion greater than 40 mcg/24 hours or the testing laboratory's upper limit of normal v. Hepatic parenchymal copper content greater than 40 mcg/g dry weight vi. Presence of neurological symptoms (e.g., dystonia, hypertonia, rigidity with tremors, dysarthria, muscle spasms, dysphasia, polyneuropathy, dysautonomia) AND 2. ONE of the following: A. Patient has tried and had an inadequate response to penicillamine OR B. Patient has an intolerance or hypersensitivity to penicillamine OR C. Patient has an FDA labeled contraindication to penicillamine Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of Wilson's disease AND 3. Patient has had clinical benefit with the requested agent as evidenced by ONE of the following: A. Improvement and/or stabilization in hepatic abnormality OR B. Reduction in Kayser-Fleischer rings OR C. Improvement and/or stabilization in neurological symptoms (e.g., dystonia, hypertonia, rigidity with tremors, dysarthria, muscle spasms, dysphasia, polyneuropathy, dysautonomia) OR D. Basal urinary copper excretion greater than 200 mcg/24 hours

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist,

neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

TRIKAFTA PA

MEDICATION(S)
TRIKAFTA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of cystic fibrosis AND 2. ONE of the following: A. Patient has the presence of the F508del mutation in at least ONE allele (heterozygous OR homozygous) of the CFTR gene confirmed by genetic testing OR B. Patient has ONE of the CFTR gene mutations or a mutation in the CFTR gene that is responsive based on in vitro data, as indicated in the FDA label, confirmed by genetic testing OR C. Patient has another CFTR gene mutation(s) that is responsive to the requested agent, as indicated in the FDA label, confirmed by genetic testing AND 3. Patient will NOT be using the requested agent in combination with another CFTR modulator agent for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of cystic fibrosis AND 3. Patient has had improvement or stabilization with the requested agent [e.g., improvement in FEV1 from baseline, increase in weight/BMI, improvement from baseline Cystic Fibrosis Questionnaire-Revised (CFQ-R) Respiratory Domain score, improvements in respiratory symptoms (cough, sputum production, and difficulty breathing), and/or reduced number of pulmonary exacerbations] AND 4. Patient will NOT be using the requested agent in combination with another CFTR modulator agent for the requested indication

AGE RESTRICTION
Patient is within the FDA labeled age for the requested agent

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., cystic fibrosis, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

TRULICITY PA

MEDICATION(S)
TRULICITY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Requested agent will be used for weight loss alone

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. Patient has a diagnosis of type 2 diabetes mellitus AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR B. Prescriber states the patient is currently being treated with the requested agent within the past 180 days OR C. ALL of the following: i. ONE of the following: 1. Patient's medication history includes use of a non glucagon-like peptide-1 (GLP-1) oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) within the past 90 days OR 2. Patient had an ineffective treatment response to a non GLP-1 oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) OR 3. Patient has an intolerance or hypersensitivity to a non GLP-1 oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) OR 4. Patient has an FDA labeled contraindication to a non GLP-1 oral diabetes medication (e.g., metformin, an agent containing metformin, glipizide) OR 5. BOTH of the following: a. Patient has a diagnosis of established cardiovascular disease [e.g., myocardial infarction, stroke, any revascularization procedure, transient ischemic attack, unstable angina, amputation, symptomatic or asymptomatic coronary artery disease] AND b. The requested agent will be used to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) AND ii. Patient does NOT have any FDA labeled contraindications to the requested agent AND iii. Patient will NOT be using the requested agent in combination with another GLP-1 agonist agent, or an agent containing a GLP-1 agonist AND iv. Patient will NOT be using the requested agent in combination with an agent containing a dipeptidyl peptidase-4 (DPP-4) inhibitor

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

TYMLOS PA

MEDICATION(S)
TYMLOS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require ALL of the following: 1. Patient (pt) has ONE of the following: A. Postmenopausal osteoporosis OR B. Pt's sex is male with osteoporosis AND 2. BOTH of the following: A. Pt's diagnosis was confirmed by ONE of the following: i. A fragility fracture in the hip or spine OR ii. A T-score of -2.5 or lower OR iii. A T-score of -1.0 to -2.5 AND ONE of the following: a. A fragility fracture of proximal humerus, pelvis, or distal forearm OR b. A FRAX 10-year probability for major osteoporotic fracture of 20% or greater OR c. A FRAX 10-year probability of hip fracture of 3% or greater AND B. ONE of the following: i. Pt is at a very high fracture risk as defined by ONE of the following: a. Pt had a recent fracture (within the past 12 months) OR b. Pt had fractures while on FDA approved osteoporosis therapy OR c. Pt has had multiple fractures OR d. Pt had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) OR e. Pt has a very low T-score (less than -3.0) OR f. Pt is at high risk for falls or has a history of injurious falls OR g. Pt has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm OR ii. ONE of the following: a. Pt has tried and had an inadequate response to a bisphosphonate OR b. Pt has an intolerance or hypersensitivity to a bisphosphonate OR c. Pt has an FDA labeled contraindication to a bisphosphonate AND 3. Pt will NOT be using the requested agent in combination with a bisphosphonate, denosumab (e.g., Prolia, Xgeva), romosozumab-aqqg, or another parathyroid hormone analog (e.g., teriparatide) for the requested indication AND 4. The requested dose is within FDA labeled dosing for the requested indication AND 5. The total cumulative duration of treatment with teriparatide and Tymlos (abaloparatide) has not exceeded 2 years

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

No prior Tymlos and/or teriparatide use approve 2 years, Prior use - see Other Criteria

OTHER CRITERIA

Prior Tymlos and/or teriparatide use approve remainder of 2 years of total cumulative therapy

PART B PREREQUISITE

N/A

UBRELVY PA

MEDICATION(S)
UBRELVY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of migraine AND 2. The requested agent is being used for the treatment of acute migraine with or without aura AND 3. ONE of the following: A. Patient has tried and had an inadequate response to a triptan (e.g., sumatriptan, rizatriptan) agent OR B. Patient has an intolerance, or hypersensitivity to a triptan OR C. Patient has an FDA labeled contraindication to a triptan AND 4. Patient will NOT be using the requested agent in combination with another acute migraine agent (e.g., triptan, 5HT-1F, ergotamine, acute CGRP) Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of migraine AND 3. The requested agent is being used for the treatment of acute migraine with or without aura AND 4. Patient has had clinical benefit with the requested agent AND 5. Patient will NOT be using the requested agent in combination with another acute migraine agent (e.g., triptan, 5HT-1F, ergotamine, acute CGRP)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

UREA CYCLE DISORDERS PA - SODIUM PHENYLBUTYRATE

MEDICATION(S)
BUPHENYL 500 MG TABLET, SODIUM PHENYLBUTYRATE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require BOTH of the following: 1. Patient has a diagnosis of ONE of the following: a. Urea cycle disorder with neonatal-onset involving deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase, or argininosuccinic acid synthetase OR b. Urea cycle disorder with late-onset and history of hyperammonemic encephalopathy involving deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase, or argininosuccinic acid synthetase AND 2. The requested dose is within FDA labeled dosing for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., geneticist, metabolic disorders) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

VALCHLOR PA

MEDICATION(S)
VALCHLOR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR B. Prescriber states the patient is currently being treated with the requested agent OR C. BOTH of the following: i. ONE of the following: a. BOTH of the following: 1. Patient has a diagnosis of Stage IA or IB mycosis fungoides-type cutaneous T-cell lymphoma AND 2. Patient's medication history indicates use of at least ONE prior skin-directed therapy (e.g., topical corticosteroid) OR b. Patient has an indication that is supported in CMS approved compendia for the requested agent AND ii. Prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, oncologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND 3. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR B. Prescriber states the patient is currently being treated with the requested agent OR C. BOTH of the following: i. Patient has had clinical benefit with the requested agent AND ii. Prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, oncologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

VEOZAH PA

MEDICATION(S)
VEOZAH

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has an FDA labeled indication for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

VIBERZI PA

MEDICATION(S)
VIBERZI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has a diagnosis of irritable bowel syndrome with diarrhea (IBS-D)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

VORICONAZOLE PA

MEDICATION(S)
VFEND IV, VORICONAZOLE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require the following: 1. ONE of the following: A. Patient has a diagnosis of invasive Aspergillus OR B. Patient has a serious infection caused by Scedosporium apiospermum or Fusarium species OR C. Patient has a diagnosis of esophageal candidiasis or candidemia in nonneutropenic patient AND ONE of the following: i. Patient has tried and had an inadequate response to fluconazole or an alternative antifungal agent OR ii. Patient has an intolerance or hypersensitivity to fluconazole or an alternative antifungal agent OR iii. Patient has an FDA labeled contraindication to fluconazole or an alternative antifungal agent OR D. Patient has a diagnosis of blastomycosis AND ONE of the following: i. Patient has tried and had an inadequate response to itraconazole OR ii. Patient has an intolerance or hypersensitivity to itraconazole OR iii. Patient has an FDA labeled contraindication to itraconazole OR E. The requested agent is being prescribed for prophylaxis of invasive Aspergillus or Candida AND patient is severely immunocompromised, such as a hematopoietic stem cell transplant [HSCT] recipient, or hematologic malignancy with prolonged neutropenia from chemotherapy, or is a high-risk solid organ (lung, heart-lung, liver, pancreas, small bowel) transplant patient, or long term use of high dose corticosteroids (greater than 1 mg/kg/day of prednisone or equivalent) OR F. Patient has another indication that is supported in CMS approved compendia for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

One month for esophageal candidiasis, 6 months for all other indications

OTHER CRITERIA

Criteria for renewal approval require BOTH of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. ONE of the following: A. Patient has a diagnosis of invasive Aspergillus, a serious infection caused by Scedosporium apiospermum or Fusarium species, esophageal candidiasis, candidemia in nonneutropenic patient, or blastomycosis and patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) OR B. The requested agent is being prescribed for prophylaxis of invasive Aspergillus or Candida and patient continues to be severely immunocompromised, such as a hematopoietic stem cell transplant [HSCT] recipient, or hematologic malignancy with prolonged neutropenia from chemotherapy, or is a high-risk solid organ (lung, heart-lung, liver, pancreas, small bowel) transplant patient, or long term use of high dose corticosteroids (greater than 1 mg/kg/day of prednisone or equivalent) OR C. BOTH of the following: i. Patient has another indication that is supported in CMS approved compendia for the requested agent AND ii. Patient has had clinical benefit with the requested agent

PART B PREREQUISITE

N/A

VOWST PA

MEDICATION(S)
VOWST

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require ALL of the following: 1. The requested agent will be used to prevent the recurrence of Clostridioides difficile infection (CDI) AND 2. Patient has had a confirmed diagnosis of recurrent CDI as defined by greater than or equal to 3 episodes of CDI in a 12 month period AND 3. Patient has completed a standard of care antibiotic regimen (e.g., vancomycin, fidaxomicin) for recurrent CDI at least 2 to 4 days before initiating treatment with the requested agent AND 4. Patient will NOT be using the requested agent in combination with any antibiotic regimen for any indication

AGE RESTRICTION
Patient is within the FDA labeled age for the requested agent

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., infectious disease, gastroenterologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

VYNDAMAX PA

MEDICATION(S)
VYNDAMAX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) AND 2. The diagnosis has been confirmed by testing [e.g., stannous pyrophosphate (PYP) scanning, monoclonal antibody studies, biopsy, scintigraphy, genetic testing] AND 3. The requested agent will be used to reduce cardiovascular mortality and cardiovascular-related hospitalization AND 4. Patient will NOT be using the requested agent in combination with another tafamidis agent for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) AND 3. The requested agent will be used to reduce cardiovascular mortality and cardiovascular-related hospitalization AND 4. Patient has had clinical benefit with the requested agent AND 5. Patient will NOT be using the requested agent in combination with another tafamidis agent for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

VYNDAQEL PA

MEDICATION(S)
VYNDAQEL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) AND 2. The diagnosis has been confirmed by testing [e.g., stannous pyrophosphate (PYP) scanning, monoclonal antibody studies, biopsy, scintigraphy, genetic testing] AND 3. The requested agent will be used to reduce cardiovascular mortality and cardiovascular-related hospitalization AND 4. Patient will NOT be using the requested agent in combination with another tafamidis agent for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) AND 3. The requested agent will be used to reduce cardiovascular mortality and cardiovascular-related hospitalization AND 4. Patient has had clinical benefit with the requested agent AND 5. Patient will NOT be using the requested agent in combination with another tafamidis agent for the requested indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

XDEMVY PA

MEDICATION(S)
XDEMVY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has an FDA labeled indication for the requested agent

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 6 weeks

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

XERMELO PA

MEDICATION(S)
XERMELO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. Patient has a diagnosis of carcinoid syndrome diarrhea AND 2. Patient has tried and had an inadequate response to treatment with a somatostatin analog (e.g., Sandostatin [octreotide], Sandostatin LAR [octreotide], Somatuline Depot [lanreotide]) AND 3. The requested agent will be used in combination with a somatostatin analog (e.g., Sandostatin [octreotide], Sandostatin LAR [octreotide], Somatuline Depot [lanreotide]) Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of carcinoid syndrome diarrhea AND 3. Patient has had clinical benefit with the requested agent (e.g., reduction in the average number of daily bowel movements) AND 4. The requested agent will be used in combination with a somatostatin analog (e.g., Sandostatin [octreotide], Sandostatin LAR [octreotide], Somatuline Depot [lanreotide])

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

XGEVA PA

MEDICATION(S)
XGEVA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require ALL of the following: 1. ONE of the following: A. Patient has a diagnosis of multiple myeloma AND BOTH of the following: i. The requested agent will be used for the prevention of skeletal-related events AND ii. ONE of the following: 1. Patient has a pretreatment or current calcium level that is NOT below the limits of the testing laboratory's normal range OR 2. Patient has a pretreatment or current calcium level that is below the limits of the testing laboratory's normal range AND it will be corrected prior to use of the requested agent OR 3. Prescriber has indicated that the patient is not at risk for hypocalcemia (not including risk associated with the requested agent) OR B. Patient has a diagnosis of prostate cancer AND ALL of the following: i. The requested agent will be used for the prevention of skeletal-related events AND ii. Patient has bone metastases AND iii. ONE of the following: 1. Patient has a pretreatment or current calcium level that is NOT below the limits of the testing laboratory's normal range OR 2. Patient has a pretreatment or current calcium level that is below the limits of the testing laboratory's normal range AND it will be corrected prior to use of the requested agent OR 3. Prescriber has indicated that the patient is not at risk for hypocalcemia (not including risk associated with the requested agent) OR Criteria continues: see Other Criteria

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA

C. Patient has a solid tumor cancer diagnosis (e.g., thyroid, non-small cell lung, kidney cancer, or breast cancer) AND ALL of the following: i. The requested agent will be used for the prevention of skeletal-related events AND ii. Patient has bone metastases AND iii. ONE of the following: 1. Patient has a pretreatment or current calcium level that is NOT below the limits of the testing laboratory's normal range OR 2. Patient has a pretreatment or current calcium level that is below the limits of the testing laboratory's normal range AND it will be corrected prior to use of the requested agent OR 3. Prescriber has indicated that the patient is not at risk for hypocalcemia (not including risk associated with the requested agent) OR D. Patient has a diagnosis of giant cell tumor of bone AND ONE of the following: i. Patient has a pretreatment or current calcium level that is NOT below the limits of the testing laboratory's normal range OR ii. Patient has a pretreatment or current calcium level that is below the limits of the testing laboratory's normal range AND it will be corrected prior to use of the requested agent OR iii. Prescriber has indicated that the patient is not at risk for hypocalcemia (not including risk associated with the requested agent) OR E. Patient has a diagnosis of hypercalcemia of malignancy AND 2. Patient will NOT be using the requested agent in combination with Prolia (denosumab) AND 3. The requested dose is within FDA labeled dosing for the requested indication

PART B PREREQUISITE

N/A

XIFAXAN PA

MEDICATION(S)
XIFAXAN 550 MG TABLET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require the following: 1. Patient has ONE of the following: a. A diagnosis of irritable bowel syndrome with diarrhea (IBS-D) OR b. A diagnosis of hepatic encephalopathy [reduction in risk of overt hepatic encephalopathy (HE) recurrence]

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

XOLAIR PA

MEDICATION(S)
XOLAIR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require ALL of the following: 1. ONE of the following: A. Patient has a diagnosis of moderate to severe persistent asthma AND ALL of the following: i. ONE of the following: a. Patient is 6 to less than 12 years of age AND BOTH of the following: I. Patient's pretreatment IgE level is 30 IU/mL to 1300 IU/mL AND II. Patient's weight is 20 kg to 150 kg OR b. Patient is 12 years of age or over AND BOTH of the following: I. Patient's pretreatment IgE level is 30 IU/mL to 700 IU/mL AND II. Patient's weight is 30 kg to 150 kg AND ii. Allergic asthma has been confirmed by a positive skin test or in vitro reactivity test to a perennial aeroallergen AND iii. ONE of the following: a. Patient is currently being treated with AND will continue asthma control therapy (e.g., ICS, ICS/LABA, LRTA, LAMA, theophylline) in combination with the requested agent OR b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to an asthma control therapy OR B. Patient has a diagnosis of chronic idiopathic urticaria AND BOTH of the following: i. Patient has had over 6 weeks of hives and itching AND ii. ONE of the following: a. Patient has tried and had an inadequate response to maximum tolerable H1 antihistamine therapy OR b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to H1 antihistamine therapy OR C. Patient has a diagnosis of nasal polyps AND BOTH of the following: i. ONE of the following: a. Patient has tried and had an inadequate response to an intranasal corticosteroid OR b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to an intranasal corticosteroid AND ii. ONE of the following: a. The requested agent will be used in combination with an intranasal corticosteroid OR b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to an intranasal corticosteroid OR Initial criteria continues: see Other Criteria

AGE RESTRICTION
For diagnosis of moderate to severe persistent asthma, patient is 6 years of age or over. For diagnosis

of chronic idiopathic urticaria, patient is 12 years of age or over. For diagnosis of nasal polyps, patient is 18 years of age or over. For diagnosis of IgE-mediated food allergy, patient is 1 year of age or over.

PRESCRIBER RESTRICTION

Prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, otolaryngologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION

Approval will be 6 months for initial, 12 months for renewal

OTHER CRITERIA

D. Patient has a diagnosis of IgE-mediated food allergy AND ALL of the following: i. Patient is using the requested agent for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods AND ii. IgE-mediated food allergy has been confirmed by an allergy diagnostic test (e.g., skin prick test, serum specific IgE test, oral food challenge) AND iii. Patient will avoid known food allergens while treated with the requested agent AND iv. The requested agent will NOT be used for the emergency treatment of allergic reactions, including anaphylaxis AND 2. Patient will NOT be using the requested agent in combination with Dupixent or an injectable Interleukin 5 (IL-5) inhibitor (e.g., Cinqair, Fasenra, Nucala) for the requested indication AND 3. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. ONE of the following: A. Patient has a diagnosis of moderate to severe persistent asthma AND BOTH of the following: i. Patient has had clinical benefit with the requested agent AND ii. ONE of the following: a. Patient is currently being treated with AND will continue asthma control therapy (e.g., ICS, ICS/LABA, LRTA, LAMA, theophylline) in combination with the requested agent OR b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to an asthma control therapy OR B. Patient has a diagnosis of chronic idiopathic urticaria AND the following: a. Patient has had clinical benefit with the requested agent OR C. Patient has a diagnosis of nasal polyps AND the following: a. Patient has had clinical benefit with the requested agent OR D. Patient has a diagnosis of IgE-mediated food allergy AND ALL of the following: a. Patient is using the requested agent for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods AND b. Patient has had clinical benefit with the requested agent AND c. Patient will avoid known food allergens while treated with the requested agent AND d. The requested agent will NOT be used for the emergency treatment of allergic reactions, including anaphylaxis AND 3. Patient will NOT be using the requested agent in combination with Dupixent or an injectable interleukin 5 (IL-5) inhibitor (e.g., Cinqair, Fasenra, Nucala) for the requested indication AND 4. The requested dose is within FDA labeled dosing for the requested

indication

PART B PREREQUISITE

N/A

ZEPATIER PA

MEDICATION(S)
ZEPATIER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for approval require ALL of the following: 1. Patient has a diagnosis of hepatitis C confirmed by serological markers AND 2. Prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection and if positive, will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent AND 3. The requested agent will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling or AASLD/IDSA guidelines for the patient's diagnosis and genotype AND 4. The requested dose is within FDA labeled dosing or supported in AASLD/IDSA guideline dosing for the requested indication AND 5. If genotype 1, the patient's subtype has been identified and provided AND 6. If genotype 1a, the prescriber has tested the patient for the presence of virus with NS5A resistance-associated polymorphisms AND 7. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR B. Prescriber states the patient is currently being treated with the requested agent within the past 90 days OR C. Patient has an FDA labeled contraindication or hypersensitivity to the preferred agent: Mavyret for supported genotypes OR D. Prescriber has provided information based on FDA approved labeling or AASLD/IDSA guidelines supporting the use of the non-preferred agent for the patient's diagnosis and genotype over the preferred agent: Mavyret for supported genotypes

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist or infectious disease) or the prescriber has consulted with a specialist in the area of the patient's

diagnosis

COVERAGE DURATION

Duration of therapy: Based on FDA approved labeling or AASLD/IDSA guideline supported

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ZOKINVY PA

MEDICATION(S)
ZOKINVY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FDA labeled contraindications to the requested agent

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require the following: 1. ONE of the following: A. BOTH of the following: i. Patient has a diagnosis of Hutchinson-Gilford progeria syndrome (HGPS) AND ii. Genetic testing has confirmed a pathogenic variant in the LMNA gene that results in production of progerin OR B. Patient has a diagnosis of processing-deficient progeroid laminopathy AND ONE of the following: i. Genetic testing has confirmed heterozygous LMNA mutation with progerin-like protein accumulation OR ii. Genetic testing has confirmed homozygous or compound heterozygous ZMPSTE24 mutations Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of ONE of the following: A. Hutchinson-Gilford progeria syndrome (HGPS) OR B. Processing-deficient progeroid laminopathies with either: heterozygous LMNA mutation with progerin-like protein accumulation OR homozygous or compound heterozygous ZMPSTE24 mutations AND 3. Patient has had clinical benefit with the requested agent

AGE RESTRICTION
Patient is within the FDA labeled age for the requested agent

PRESCRIBER RESTRICTION
Prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, geneticist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

COVERAGE DURATION
Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

ZTALMY PA

MEDICATION(S)
ZTALMY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria for initial approval require BOTH of the following: 1. Patient has a diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR B. Prescriber states the patient is currently being treated with the requested agent OR C. BOTH of the following: i. Patient's diagnosis has been confirmed with genetic testing indicating variant in CDKL5 gene AND ii. Prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has a diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) AND 3. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR B. Prescriber states the patient is currently being treated with the requested agent OR C. BOTH of the following: i. Patient has had clinical benefit with the requested agent AND ii. Prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

AGE RESTRICTION
Patient is within the FDA labeled age for the requested agent

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

Approval will be for 12 months

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A